EUROPEAN UNION

Brussels
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Subject: **EU comments on the report of the February 2013 Code Commission meeting**

Dear Director General,

Please find here attached comments of the European Union on Annexes XXXII, XXXV, XXXIX, XL, XLI and XLII of the report of the February 2013 meeting of the Terrestrial Animal Health Standards Commission, for consideration at its next meeting in September 2013.

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

Yours sincerely,

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Annexes: 6

Copy: All Directors / Chief Veterinary Officers of the EU 28 and Iceland, Liechtenstein, Norway, Switzerland and Turkey.

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Annex XXXII

U S E R ' S G U I D E

EU comments

The EU thanks the OIE once again for having considered its request and for having provided this draft revised User's Guide for Member Country comments.

The EU strongly supports the revision of the User's Guide to clarify the role, scope and correct use of the Terrestrial Code and very much looks forward to it being submitted for adoption by the World Assembly at a future OIE General Session.

Indeed, the EU would support adopting the User's Guide as a "standard", which could be in the form of an "introductory chapter" to the Code, so as to give it the appropriate standing.

Specific comments are inserted in the text below.

A. Introduction

1) The OIE *Terrestrial Animal Health Code* (hereafter referred to as the *Terrestrial Code*) sets out standards for the improvement of terrestrial animal health and welfare and veterinary public health worldwide. The purpose of this guide is to advise the Veterinary Authorities of OIE Member Countries on how to use the *Terrestrial Code*.

EU comments

The EU suggests adding a sentence to the above point, after the first sentence, to clarify what is meant by standards, along the lines suggested by the Code Commission in its meeting report of February 2013 (cf. Item 2 Horizontal issues point b) on p. 4), as follows:

"The term "standards" refers to provisions that have been adopted by the OIE World Assembly of Delegates (OIE Codes and Manuals)."

Furthermore, as is common in the rest of the Code, the EU suggests that terms that are defined in the glossary be italicised throughout this user's guide. Thus, e.g. in the above point, the words "Veterinary Authorities" should be italicised, whereas "Terrestrial Animal Health Code" should not.

2) The standards in the *Terrestrial Code* should be used by the Veterinary Authorities of Member Countries to set up measures providing for early detection, reporting and control of pathogenic agents, including zoonotic, in terrestrial animals (mammals, birds and bees) and preventing their spread via international trade in animals and animal products, while avoiding unjustified sanitary barriers to trade.

EU comments

In the above point, the EU suggests adding the word "<u>, notification</u>" after "reporting", and the word "<u>agents</u>" after the word "zoonotic".

3) Correctly applied, the OIE standards provide for animal production and trade in animals and animal products to take place with an optimal level of animal and veterinary public health safety, based on the most recent scientific information and available techniques.

B. *Terrestrial Code* content

1) Key terms and expressions used more than once in the *Terrestrial Code* are defined in the Glossary. When reading and using the *Terrestrial Code*, the Veterinary Authorities of Member Countries should be aware of the definitions given in the Glossary. Defined terms appear in italics. In the on-line version of the *Terrestrial Code*, a hyperlink leads to the relevant definition.

EU comment

The EU suggests replacing the words "used more than once" by "used in more than one Chapter".

2) The term '(under study)' is found in some rare instances, with reference to an article or part of an article. This means that this part of the text has not yet been adopted by the World Assembly of OIE Delegates and the particular provisions are thus not yet part of the *Terrestrial Code*.

EU comment

As the term "under study" has recently been used also in instances where existing text was to be deleted from the Code, the EU suggests amending the point above as follows:

"This means that this part of the text has not ~~yet~~ been ~~adopted~~ endorsed by the World Assembly of OIE Delegates and the particular provisions are thus not ~~yet~~ part of the Terrestrial Code."

Indeed, the proposed wording does not differentiate between new text (not yet adopted) and old text (to be deleted) that is marked "under study", while clearly stating that text that is "under study" is not part of the Code.

3) The standards in the chapters of Section 1 of the *Terrestrial Code* are designed for the implementation of measures for the diagnosis, surveillance and notification of pathogenic agents, including procedures for notification to the OIE, tests for international trade, and procedures for the assessment of the health status of a country or zone.

4) The standards in the chapters of Section 2 of the *Terrestrial Code* are designed for conducting import risk analysis used by an importing country in the absence of OIE trade standards or to justify import measures more stringent than existing OIE trade standards.

5) The standards in the chapters of Section 3 of the *Terrestrial Code* are designed for the establishment, maintenance and evaluation of quality Veterinary Services, including veterinary legislation. These standards are to assist the Veterinary Services of OIE Member Countries to meet their objectives of improving terrestrial animal health and welfare and veterinary public health, as well as to establish and maintain confidence in their international veterinary certificates.

6) The standards in the chapters of Section 4 of the *Terrestrial Code* are designed for the implementation of measures for the prevention and control of pathogenic agents, including through animal identification, traceability, zoning, compartmentalisation, disposal of dead animals, disinfection, disinsectisation and general hygiene precautions. Some chapters address the specific sanitary measures to be applied for the collection and processing of semen and embryos of animals.

7) The standards in the chapters of Section 5 of the *Terrestrial Code* are designed for the implementation of general sanitary measures for trade, in particular veterinary certification and the measures applicable by the exporting, transit and importing countries, especially Members of the World Trade Organization (WTO). It also includes a range of model veterinary certificates to be used as a harmonised basis for international trade.

EU comment

As the chapters of Section 5 not only apply to Members of the WTO, the EU suggests replacing the word "especially" in the point above it by "including a specific chapter for".

8) The standards in the chapters of Section 6 of the *Terrestrial Code* are designed for the implementation of preventive measures in animal production systems, to assist OIE Member Countries in meeting their veterinary public health objectives. This includes ante- and port-mortem inspection, control of hazards in feed, biosecurity at the animal production level, and the control of antimicrobial resistance in animals.

9) The standards in the chapters of Section 7 of the *Terrestrial Code* are designed for the implementation of animal welfare measures, including those at the level of production, transport, and slaughter or killing. Additional standards address the animal welfare aspects of stray dog population control and the use of animals in research and education.

10) The standards in each of the chapters of Sections 8 to 15 of the *Terrestrial Code* are designed to prevent the agents of OIE listed diseases, infections or infestations from being introduced into an importing country, taking into account the nature of the traded commodity, the animal health status of the exporting country, zone or compartment, and the risk reduction measures applicable to each commodity. These standards assume that the agent is either not present in the importing country or is the subject of a control or eradication programme. Sections 8 to 15 each relate to the host species of the pathogenic agent: multiple species or single species of the families apidae, aves, bovidae, equidae, leporidae, caprinae and suidae. Some chapters include specific measures to prevent and control the infections of global concern. Although the OIE aims to include a chapter for each OIE listed disease, not all OIE listed diseases have been covered yet by a specific chapter. This is work in progress, depending on available scientific knowledge and the priorities set by the World Assembly.

C. Specific issues

1) Notification

Chapter 1.1. describes Member Countries' obligations under the OIE Organic Statutes. Although only listed and emerging diseases, as prescribed in Chapter 1.1., are compulsorily notifiable, Member Countries are encouraged to provide information to the OIE on any animal health event of epidemiological significance.

Chapter 1.2. describes the criteria for the inclusion of a disease, infection or infestation in the OIE List and gives the updated list. Diseases are divided into nine categories, depending of the host species of the agents.

EU comments

The EU suggests adding the words "of the Terrestrial Code" after the words "Chapter 1.1." and "Chapter 1.2.". For consistency, the same should be done throughout the rest of the text below where appropriate.

Furthermore, at the end of the point above, the EU suggests adding the word "aetiological" before the word "agents" (cf. Article 1.1.2.).

2) Diagnostic tests and vaccines

The use of specified diagnostic tests and vaccines in *Terrestrial Code* chapters is recommended with a reference to the relevant section in the OIE *Manual of Diagnostic Tests and Vaccines for Terrestrial Animals* (hereafter referred to as the *Terrestrial Manual*). Chapter 1.3. provides a table summarising the recommended diagnostic tests for OIE listed diseases. Facilities responsible for disease diagnosis and vaccine production should be fully conversant with the standards in the *Terrestrial Manual*.

3) Prevention and control

Chapters 4.5. to 4.11. describe the measures which should be implemented during collection and processing of semen and embryos of animals, including micromanipulation and cloning, in order to prevent animal health risks, especially when trading these commodities. Although this relates principally to OIE listed

diseases or infections, general standards applies to all health risks. Moreover, in Chapter 4.7. diseases that are not listed diseases are mentioned for the information of OIE Member Countries.

EU comments

In the paragraph above, please replace the word "applies" by "apply".

Moreover, in the third sentence of the paragraph above, the EU suggests replacing the word "mentioned" by "marked as such". Indeed, non-listed diseases are not merely mentioned in Chapter 4.7. for information, but are included in that Standard and are clearly marked as being non-listed to distinguish them from listed diseases.

Chapter 4.14. addresses the specific issue of the control of bee diseases and some of its trade implications. This chapter should be read in conjunction with the specific bee disease chapters in Section 9.

Chapter 6.4. is designed for the implementation of general biosecurity measures in intensive poultry production, whereas Chapter 6.5. gives an example of a specific on-farm prevention and control plan for the non-listed food borne pathogen *Salmonella* in poultry, including standards for introduction of live poultry and hatching eggs.

Chapter 6.11. deals specifically with the zoonotic risk associated with the movements of non-human primates and gives standards for certification, transportation and import conditions of these animals.

4) Trade requirements

An OIE Member Country may authorise the importation of animals or animal products into its territory under conditions more or less restrictive than those recommended by the *Terrestrial Code*. However, where the conditions are more restrictive, they should be scientifically justified by a risk analysis conducted in accordance with OIE standards, as described in Chapter 2.1. For Members of the WTO to meet their obligations under the WTO Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement), international trade animal health measures should be based on an OIE standard or an import risk analysis.

Chapters 5.1. to 5.3. describe the obligations and ethics in international trade. Veterinary Authorities and all veterinarians directly involved in international trade should be familiar with these chapters, which also provide guidance for informal mediation by the OIE.

The OIE aims to include, at the beginning of each chapter relating to a specific agent in Sections 8 to 15 an article listing the commodities that are considered safe for trade regardless of the status of the country or zone for the agent in question. This is a work in progress and some chapters do not yet contain articles listing safe commodities. Where such a list is present, there should be no trade restrictions applied to the listed commodity in relation to the agent in question.

EU comment

For reasons of consistency, the EU suggests adding the word "aetiological" before the word "agents" in the first line, and "international" before the word "trade" in the second line of the paragraph above.

5) International veterinary certificates

An international veterinary certificate is an official document drawn up by the Veterinary Authority of an exporting country in accordance with Chapter 5.1. and Chapter 5.2., describing the animal health requirements and, where appropriate, public health requirements for the exported commodity. The quality of the exporting country's Veterinary Services, including the ethical approach to the provision of veterinary certificates and their history in meeting their notification obligations, is essential in providing assurance to trading partners regarding the safety of exported animals and products.

EU comment

For reasons of consistency, the EU suggests adding the word "animal" before the word "products" at the end of the paragraph above.

International veterinary certificates underpin international trade and provide assurances to the importing country regarding the health status of the animals and products imported. The measures prescribed should take into account the health status of both exporting and importing countries and be based upon the standards in the *Terrestrial Code*.

EU comment

The EU suggests adding the word "guarantees and the" before the words "measures prescribed" in the paragraph above.

The following steps should be taken when drafting international veterinary certificates:

a) List the diseases for which the importing country is justified in seeking protection in regards to its own disease status. Importing countries should not impose measures in regards to diseases that occur in their own territory but are not subject to official control or eradication programmes;

EU comments

In the first sentence of point a) above (and also in point b) below), the EU suggests adding the words "infections or infestations" after the word "diseases", for reasons of consistency.

Furthermore, in view of harmonising point a) above with point b) below, the EU suggests adding the following sentence after the first sentence in point a) above:

"Such disease status should be established in accordance with the relevant articles of the disease chapters concerned, or to Chapter 1.4. when there are no such articles.".

Finally, in the last sentence of point a) above, the word "but" should be replaced by "and".

b) For commodities capable of transmitting these diseases through international trade, the importing country should apply the articles addressing the commodity in question in the relevant disease specific chapters, adapted to the disease status of the exporting country, zone or compartment. Such status should be established according to the articles of the relevant disease chapter, or to Chapter 1.4. when there are no such articles.

EU comments

In the first sentence of point b) above, the EU suggests adding the words "of Sections 8 to 15 of the Terrestrial Code" after the words "relevant disease specific chapters" (consistency).

Moreover, the words "pertaining to surveillance" should be added after the words "according to the articles" in the second sentence of point b) above.

c) When preparing international veterinary certificates, the importing country should endeavour to use terms and expressions in accordance with the definitions given in the Glossary. As stated in Article 5.2.2., international veterinary certificates should be kept as simple as possible and should be clearly worded, to avoid misunderstanding of the importing country's requirements.

EU comment

In point c) above, the EU suggests adding the words "of the Terrestrial Code" after the word "Glossary" (clarity).

d) Chapters 5.10. to 5.12. contain model certificates as a further guidance to Member Countries and should be used as a baseline.

EU comment

The EU suggests rewording point d) above as follows:

"Chapters 5.10. to 5.12. ~~contain~~ provide model certificates as a further guidance to Member Countries ~~and~~ that should be used as a baseline".

6) Guidance notes for importers and exporters

To provide a clear understanding of trade requirements, it is advisable that Veterinary Authorities of OIE Member Countries prepare 'guidance notes' to assist importers and exporters. These notes should identify and explain the trade conditions, including the measures to be applied before and after export, during transport and unloading, relevant legal obligations and operational procedures. Exporters should also be reminded of the International Air Transport Association rules governing air transport of animals and animal products. The guidance notes should advise on all details to be included in the health certification accompanying the consignment to its destination.

EU comment

The EU suggests moving the sentence on the International Air Transport Association rules to the end of the paragraph above.

Annex XXXV

CHAPTER 6.10.

RISK ANALYSIS ~~ASSESSMENT~~ FOR ANTIMICROBIAL RESISTANCE ARISING FROM THE USE OF ANTIMICROBIAL AGENTS IN ANIMALS

EU comments

The EU thanks the OIE for having taken many of its prior comments into account and for having provided clarification on certain questions, and in general supports the proposed changes to this chapter.

Article 6.10.1.

Recommendations for analysing the risks to animal and human ~~public~~ health from antimicrobial resistant microorganisms of animal origin

EU comment

For reasons of consistency, the EU suggests replacing the word "microorganisms" by the word "bacteria" in the title above, and throughout the text. Indeed, the term "microorganism" is very broad and would include e.g. fungi and viruses, whereas the scope of the AMR chapters of the Code primarily covers bacteria (cf. first sentence of Article 6.6.1. concerning the objective of Chapters 6.7. to 6.10.). Furthermore, the term "bacteria" is used in Chapters 6.7. and 6.9.

1. Introduction

Problems related to antimicrobial resistance are inherently linked to *antimicrobial agent* use in any environment, including human and non-human usages. However the emergence or dissemination of antimicrobial resistance can occur or be influenced by ~~through~~ factors other than the use of *antimicrobial agents*.

The use of *antimicrobial agents* for ~~therapy~~ therapeutic and non therapeutic purposes ~~, prophylaxis and growth promotion~~ in *animals* can reduce their efficacy in animal and human medicine, through the development of ~~antimicrobial~~ resistant strains of pathogenic microorganisms. This *risk* may be represented by the loss of therapeutic efficacy of one or several *antimicrobial agents* ~~drugs~~ ~~and includes the selection and dissemination of antimicrobial resistant micro-organisms~~ ~~emergence of multi-resistant micro-organisms~~.

EU comments

The EU suggests slightly amending the first sentence of the paragraph above as follows:

"[…] through the development and spread of ~~antimicrobial~~ resistant strains of pathogenic ~~microorganisms~~ and commensal bacteria.".

Indeed, spread should be included as it is an additional aspect. Furthermore, resistant commensal bacteria can also develop and may play a role in the dissemination of resistance genes and the exposure of the hosts.

2. Objective

For the purpose of this chapter, the principal aim of *risk analysis* ~~, for the purpose of this chapter, for antimicrobial resistance in micro-organisms from *animals*~~ is to provide OIE Member~~s~~ Countries with a

transparent, objective and scientifically defensible method of assessing and managing the human and animal health *risks* associated with the development of resistance arising from the use of *antimicrobial agents* in *animals*.

EU comment

As explained in the comment above, the words "and spread" should be added after "development" in the point above.

Guidance on the issue of foodborne antimicrobial resistance related to the non-human use of *antimicrobial agents* is covered by the Codex Guidelines for risk analysis of foodborne antimicrobial resistance (CAC/GL77-2011).

3. The risk analysis process

The principles of *risk analysis* are described in Chapter 2.1. ~~Section~~ ~~of this *Terrestrial Code*~~. The components of *risk analysis* described in this chapter are *hazard identification*, *risk assessment*, *risk management* and *risk communication*.

The chapter includes factors to be considered at various steps of the *risk analysis* process. These factors are not intended to be exhaustive and not all elements may be applicable in all situations.

~~A qualitative risk assessment should always be undertaken. Its outcome will determine whether progression to a quantitative risk assessment is feasible and/or necessary.~~

4. Hazard identification

Hazard identification is defined ~~under the OIE *Terrestrial Code*~~ in Chapter 2.1.

For the purpose of this chapter, the *hazard* is the resistant microorganism or resistance determinant that emerges as a result of the use of a specific *antimicrobial agent* in *animals*. This definition reflects the ~~development of resistance in a species of pathogenic~~ ~~micro-organisms, as well as the development of a resistance determinant that may be passed from one species of micro-organisms to another~~ potential for resistant microorganisms to cause adverse health effects, as well as the potential for horizontal transfer of genetic determinants between microorganisms. The conditions under which the *hazard* might produce adverse consequences include any scenarios through which humans or *animals* could become exposed to an antimicrobial resistant pathogen ~~which contains that resistance determinant~~, fall ill and then be treated with an *antimicrobial agent* that is no longer effective ~~because of the resistance~~.

EU comments

The EU suggests explaining the meaning of "resistance determinant" in the paragraph above. Indeed, it is not clear what exactly is meant (resistance gene, resistance mediating mutations or protein that confers resistance).

Furthermore, the words "or commensal bacteria" should be added after "pathogen" in the paragraph above (for rationale see comment above).

5. Risk assessment

The assessment of the *risk* to human and animal health from antimicrobial-resistant microorganisms resulting from the use of *antimicrobial agents* in *animals* should examine:

a) the likelihood of emergence of resistant microorganisms arising from the use of *antimicrobial agent*(s), or more particularly, dissemination ~~production~~ of the resistance determinants if transmission is possible between microorganisms;

b) consideration of all pathways and their importance, by which humans and *animals* could be exposed to these resistant microorganisms or resistance determinants, together with the ~~possible degree~~ likelihood of exposure;

c) the consequences of exposure in terms of *risks* to human and~~/or~~ animal health.

The general principles of *risk assessment* as defined in Chapter 2.1. ~~of the *Terrestrial Code*~~ applyies ~~ies~~ equally to both qualitative and quantitative *risk assessment*. At a minimum, a qualitative *risk assessment* should always be undertaken.

Article 6.10.2.

Analysis of risks to human health

1. Definition of the risk

The *infection* of humans with microorganisms that have acquired resistance to a specific *antimicrobial agent* due to ~~the~~ its used ~~d~~ in *animals*, and resulting in the loss of benefit of antimicrobial therapy used to manage the human *infection*.

EU comments

In general, a causal relationship between a particular resistant microorganism and the use of antimicrobial agents in animals will be very difficult if not impossible to be shown. For example, how will it be possible to determine whether a microorganism, e.g. Staphylococcus aureus, has acquired a macrolide resistance from use of tilmicosin in animals or clarithromycin in humans? The resistance genes in Staphylococcus of humans and animals are the same; the plasmids/transposons that carry these genes are very similar or even the same. It should be considered that it is very difficult to determine the direction of transfer of resistance. This comment pertains to several points in this chapter.

What's more, the current definition of risk seems to be limited to situations when it is clear that a specific type of resistance has emerged because of the use of this specific antimicrobial in animals. This definition is rather narrow as it does not cover possible co-selection. For example, MRSA is resistant to penicillinase stable penicillins and cephalosporins. The way the definition is now worded, the definition of the risk for infections of humans with MRSA would be limited to the fraction that could be due to use of penicillinase stable penicillins (e.g. oxacillin) and cephalosporins. Assessment of co-selection with e.g. tetracycline would not be included.

Therefore, the following modification is suggested to include also co-selection:

"The infection of humans with microorganisms that have acquired resistance to a specific antimicrobial agent due to the use of a specified antimicrobial class in animals, and resulting in the loss of benefit of antimicrobial therapy used to manage the human infection.".

2. Hazard identification

- Microorganisms that have acquired resistance, (including multiple resistance) arising from the use of an *antimicrobial agent*(s) in *animals*.
- Microorganisms having obtained a resistance determinant(s) from other microorganisms which have acquired resistance arising from the use of an *antimicrobial agent(s)* in *animals*.

The identification of the *hazard* ~~must~~ should include consideration of the class or subclass of the *antimicrobial agent(s)*. This definition should be read in conjunction with point 4~~)~~ of Article 6.10.1.

3. Release assessment

A release assessment describes the biological pathways necessary to lead to the release of resistant microorganisms or resistance determinants into a particular environment due to ~~for~~ the use of a specific *antimicrobial agent* in *animals* ~~to lead to the release of resistant micro-organisms or resistance determinants into a particular environment,~~. It also estimates ~~and estimating~~ either qualitatively or quantitatively the

probability of that complete process occurring. The release assessment describes the probability of the release of each of the potential *hazards* under each specified set of conditions with respect to amounts and timing, and how these might change as a result of various actions, events or measures.

The following factors should be considered in the release assessment:

- animal species and, where appropriate, production type (e.g. veal calves or dairy cattle, broilers or laying hens) ~~of animal~~ treated with the *antimicrobial agent(s)* in question;
- number of *animals* treated, sex, age and their geographical distribution ~~of those *animals*~~;
- prevalence of *infection* or *disease* for which the *antimicrobial agent* is indicated in the target animal population;

EU comment

As the prevalence of a disease seems more a factor of the assessment of the need to treat a disease than a factor of a release assessment on AMR, the EU suggests deleting the point above.

- data on trends in *antimicrobial agent* use and changes in farm production systems;

EU comment

The risk assessment should assess the current situation. It is not the purpose of such assessment to predict trends, even if trends have been observed in the past. Therefore, the EU suggests deleting the point above. If maintained, trends that have been observed in the prevalence of AMR should also be included.

- data on ~~potential~~ extra-label or off-label use;
- ~~variation in~~ methods and routes of administration of the *antimicrobial agent(s)*;
- dosage regimen (dose, dosing interval and duration of the treatment) ~~including duration of use~~;
- ~~the~~ pharmacokinetics or pharmacodynamics~~/pharmacokinetics~~ of the *antimicrobial agent(s)*;
- ~~micro-organisms developing resistance as a result of the antimicrobial(s) use~~ prevalence of pathogens that are likely to acquire resistance in animal host;

EU comment

In the above point, the process of selection of resistance should be added, as it is not always a process of acquiring new resistance mechanisms.

- commensal bacteria which are able to transfer resistance to human pathogens;

EU comment

The EU suggests adding the words "the prevalence of" at the beginning of the point above.

- mechanisms and pathways of direct or indirect transfer of resistance;
- potential linkage of virulence attributes and resistance;
- cross-resistance ~~and/~~or co-resistance with other *antimicrobial agents*;
- data on occurrence of resistant microorganisms through surveillance of *animals*, products of animal origin and animal waste products ~~for the existence of resistant micro-organisms~~.

4. Exposure assessment

An exposure assessment describes the biological pathways necessary for exposure of humans to the resistant microorganisms or resistance determinants released from a given antimicrobial use in *animals*, and estimating the probability of the exposures occurring. The probability of exposure to the identified *hazards* is estimated for specified exposure conditions with respect to amounts, timing, frequency, duration of exposure, routes of exposure and the number, species and other characteristics of the human populations exposed.

The following factors should be considered in the exposure assessment:

- human demographics, including population subgroups, and food consumption patterns, including traditions and cultural practices in respect to the preparation and storage of food;
- prevalence of resistant microorganisms in food at the point of consumption or exposure;
- microbial load in contaminated food at the point of consumption or exposure ~~for quantitative risk assessment~~;

EU comment

The EU suggests adding the word "other" before the word "exposure" in the two indents above, since consumption also is an exposure.

- environmental contamination with resistant microorganisms;
- occurrence of resistant microorganisms in animal feed ~~prevalence of animal feed contaminated with resistant micro-organisms~~;
- transfer ~~cycling~~ of resistant microorganisms between humans, *animals* and the environment;
- ~~steps~~ measures taken for ~~of~~ microbial decontamination of food;
- ~~microbial load in contaminated food at the point of consumption;~~
- survival capacity and spread ~~redistribution~~ of resistant microorganisms during the food production process (including slaughtering, processing, storage, transportation and retailing);
- disposal practices for waste products and the opportunity for human exposure to resistant microorganisms or resistance determinants in those waste products;
- ~~point of consumption of food (professional catering, home cooking);~~
- ~~variation in consumption and food handling methods of exposed populations and subgroups of the population;~~
- capacity of resistant microorganisms to become established in humans;
- human-to-human transmission of the microorganisms under consideration;
- capacity of resistant microorganisms to transfer resistance to human commensal microorganisms and zoonotic agents;
- amount and type of *antimicrobial agents* used in response to human illness;
- pharmacokinetics (such as metabolism, bioavailability and, access to intestinal flora).

5. Consequence assessment

A consequence assessment describes the relationship between specified exposures to resistant microorganisms or resistance determinants and the consequences of those exposures. A causal process ~~must~~ should exist by which exposures produce adverse health or environmental consequences, which may

in turn lead to socio-economic consequences. The consequence assessment describes the potential consequences of a given exposure and estimates the probability of them occurring.

The following factors should be considered in the consequence assessment:

- microbial dose – host response relationships;
- variation in susceptibility of exposed populations or subgroups of the population;
- variation and frequency of human health effects resulting from loss of efficacy of *antimicrobial agents* and associated costs;
- potential linkage of virulence attributes and resistance;
- ~~changes in human medicinal practices resulting from reduced confidence in antimicrobials;~~
- changes in food consumption patterns due to loss of confidence in the safety of food products and any associated secondary *risks*;
- ~~associated costs;~~
- interference with first-line or ~~/~~choice antimicrobial therapy in humans;
- importance of the *antimicrobial agent* in human medicine ~~perceived future usefulness of the antimicrobial (time reference)~~;
- prevalence of resistance in human bacterial pathogens under consideration.

6. Risk estimation

A *risk* estimation integrates the results from the release assessment, exposure assessment and consequence assessment to produce overall estimates of *risks* associated with the *hazards*. Thus, *risk* estimation takes into account the whole of the *risk* pathway from *hazard identification* to the unwanted consequences.

The following factors should be considered in the *risk* estimation:

- number of people falling ill and the proportion of that number infected ~~affected~~ with antimicrobial resistant ~~strains of~~ microorganisms;
- adverse effects on vulnerable human sub-population (children, immunocompromised persons, elderly, etc.);
- increased severity or duration of infectious *disease*;
- number of person~~/~~ ~~/ or~~ days of illness per year;
- deaths (total per year; probability per year or lifetime for a random member of the population or a member of a specific more exposed sub-population);
- ~~importance~~ severity of the ~~pathology~~ *disease* ~~infection~~ caused by the target microorganisms;
- availability ~~existence or~~ ~~absence~~ of alternative antimicrobial therapy;
- potential impact of switching to an alternative *antimicrobial agent* (e.g. alternatives with potential increased toxicity);
- occurrence ~~incidence~~ of antimicrobial resistance in target pathogens observed in humans;
- consequences of the overall ~~to allow weighted summation of different~~ *risk* impacts (e.g. illness and hospitalisation).

7. Risk management components ~~options and risk communication~~

The OIE defines risk management as consisting of the steps described below. ~~Risk management options and risk communication have to be continuously monitored and reviewed in order to ensure that the objectives are being achieved.~~

a) Risk evaluation – the process of comparing the risk estimated in the risk assessment with the Member Country's appropriate level of protection.

b) Option evaluation

A range of risk management options is available to minimise the emergence and spread of antimicrobial resistance and these include both regulatory and non-regulatory ~~risk management~~ options, such as the development of codes of practice ~~concerning~~ for the use of *antimicrobial agents* in animal husbandry. *Risk management* decisions need to consider fully the implications of these different options for human health and animal health and welfare and also take into account economic considerations and any associated environmental issues. Effective control of certain bacterial diseases of *animals* will have the dual benefit of reducing the risks linked to antimicrobial resistance, in cases where the ~~bacterial disease~~ pathogen under consideration has also developed antimicrobial resistance.

c) Implementation

Risk managers should develop an implementation plan that describes how the decision will be implemented, by whom and when. ~~National or regional authorities~~ *Competent Authorities* should ensure an appropriate regulatory framework and infrastructure.

d) Monitoring and review

Risk management options ~~have to~~ should be continuously monitored and reviewed in order to ensure that the objectives are being achieved.

8. Risk communication

Communication with all interested parties should be promoted at the earliest opportunity and integrated into all phases of a *risk analysis*. This will provide all interested parties, including risk managers, with the better understanding of risk management approaches. Risk communication should be also well documented.

Article 6.10.3.

Analysis of risks to animal health

1. Definition of the risk

The *infection* of *animals* with microorganisms that have acquired resistance to ~~from the use of~~ a specific *antimicrobial agent*~~(s)~~ due to ~~the~~ its use in *animals*, and resulting in the loss of benefit of antimicrobial therapy used to manage the animal *infection*.

EU comment

As already explained in the comment above on risks to human health, the current definition of risk is limited to situations when it is clear that a specific type of resistance has emerged because of the use of this specific antimicrobial in animals. This definition is rather narrow as it does not cover possible co-selection.

Therefore, the following modification is suggested to include also cases where co-selection is a major factor:

"The infection of animals with microorganisms that have acquired resistance to a specific antimicrobial agent due to use of a specified antimicrobial class in animals, and resulting in the loss of benefit of antimicrobial therapy used to manage the animal infection.".

2. Hazard identification

- mMicroorganisms that have acquired resistance, (including multiple resistance) arising from the use of an *antimicrobial agent(s)* in *animals*;

- mMicroorganisms having obtained a resistance determinant(s) from another microorganisms which hasve acquired resistance arising from the use of an *antimicrobial agent(s)* in *animals*.

The *identification of the hazard* must should include considerations of the class or subclass of the *antimicrobial agent(s)*. This definition should be read in conjunction with point 4) of Article 6.10.1.

3. Release assessment

The following factors should be considered in the release assessment:

- animal species and, where appropriate, production type (e.g. veal calves or dairy cattle, broilers or laying hens) treated with the *antimicrobial agent(s)* in question;

- number of *animals* treated, sex, age and their geographical distribution;

- prevalence of *infection* or *disease* for which the *antimicrobial agent* is indicated in the target animal population;

- data on trends in *antimicrobial agent* use and changes in farm production systems;

- potential extra-label or off-label use;

- dosage regimen including ~~amounts used and~~ duration of ~~treatment~~ use;

- ~~variation in~~ methods and routes of administration of the *antimicrobial agent(s)*;

- the pharmacokinetics or pharmacodynamics~~/ pharmacokinetics~~ of the *antimicrobial agent(s)*;

- site and type of *infection;*

- development of resistant microorganisms;

- mechanisms and pathways of resistance transfer;

- cross-resistance ~~and/~~or co-resistance with other *antimicrobial agents*;

- data on occurrence of resistant microorganisms through surveillance of *animals*, products of animal origin and animal waste products ~~for the existence of resistant micro-organisms~~.

4. Exposure assessment

The following factors should be considered in the exposure assessment:

- prevalence and trends of resistant microorganisms in clinically ill and clinically unaffected *animals*;

EU comment

In the above point, the EU suggests replacing the words "clinically unaffected animals" by "asymptomatic animals.

- occurrence ~~prevalence~~ of resistant microorganisms in feed and in~~/~~ the animal environment;

- animal-to-animal transmission of the resistant microorganisms (animal husbandry practices ~~methods~~ , movement of *animals*);

- number~~/~~ or percentage of *animals* treated;

- ~~dissemination of resistant micro-organisms from *animals* (animal husbandry methods, movement of *animals*);~~

- quantity and trends of *antimicrobial agent(s)* used in *animals*;
- ~~treatment regimens (dose, route of administration, duration);~~
- survival capacity ~~of resistant micro-organisms~~ and spread of resistant microorganisms;
- exposure of *wildlife* to resistant microorganisms;
- disposal practices for waste products and the opportunity for animal exposure to resistant microorganisms or resistance determinants in those products;
- capacity of resistant microorganisms to become established in *animals* ~~intestinal flora~~;
- exposure to resistance determinants from other sources such as water, effluent, waste pollution, etc.;
- ~~dose, route of administration and duration of treatment;~~
- pharmacokinetics, such as ~~(~~metabolism, bioavailability, access to intestinal flora~~)~~;
- transfer ~~cycling~~ of resistant microorganisms between humans, *animals* and the environment.

5. Consequence assessment

The following factors should be considered in the consequence assessment:

- microbial dose – host response relationships;
- variation in disease susceptibility of exposed populations and subgroups of the populations;
- variation and frequency of animal health effects resulting from loss of efficacy of *antimicrobial agents* and associated costs;
- potential linkage of virulence attributes and resistance;
- ~~changes in practices resulting from reduced confidence in antimicrobials;~~
- ~~associated cost;~~
- ~~perceived future~~ importance ~~usefulness~~ of the ~~drug~~ *antimicrobial agent* in animal health (see OIE list of *antimicrobial agents* of veterinary importance) ~~(time reference)~~.

6. Risk estimation

The following factors should be considered in the *risk* estimation:

- additional burden of disease due to antimicrobial resistant microorganisms;
- number of therapeutic failures due to antimicrobial resistant microorganisms;
- increased severity and duration of infectious disease;
- impact on *animal welfare;*
- ~~economic cost;~~
- deaths (total per year; probability per year or lifetime for a random member of the population or a member of a specific more exposed sub-population);
- availability ~~existence or absence~~ of alternative antimicrobial therapy;
- potential impact of switching to an alternative *antimicrobial agent*, e.g. alternatives with potential increased toxicity;

- estimation of the economic impact and cost on animal health and production.

- ~~incidence of resistance observed in *animals*.~~

7. Risk management ~~options~~components ~~and risk communication~~

The relevant provisions contained in Article 6.9.7. do apply.

~~Risk management options and risk communication have to be continuously monitored and reviewed in order to ensure that the objectives are being achieved.~~

~~The relevant recommendations (Articles 2.1.5., 2.1.6. and 2.1.7.) in the *Terrestrial Code* apply.~~

~~A range of *risk management* options is available to minimize the emergence and spread of antimicrobial resistance and these include both regulatory and non regulatory *risk management* options, such as the development of codes of practice concerning the use of antimicrobials in animal husbandry. *Risk management* decisions need to consider fully the implications of these different options for human health and animal health and *welfare* and also take into account economic considerations and any associated environmental issues. Effective control of certain bacterial *diseases* of *animals* will have the dual benefit of reducing the *risks* linked to antimicrobial resistance, in cases where the bacterial *disease* under consideration has also developed antimicrobial resistance. Appropriate communication with all stakeholders is essential throughout the *risk assessment* process.~~

8. Risk communication

The relevant provisions ~~contained~~ in Article 6.9.8. ~~do~~ apply.

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— Text deleted

Annex XXXIX

CHAPTER 8.5.

INFECTION WITH FOOT AND MOUTH DISEASE VIRUS

EU comments

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

Specific comments are inserted in the text below.

Article 8.5.1.

~~**Introduction**~~

1) For the purposes of the *Terrestrial Code*, foot and mouth disease (FMD) is defined as an *infection* of animals of the suborder *ruminantia* and of the family *suidae* of the order *Artiodactyla,* and *Camelus bactrianus* with foot and mouth disease virus (FMDV).

2) The following defines the occurrence of FMDV *infection*:

Detection in a sample from an animal listed above, of the virus, viral antigen, nucleic acid or virus-specific antibodies that are not a consequence of *vaccination* by a test as specified in the *Terrestrial Manual*.

3) The following defines the occurrence of FMDV circulation:

Transmission of FMDV, as demonstrated by clinical signs or change in virological or serological status indicative of recent *infection*.

4) For the purposes of the *Terrestrial Code*, the *incubation period* ~~for~~ of FMD shall be 14 days.

5) Many different species belonging to diverse taxonomic orders are known to be susceptible to *infection* with FMDV. Their epidemiological significance depends upon the degree of susceptibility, the husbandry system, the density and extent of populations and the contact between them. Amongst *Camelidae* only Bactrian camels (*Camelus bactrianus*) are of sufficient susceptibility to have potential for epidemiological significance. South American camelids and dromedaries are not considered of epidemiological importance.

~~For the purposes of this chapter, ruminants include *animals* of the family of Camelidae (except *Camelus dromedarius*).~~

~~For the purposes of this chapter, a *case* is an *animal* infected with FMD virus (FMDV).~~

6) *Infection* with FMDV can give rise to *disease* of variable severity and to FMDV circulation. FMDV *infection* in ruminants may persist leading to carriers. Although live FMDV can be recovered from carriers, transmission of FMDV from these carriers has not been proven, except from ~~for~~ African buffalo (*Syncerus caffer*).

7) The chapter deals not only with the occurrence of clinical signs caused by FMDV, but also with the presence of *infection* with FMDV in the absence of clinical signs.

~~The following defines the occurrence of FMDV *infection:*~~

~~1. FMDV has been isolated and identified as such from an *animal* or a product derived from that *animal*; or;~~

~~2. viral antigen or viral ribonucleic acid (RNA) specific to one or more of the serotypes of FMDV has been identified in samples from one or more *animals*, whether showing clinical signs consistent with FMD or not,~~

~~or epidemiologically linked to a confirmed or suspected *outbreak* of FMD, or giving cause for suspicion of previous association or contact with FMDV; or~~

~~3. antibodies to structural or nonstructural proteins of FMDV that are not a consequence of vaccination, have been identified in one or more *animals* showing clinical signs consistent with FMD, or epidemiologically linked to a confirmed or suspected *outbreak* of FMD, or giving cause for suspicion of previous association or contact with FMDV.~~

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

Article 8.5.2.

FMD free country or zone where vaccination is not practised

In defining a *zone* where *vaccination* is not practised the principles of Chapter 4.3. should be followed.

Susceptible *animals* in the FMD free country *or zone* where *vaccination* is not practised should be protected ~~from neighbouring infected countries~~ by the application of animal health measures that effectively prevent the entry of the virus into the free country or *zone*. ~~t~~Taking into consideration physical or geographical barriers with any neighbouring infected country or *zone*. ~~T~~these measures may include a *protection zone*.

To qualify for inclusion in the existing list of FMD free countries or *zones* where *vaccination* is not practised, a Member should:

1) have a record of regular and prompt animal *disease* reporting;

2) send a declaration to the OIE stating that within the proposed FMD free country or *zone*:

   a) there has been no *outbreak* of FMD during the past 12 months;

   b) no evidence of FMDV *infection* has been found during the past 12 months;

   c) no *vaccination* against FMD has been carried out during the past 12 months;

   ~~d) no vaccinated *animal* has been introduced since the cessation of vaccination;~~

3) supply documented evidence that for at least the past 12 months:

   a) *surveillance* for FMD and FMDV *infection* in accordance with Articles 8.5.~~42~~40. to 8.5.~~47~~46. ~~and Article 8.5.49.~~ is in operation;

   b) regulatory measures for the early detection, prevention and control of FMD have been implemented;

4) describe in detail and supply documented evidence that for at least the past 12 months these are properly implemented and supervised: ~~the boundaries and measures of a *protection zone*, if applicable.~~

EU comment

For reasons of clarity, the EU suggests replacing the word "these" by the words "the following" in the point above.

   a) in case of FMD free *zone*, the boundaries of the proposed FMD free *zone*;

   b) the boundaries and measures of a *protection zone*, if applicable;

   c) the system for preventing the entry of the virus into the proposed FMD free country or *zone*;

   d) the control of the movement of susceptible *animals* into the proposed FMD free country or *zone* in particular if the procedure described in Articles 8.5.8., 8.5.9. and 8.5.12. are implemented;

   e) no vaccinated *animal* has been introduced during the past 12 months except in accordance with Articles 8.5.8. and 8.5.9.

The Member or the proposed free *zone* will be included in the list of FMD free countries or *zones* where *vaccination* is not practiced only after the submitted evidence, based on the provisions of Article 1.6.4., has been accepted by the OIE.

EU comment

For reasons of clarity and consistency, the EU suggests replacing the words "The Member or the proposed free zone" by the word "The proposed FMD free country or zone" in the paragraph above.

Retention on the list requires that the information in points 2, 3 and 4 above be re-submitted annually and changes in the epidemiological situation or other significant events including those relevant to points 3b) and 4 should be reported to the OIE according to the requirements in Chapter 1.1.

The status of a country or *zone* will not be affected by applying official emergency *vaccination* in zoological collections in the face of a clearly identifiable FMD threat, provided that the following conditions are met:

a) the zoological collection has a primary purpose to exhibit *animals* or preserve rare species and should be identified in advance, including the boundaries of the facility and be included in the country's contingency plan for FMD;

b) appropriate biosecurity measures are in place, including effective separation from other susceptible domestic populations or *wildlife*;

c) the *animals* are identifiable as belonging to the collection;

d) the vaccine used complies with the *Terrestrial Manual*;

e) *vaccination* is conducted under the supervision of the *Veterinary Authority*;

f) the zoological collection is placed under active clinical *surveillance* for at least 12 months after *vaccination*.

In the event of the application for the status of an FMD free *zone* where *vaccination* is not practised to be assigned to a new *zone* adjacent to another FMD free *zone* where *vaccination* is not practised, it should be indicated if the new *zone* is being merged with the adjacent *zone* to become one enlarged *zone*. If the two *zones* remain separate, details should be provided on the control measures to be applied for the maintenance of the status of the separate *zones* and particularly on the identification and the control of the movement of *animals* between the *zones* of the same status in accordance with Chapter 4.3.

Article 8.5.3.

FMD free country or zone where vaccination is practised

In defining a *zone* where *vaccination* is practised the principles of Chapter 4.3. should be followed.

Susceptible *animals* in the FMD free country or *zone* where *vaccination* is practised should be protected ~~from neighbouring infected countries~~ by the application of animal health measures that effectively prevent the entry of the virus into the free country or *zone*~~,~~. ~~t~~Taking into consideration physical or geographical barriers with any neighbouring infected country or *zone*~~,~~. ~~T~~these measures may include a *protection zone*. Based on the epidemiology of FMD in the country, it may be decided to vaccinate only a defined *subpopulation* comprised of certain species or other subsets of the total susceptible population.

To qualify for inclusion in the list of FMD free countries or *zones* where *vaccination* is practised, a Member should:

1) have a record of regular and prompt animal *disease* reporting;

2) send a declaration to the OIE stating that within the proposed FMD free country or *zone*:

   a) there has been no *outbreak* of FMD during the past two years;

   b) no evidence of FMDV circulation has been found during the past 12 months;

3) supply documented evidence that:

a) *surveillance* for FMD and FMDV circulation in accordance with Articles 8.5.~~42~~40. to 8.5.~~47~~46. ~~and Article 8.5.49.~~ is in operation;

b) regulatory measures for the early detection, prevention and control of FMD have been implemented;

c) ~~routine~~ compulsory systematic *vaccination* in the target population is carried out ~~for the purpose of the prevention of FMD~~;

d) the vaccine used complies with the standards described in the *Terrestrial Manual*, including appropriate vaccine strain selection;

4) describe in detail and supply documented evidence that these are properly implemented and supervised ~~the boundaries and measures of a *protection zone*, if applicable.~~:

EU comment

For reasons of clarity, the EU suggests replacing the word "these" by the words "the following" in the point above.

a) in case of FMD free *zone*, the boundaries of the proposed FMD free *zone*;

b) the boundaries and measures of a *protection zone*, if applicable;

c) the system for preventing the entry of the virus into the proposed FMD free country or *zone* (in particular if the procedure described in Article 8.5.8. is implemented);

d) the control of the movement of susceptible *animals* into the proposed FMD free country or *zone*.

The Member or the proposed free *zone* will be included in the list of FMD free countries or *zones* where *vaccination* is practised only after the submitted evidence, based on the provisions of Article 1.6.4., has been accepted by the OIE.

EU comment

For reasons of clarity and consistency, the EU suggests replacing the words "The Member or the proposed free zone" by the word "The proposed FMD free country or zone" in the paragraph above.

Retention on the list requires that the information in points 2, 3 and 4 above be re-submitted annually and changes in the epidemiological situation or other significant events including those relevant to points 3b) and 4 should be reported to the OIE according to the requirements in Chapter 1.1.

If a Member that meets the requirements of an FMD free country or *zone* where *vaccination* is practised wishes to change its status to FMD free country or *zone* where *vaccination* is not practised, it should notify the OIE in advance on the intended date of cessation of *vaccination* and apply for the new status within 24 months. The status of this country or *zone* remains unchanged until compliance with Article 8.5.2. is approved by the OIE. If the dossier for the new status is not provided within 24 months then the status will be suspended. If the country does not comply with requirements of Article 8.5.2., evidence should be provided within 3 months that they comply with Article 8.5.3. ~~the status of this country remains unchanged for a period of at least 12 months after vaccination has ceased. Evidence should also be provided showing that FMDV *infection* has not occurred during that period.~~

In the event of the application for the status of an FMD free *zone* where *vaccination* is practised to be assigned to a new *zone* adjacent to another FMD free *zone* where *vaccination* is practised, it should be indicated if the new *zone* is being merged with the adjacent *zone* to become one enlarged *zone*. If the two *zones* remain separate, details should be provided on the control measures to be applied for the maintenance of the status of the separate *zones* and particularly on the identification and the control of the movement of *animals* between the *zones* of the same status in accordance with Chapter 4.3.

~~Article 8.5.4.~~

~~**FMD free zone where vaccination is not practised**~~

An FMD free *zone* where vaccination is not practised can be established in either an FMD free country where vaccination is practised or in a country of which parts are infected. In defining such a *zones* the principles of Chapter 4.3. should be followed. Susceptible *animals* in the FMD free *zone* should be protected from the rest of the country and from neighbouring countries if they are of a different *animal health status* by the application of animal health measures that effectively prevent the entry of the virus, taking into consideration physical or geographical barriers. These measures may include a *protection zone*.

To qualify for inclusion in the list of FMD free *zones* where vaccination is not practised, a Member should:

1. have a record of regular and prompt animal *disease* reporting;

2. send a declaration to the OIE stating that within the proposed FMD free *zone*:

    a) there has been no *outbreak* of FMD during the past 12 months;

    b) no evidence of FMDV *infection* has been found during the past 12 months;

    c) no vaccination against FMD has been carried out during the past 12 months;

    d) no vaccinated *animal* has been introduced into the *zone* since the cessation of vaccination, except in accordance with Article 8.5.10.;

3. supply documented evidence that:

    a) *surveillance* for FMD and FMDV *infection* in accordance with Articles 8.5.42. to 8.5.47. and Article 8.5.49. is in operation;

    b) regulatory measures for the early detection, prevention and control of FMD have been implemented;

4. describe in detail and supply documented evidence that these are properly implemented and supervised:

    a) the boundaries of the proposed FMD free *zone*;

    b) the boundaries and measures of a *protection zone*, if applicable;

    c) the system for preventing the entry of the virus (including the control of the movement of susceptible *animals*) into the proposed FMD free *zone* (in particular if the procedure described in Article 8.5.10. is implemented).;

The proposed free *zone* will be included in the list of FMD free *zones* where vaccination is not practised only after the submitted evidence has been accepted by the OIE.

The information required in points 2, 3 and 4 b)-c) above should be re-submitted annually and changes in the epidemiological situation or other significant events including those relevant to points 3b) and 4 should be reported to the OIE according to the requirements in Chapter 1.1.

Article 8.5.5.

FMD free zone where vaccination is practised

An FMD free *zone* where vaccination is practised can be established in either an FMD free country where vaccination is not practised or in a country of which parts are infected. In defining such *zones* the principles of Chapter 4.3. should be followed. Susceptible *animals* in the FMD free *zone* where vaccination is practised should be protected from neighbouring countries or *zones* if they are of a lesser *animal health status* by the application of animal health measures that effectively prevent the entry of the virus, taking into consideration physical or geographical barriers. These measures may include a *protection zone*.

To qualify for inclusion in the list of FMD free *zones* where vaccination is practised, a Member should:

1. have a record of regular and prompt animal *disease* reporting;

2. send a declaration to the OIE that within the proposed FMD free *zone*;

    a) there has been no *outbreak* of FMD for the past two years;

b) no evidence of FMDV circulation has been found during the past 12 months;

3. supply documented evidence that:

a) *surveillance* for FMD and FMDV *infection*/circulation in accordance with Articles 8.5.42. to 8.5.47. and Article 8.5.49. is in operation;

b) regulatory measures for the early detection, prevention and control of FMD have been implemented;

c) routine vaccination is carried out for the purpose of the prevention of FMD;

d) the vaccine used complies with the standards described in the *Terrestrial Manual*;

4. describe in detail and supply documented evidence that these are properly implemented and supervised:

a) the boundaries of the proposed FMD free *zone*;

b) the boundaries and measures of a *protection zone*, if applicable;

c) the system for preventing the entry of the virus (including the control of the movement of susceptible *animals*) into the proposed FMD free *zone* (in particular if the procedure described in Article 8.5.10. is implemented).

The proposed free *zone* will be included in the list of FMD free *zones* where vaccination is practised only after the submitted evidence has been accepted by the OIE. The information required in points 2, 3 and 4 b) c) above should be re-submitted annually and changes in the epidemiological situation or other significant events including those relevant to points 3 b) and 4 should be reported to the OIE according to the requirements in Chapter 1.1.

If a Member that has a *zone* which meets the requirements of a FMD free *zone* where vaccination is practised wishes to change the status of the *zone* to FMD free *zone* where vaccination is not practised, the status of this *zone* remains unchanged for a period of at least 12 months after vaccination has ceased. Evidence should also be provided showing that FMDV *infection* has not occurred in the said *zone* during that period.

Article 8.5.4~~6~~.

FMD free compartment

An FMD free *compartment* can be established in either an FMD free country or *zone* or in an infected country or *zone*. In defining such a *compartment* the principles of Chapters 4.3. and 4.4. should be followed. Susceptible *animals* in the FMD free *compartment* should be separated from any other susceptible *animals* by the application of an effective biosecurity management system.

A Member wishing to establish an FMD free *compartment* should:

1) have a record of regular and prompt animal *disease* reporting and if not FMD free, have an official control programme and a *surveillance* system for FMD in place according to Articles 8.5.~~42~~40. to 8.5.4~~7~~42. and Article 8.5.4~~9~~46. that allows ~~an~~ ~~accurate~~ knowledge of the prevalence, distribution and characteristics of FMD in the country or *zone*;

2) declare for the FMD free *compartment* that:

a) there has been no *outbreak* of FMD during the past 12 months;

b) no evidence of FMDV *infection* has been found during the past 12 months;

c) either: ~~*vaccination* against FMD is prohibited;~~

i) no *vaccination* against FMD has been carried out during the past 12 months; no vaccinated *animal* has been introduced during the past 12 months; or

ii) compulsory systematic *vaccination* is carried out and the vaccine used complies with the standards described in the *Terrestrial Manual*, including appropriate vaccine strain selection;

~~d)~~ ~~no *animal* vaccinated against FMD within the past 12 months is in the compartment;~~

d~~e~~) *animals*, semen and embryos should only enter the *compartment* in accordance with relevant articles in this chapter;

e~~f~~) documented evidence shows that *surveillance* in accordance with Articles 8.5.~~42~~40. to 8.5.~~47~~46. ~~and Article 8.5.49.~~ is in operation for FMD and FMDV *infection*;

f~~g~~) an *animal identification* and *traceability* system in accordance with Chapters 4.1. and 4.2. is in place;

3) describe in detail:

a) the animal subpopulation in the *compartment*; ~~and~~

b) the biosecurity plan ~~for FMD and FMDV *infection*~~ and, where applicable, the *vaccination* plan, to mitigate the risks identified by the *surveillance* carried out according to point 1 of Article 8.5.4.

The *compartment* should be approved by the *Veterinary Authority*. The first approval should only be granted when no *outbreak* of FMD has occurred within a ten-kilometre radius of ~~the *zone* in which~~ the *compartment* ~~is situated,~~ during the ~~last~~ past three months.

Article 8.5.5 ~~7~~.

FMD infected country or zone

For the purposes of this chapter, when the requirements for acceptance as an FMD free country or *zone* where *vaccination* is not practised or an FMD free country or *zone* where *vaccination* is practised are not fulfilled, such country or *zone* shall be considered as FMD infected. ~~an FMD infected country is a country that does not fulfil the requirements to qualify as either an FMD free country where vaccination is not practised or an FMD free country where vaccination is practised.~~

~~For the purposes of this chapter, an FMD *infected zone* is a *zone* that does not fulfil the requirements to qualify as either an FMD free *zone* where vaccination is not practised or an FMD free *zone* where vaccination is practised.~~

Article 8.5.6 ~~8~~.

Establishment of a containment zone within an FMD free country or zone

In the event of limited *outbreaks* within an FMD free country or *zone*, including within a *protection zone*, with or without *vaccination*, a single *containment zone*, which includes all ~~*cases*~~ *outbreaks*, can be established for the purpose of minimizing the impact on the entire country or *zone*.

For this to be achieved and for the Member to take full advantage of this process, the *Veterinary Authority* should submit documented evidence as soon as possible to the OIE that:

1) the boundaries of the *containment zone* are established taking into consideration that ~~the *outbreaks* are limited based on the following factors:~~ the *outbreaks* are limited based on the following factors:

EU comment

In point 1 above, the words "the outbreaks are limited based on the following factors" should be deleted (typographical error).

a) immediately on suspicion, animal movement control has been imposed in the country or *zone*, and effective controls on the movement of other *commodities* mentioned in this chapter are in place ~~a rapid response including notification has been made~~;

~~b) standstill of animal movements has been imposed, and effective controls on the movement of other *commodities* mentioned in this chapter are in place;~~

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~~c~~b) epidemiological investigation (trace-back, trace-forward) is able to demonstrate that the *outbreaks* are epidemiologically related and limited in number and geographic distribution ~~has been completed~~;

~~d) the *infection* has been confirmed~~;

~~e~~c) ~~the primary *outbreak* has been identified, and~~ investigations on the likely source of the *outbreak* have been carried out;

~~f) all *cases* have been shown to be epidemiologically linked;~~

~~g) no new *cases* have been found in the *containment zone* within a minimum of two *incubation periods* as defined in Article 8.5.1. after the stamping-out of the last detected *case* is completed;~~

2) a *stamping-out policy*, with or without the use of emergency *vaccination,* has been applied;

3) no new *cases* have been found in the *containment zone* within a minimum of one *incubation period* as defined in Article 8.5.1. after the application of a *stamping-out policy* to the last detected *case*;

~~3.~~4) the susceptible domestic and *captive wild* animal populations within the *containment zone*~~s~~ ~~should~~ are ~~be~~ clearly identifiable as belonging to the *containment zone*;

4.5) ~~increased passive and targeted~~ *surveillance* in accordance with Articles ~~8.5.42.3 to 8.5.47~~. 8.5.41., 8.5.42. and Article 8.5.~~49~~46. in the *containment zone* and in the rest of the country or *zone* ~~has been carried out~~ is in place ~~and has not detected any evidence of~~ FMDV *infection*;

~~5.~~6) animal health measures that effectively prevent the spread of the FMDV to the rest of the country or *zone*, taking into consideration physical and geographical barriers, are in place.

~~6. ongoing *surveillance* in the *containment zone* is in place.~~

The free status of the areas outside the *containment zone* ~~would be~~ is suspended ~~pending the establishment of~~ while the *containment zone* is being established. The free status of these areas may ~~could~~ be reinstated irrespective of the provisions of Article 8.5.~~9~~7., once the *containment zone* is clearly established, by complying with points 1 to 6 above. ~~The *containment zone* should be managed in such a way that it can~~ It should be demonstrated that *commodities* for *international trade* ~~can be shown to~~ have originated outside the *containment zone*.

In the event of recurrence of FMDV circulation in the *containment zone,* the approval of the *containment zone* is withdrawn.

The recovery of the FMD free status of the *containment zone* should follow the provisions of Article 8.5.~~9~~7.

Article 8.5.7 ~~9~~.

Recovery of free status (see Figure 1)

1) When an FMD *outbreak* or FMDV *infection* occurs in an FMD free country or *zone* where *vaccination* is not practised, one of the following waiting periods is required to regain the status of FMD free country or *zone* where *vaccination* is not practised:

a) three months after the last *case* where a *stamping-out policy* and serological *surveillance* are applied in accordance with Articles 8.5.~~42~~40. to 8.5.43., 8.5.45. and 8.5.~~49~~46.; or

b) three months after the *slaughter* of all vaccinated *animals* where a *stamping-out policy*, emergency *vaccination* and serological *surveillance* are applied in accordance with Articles 8.5.~~42~~40. to 8.5.43., 8.5.45. and 8.5.~~49~~46.; or

c) six months after the last *case* or the last *vaccination* (according to the event that occurs the latest), where a *stamping-out policy*, emergency *vaccination* not followed by the slaughtering of all vaccinated *animals*, and serological *surveillance* are applied in accordance with Articles 8.5.~~42~~40. to 8.5.43., 8.5.~~47~~45. and Article 8.5.~~49~~46., provided that a serological survey based on the detection of antibodies to nonstructural proteins of FMDV demonstrates the absence of *infection* in the remaining vaccinated population. This period can be reduced to three months if additional *surveillance* in accordance to Article 8.5.45. is carried out.

The country or *zone* will regain the status of FMD free country or *zone* where *vaccination* is not practised only after the submitted evidence, based on the provisions of Article 1.6.4., has been accepted by the OIE.

The time periods in points 1a) to 1c) are not affected if official emergency *vaccination* of zoological collections has been carried out following the relevant provisions of Article 8.5.2.

Where a *stamping-out policy* is not practised, the above waiting periods do not apply, and Article 8.5.2. applies.

2) When an FMD *outbreak* or FMDV *infection* occurs in an FMD free country or *zone* where *vaccination* is not practised, the following waiting period is required to gain the status of FMD free country or *zone* where *vaccination* is practised: 6 months after stamping out of the last *case* where a *stamping-out policy* has been applied and adoption of a continued *vaccination* policy, provided that serological *surveillance* is applied in accordance with Articles 8.5.40. to 8.5.42. and Articles 8.5.44. to 8.5.46, and a serological survey based on the detection of antibodies to nonstructural proteins of FMDV demonstrates the absence of FMDV circulation.

EU comment

In point 2 above, the words "and adoption of a continued vaccination policy" should be replaced by "and a continued vaccination policy has been adopted" (language).

The country or *zone* can gain the status of FMD free country or *zone* where *vaccination* is practised only after the submitted evidence, based on the provisions of Article 1.6.4., has been accepted by the OIE.

Where a *stamping-out policy* is not practised, the above waiting periods do not apply, and Article 8.5.2. applies.

EU comment

The EU suggests amending the paragraph above as follows:

"[…], and Article 8.5.2. or Article 8.5.3. applies, as applicable.".

Indeed, a Member with suspended free country or zone status without vaccination may choose to aim at free country or zone status without (Art. 8.5.2.) or with vaccination (Art. 8.5.3.). This is also reflected in Figure 1.

~~2.~~3) When an FMD *outbreak* or FMDV ~~*infection*~~ circulation occurs in an FMD free country or *zone* where *vaccination* is practised, one of the following waiting periods is required to regain the status of FMD free country or *zone* where *vaccination* is practised:

a) 6 months after the last *case* where a *stamping-out policy*, emergency *vaccination* and serological *surveillance* in accordance with Articles 8.5.~~42~~40. to 8.5.42. and Articles 8.5.44. to 8.5.46~~8.5.45. and Article 8.5.49~~. are applied, provided that the serological *surveillance* based on the detection of antibodies to nonstructural proteins of FMDV demonstrates the absence of virus circulation; or

b) 18 months after the last *case* where a *stamping-out policy* is not applied, but emergency *vaccination* and serological *surveillance* in accordance with Articles 8.5.~~42~~40. to 8.5.42. and Articles 8.5.44. to 8.5.46. ~~8.5.47. and Article 8.5.49~~. are applied, provided that the serological *surveillance* based on the detection of antibodies to nonstructural proteins of FMDV demonstrates the absence of virus circulation.

The country or *zone* will regain the status of FMD free country or *zone* where *vaccination* is practised only after the submitted evidence, based on the provisions of Article 1.6.4., has been accepted by the OIE.

~~3.~~4) When an FMD *outbreak* or FMDV *infection* occurs in an FMD free *compartment*, Article 8.5.~~6~~4. applies. The waiting period in point 2a) and 2b) of Article 8.5.4. can be reduced to three months provided that the entire *compartment* has been depopulated, cleansed and disinfected.

5) Members applying for the recovery of status should do so as soon as the respective requirements for the recovery of status are met. When a *containment zone* has been established, the restrictions within the *containment zone* should be lifted in accordance with the requirements of this Article as soon as the *disease* has been successfully eradicated within the *containment zone*.

Article 8.5.8 ~~10~~.

Direct transfer of FMD susceptible animals from an infected zone for slaughter in a free zone (where vaccination either is or is not practised)

In order not to jeopardise the status of a free *zone*, FMD susceptible *animals* should only leave the *infected zone* if transported directly to *slaughter* in the nearest designated *abattoir* under the following conditions:

1) no FMD susceptible *animal* has been introduced into the *establishment* of origin and no *animal* in the *establishment* of origin has shown clinical signs of FMD for at least 30 days prior to movement;

2) the *animals* were kept in the *establishment* of origin for at least three months prior to movement;

3) FMD has not occurred within a ten-kilometre radius of the *establishment* of origin for at least three months prior to movement;

4) the *animals* should be transported under the supervision of the *Veterinary Authority* in a *vehicle*, which was cleansed and disinfected before *loading*, directly from the *establishment* of origin to the *abattoir* without coming into contact with other susceptible *animals*;

5) such an *abattoir* is not approved for the export of *fresh meat* during the time it is handling the *meat* of *animals* from the *infected zone*;

6) *vehicles* and the *abattoir* should be subjected to thorough cleansing and *disinfection* immediately after use.

The *meat* should be derived from *animals* that have been subjected to ante- and post-mortem inspection for FMD, with favourable results within 24 hours before and after *slaughter* and treated according to point 2 of Article 8.5.~~25~~22. or Article 8.5.~~26~~23. Other products obtained from the *animals* and any products coming into contact with them should be considered infected, and treated in such a way as to destroy any residual virus in accordance with Articles 8.5.~~34~~31. to 8.5.~~41~~38.

Animals moved into a free *zone* for other purposes should be moved under the supervision of the *Veterinary Authority* and comply with the conditions in Article 8.5.~~14~~12.

Article 8.5.9~~11~~.

Direct ~~T~~ transfer ~~directly to slaughter~~ of FMD susceptible animals from a containment zone for slaughter in ~~to~~ a free zone (where vaccination either is or is not practised) ~~within a country~~

In order not to jeopardise the status of a free *zone*, FMD susceptible *animals* should only leave the *containment zone* if moved by mechanised transport directly to *slaughter* in the nearest designated *abattoir* under the following conditions:

1) the *containment zone* has been officially established according to the requirements in Article 8.5.~~8~~6.;

2) the *animals* should be transported under the supervision of the *Veterinary Authority* in a *vehicle*, which was cleansed and disinfected before *loading*, directly from the *establishment* of origin to the *abattoir* without coming into contact with other susceptible *animals*;

3) such an *abattoir* is not approved for the export of *fresh meat* during the time it is handling the *meat* of *animals* from the *containment zone*;

4) *vehicles* and the *abattoir* should be subjected to thorough cleansing and *disinfection* immediately after use.

The *meat* should be derived from *animals* that have been subjected to ante- and post-mortem inspection for FMD, with favourable results within 24 hours before and after *slaughter* and treated according to point 2 of Article 8.5.~~25~~22. or Article 8.5.~~26~~23. Other products obtained from the *animals* and any products coming into contact with them should be treated in such a way as to destroy any residual virus in accordance with Articles 8.5.~~34~~31. to 8.5.~~41~~38.

Article 8.5.10.~~12~~.

Recommendations for importation from FMD free countries, ~~or~~ zones or compartments where vaccination is not practised ~~or FMD free compartments~~

For FMD susceptible animals

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

1) showed no clinical sign of FMD on the day of shipment;

2) were kept since birth or for at least the past three months in an FMD free country, ~~or~~ *zone* or *compartment* where *vaccination* is not practised; ~~or a FMD free *compartment*~~

3) have not been vaccinated;

4) if transiting an *infected zone*, were not exposed to any source of FMD *infection* during transportation to the *place of shipment*~~.~~;

Article 8.5.11.~~13~~.

Recommendations for importation from FMD free countries, ~~or~~ zones or compartments where vaccination is practised

For domestic ruminants and pigs

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

1) showed no clinical sign of FMD on the day of shipment;

2) were kept in an FMD free country, ~~or~~ *zone or compartment* where *vaccination* is practised, since birth or for at least the past three months; ~~and~~

3) when destined to an FMD free country or *zone* where *vaccination* is not practised, have not been vaccinated and were subjected, with negative results, to tests for antibodies against FMD virus ~~when destined to an FMD free country or *zone* where vaccination is not practised~~;

4) if transiting an *infected zone*, were not exposed to any source of FMD *infection* during transportation to the *place of shipment*.

Article 8.5. 12.~~14~~.

Recommendations for importation from FMD infected countries or zones

For domestic ruminants and pigs

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

1) the *animals* showed no clinical sign of FMD on the day of shipment;

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2) prior to isolation, the *animals* were kept in the *establishment* of origin ~~since birth, or~~

   a) for ~~the past~~ 30 days, or since birth if younger than 30 days, if a *stamping-out policy* is in force in the *exporting country*, or

   b) for ~~the past~~ 3 months, or since birth if younger than three months, if a *stamping-out policy* is not in force in the *exporting country*,

3) ~~and that~~ FMD has not occurred within a ten-kilometre radius of the *establishment* of origin for the relevant period as defined in points 2 a) and b) above;

~~3~~4) the *animals* were isolated in an *establishment* or a *quarantine station* for the 30 days prior to shipment, and all *animals* in isolation were subjected to diagnostic tests (virus detection on a probang sample in ruminants or on throat swabs in pigs and serology) for evidence of FMDV *infection* with negative results on samples collected at the end of that period, and that FMD did not occur within a ten-kilometre radius of the *establishment* or a *quarantine station* during that period; ~~or~~

4) ~~were kept in a *quarantine station* for the 30 days prior to shipment, all *animals* in quarantine were subjected to diagnostic tests (probang and serology) for evidence of FMDV *infection* with negative results at the end of that period, and that FMD did not occur within a ten-kilometre radius of the *quarantine station* during that period;~~

5) the *animals* were not exposed to any source of FMD *infection* during their transportation from the *establishment* or *quarantine station* to the *place of shipment*.

Article 8.5. 13.~~15~~.

Recommendations for importation from FMD free countries, ~~or~~ zones or compartments where vaccination is not practised ~~or FMD free compartments~~

For fresh semen of domestic ruminants and pigs

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

1) the donor *animals*:

   a) showed no clinical sign of FMD on the day of collection of the semen;

   b) were kept for at least three months prior to collection in an FMD free country, ~~or~~ *zone* or *compartment* where *vaccination* is not practised ~~or a FMD free *compartment*~~;

   c) were kept in an *artificial insemination centre* where none of the *animals* had a history of *infection*;

2) the semen was collected, processed and stored in conformity with the provisions of Chapters 4.5. and 4.6.

Article 8.5.14.~~16~~.

Recommendations for importation from FMD free countries, ~~or~~ zones or compartments where vaccination is not practised ~~or FMD free compartments~~

For frozen semen of domestic ruminants and pigs

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

1) the donor *animals*:

   a) showed no clinical sign of FMD on the day of collection of the semen and for the following 30 days;

   b) were kept for at least three months prior to collection in an FMD free country, ~~or~~ *zone* or *compartment* where *vaccination* is not practised ~~or a FMD free *compartment*~~;

2) the semen was collected, processed and stored in conformity with the provisions of Chapters 4.5. and 4.6.

Article 8.5.15.~~17~~.

Recommendations for importation from FMD free countries, ~~or~~ zones or compartments where vaccination is practised

For frozen semen of domestic ruminants and pigs

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

1) the donor *animals*:

   a) showed no clinical sign of FMD on the day of collection of the semen and for the following 30 days;

   b) were kept for at least three months prior to collection in an FMD free country, ~~or~~ *zone* or *compartment* where *vaccination* is practised;

   ~~c) if destined to an FMD free country or *zone* where vaccination is not practised:~~

   ~~i)~~c) have not been vaccinated and were subjected, not less than 21 days after collection of the semen, to tests for antibodies against FMD virus, with negative results; or

   ~~ii)~~d) had been vaccinated at least twice, with the last *vaccination* not more than 12 and not less than one month prior to collection;

~~2) no other *animal* present in the *artificial insemination centre* has been vaccinated within the month prior to collection;~~

2~~3~~) the semen:

   a) was collected, processed and stored in conformity with the provisions of Chapters 4.5. and 4.6.;

   b) was stored in the country of origin for a period of at least one month following collection, and during this period no *animal* on the *establishment* where the donor *animals* were kept showed any sign of FMD.

Article 8.5.16~~18~~.

Recommendations for importation from FMD infected countries or zones

For frozen semen of domestic ruminants and pigs

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

1) the donor *animals*:

   a) showed no clinical sign of FMD on the day of collection of the semen and for the following 30 days;

   b) were kept in an ~~*establishment*~~ *artificial insemination centre* where no *animal* had been added in the 30 days before collection, and that FMD has not occurred within 10 kilometres for the 30 days before and after collection;

   c) have not been vaccinated and were subjected, not less than 21 days after collection of the semen, to tests for antibodies against FMD virus, with negative results; or

   d) had been vaccinated at least twice, with the last *vaccination* not more than 12 and not less than one month prior to collection;

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~~2. no other *animal* present in the *artificial insemination centre* has been vaccinated within the month prior to collection;~~

~~3~~.2) the semen:

a) was collected, processed and stored in conformity with the provisions of Chapters 4.5. and 4.6.;

b) was subjected, with negative results, to a test for FMDV ~~*infection*~~ if the donor *animal* has been vaccinated within the 12 months prior to collection;

c) was stored in the country of origin for a period of at least one month following collection, and that during this period no *animal* on the *establishment* where the donor *animals* were kept showed any sign of FMD.

Article 8.5.17.~~19.~~

Recommendations for the importation of *in vivo* derived embryos of cattle

Irrespective of the FMD status of the *exporting country*, *zone* or *compartment*, *Veterinary Authorities* should authorise without restriction on account of FMD the import or transit through their territory of *in vivo* derived embryos of cattle subject to the presentation of an *international veterinary certificate* attesting that the embryos were collected, processed and stored in conformity with the provisions of Chapters 4.7. and 4.9., as relevant.

Article 8.5.18.~~20.~~

Recommendations for importation from FMD free countries, ~~or~~ zones or compartments where vaccination is not practised ~~or FMD free compartments~~

For *in vitro* produced embryos of cattle

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

1) the donor females:

a) showed no clinical sign of FMD at the time of collection of the oocytes;

b) were kept for at least three months prior to ~~at the time of~~ collection in an FMD free country, ~~or~~ *zone* or *compartment* where *vaccination* is not practised ~~or a FMD free *compartment*~~;

2) fertilisation was achieved with semen meeting the conditions referred to in Articles 8.5.~~15~~13., 8.5.~~16~~14., 8.5.~~17~~15. or 8.5.~~18~~16., as relevant;

3) the oocytes were collected, and the embryos were processed and stored in conformity with the provisions of Chapters 4.8. and 4.9., as relevant.

Article 8.5.19.~~21~~.

Recommendations for importation from FMD free countries, ~~or~~ zones or compartments where vaccination is practised

For *in vitro* produced embryos of cattle

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

1) the donor females:

   a) showed no clinical sign of FMD at the time of collection of the oocytes;

   b) were kept for at least three months prior to collection in an FMD free country, or *zones* or *compartments* where *vaccination* is practised;

   ~~c) if destined for an FMD free country or *zone* where vaccination is not practised or a FMD free *compartment*:~~

   ~~i)~~c) have not been vaccinated and were subjected, with negative results, to tests for antibodies against FMD virus; or

   ~~ii)~~d) had been vaccinated at least twice, with the last *vaccination* not less than one month and not more than 12 months prior to collection;

~~2) no other *animal* present in the *artificial insemination centre* has been vaccinated within the month prior to collection~~;

2) fertilization was achieved with semen meeting the conditions referred to in Articles 8.5.~~15~~13., 8.5.~~16~~14., 8.5.~~17~~15. or 8.5.~~18~~16., as relevant;

3) the oocytes were collected, and the embryos were processed and stored in conformity with the provisions of Chapters 4.8. and 4.9., as relevant.

Article 8.5.20.~~22~~.

Recommendations for importation from FMD free countries, ~~or~~ zones or compartments where vaccination is not practised ~~or FMD free compartments~~

For fresh meat or meat products of FMD susceptible animals

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

1) have been kept in the FMD free country, ~~or~~ *zone* or *compartment* where *vaccination* is not practised ~~or a FMD free *compartment*~~, or which have been imported in accordance with Article 8.5.~~12~~10., Article 8.5.~~13~~11. or Article 8.5.~~14~~12.;

2) have been slaughtered in an approved *abattoir* and have been subjected to ante- and post-mortem inspections for FMD with favourable results.

Article 8.5. 21.~~23~~.

Recommendations for importation from FMD free countries, ~~or~~ zones or compartments where vaccination is practised

For fresh meat and meat products of ruminants and pigs ~~cattle and buffaloes (*Bubalus bubalis*) (excluding feet, head and viscera)~~

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

1) have been kept in the FMD free country, ~~or~~ *zone* or *compartment* where *vaccination* is practised, or which have been imported in accordance with Article 8.5.~~12~~10., Article 8.5.~~13~~11. or Article 8.5.~~14~~12.;

2) have been slaughtered in an approved *abattoir* and have been subjected to ante- and post-mortem inspections for FMD with favourable results~~.~~;

3) for ruminants the head, including the pharynx, tongue and associated lymph nodes, have been removed.

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~~Article 8.5.24.~~

~~**Recommendations for importation from FMD free countries or zones where vaccination is practiced**~~

~~For fresh meat or meat products of pigs and ruminants other than cattle and buffaloes~~

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

~~1) have been kept in the FMD free country or *zone* where vaccination is practised, or which have been imported in accordance with Article 8.5.12., Article 8.5.13. or Article 8.5.14.;~~

~~2) have been slaughtered in an approved *abattoir* and have been subjected to ante- and post-mortem inspections for FMD with favourable results.~~

Article 8.5.22.~~25~~.

Recommendations for importation from FMD infected countries or zones, where an official control programme for FMD, involving compulsory systematic vaccination ~~of cattle,~~ exists

For fresh meat of cattle and buffaloes (*Bubalus bubalis*) (excluding feet, head and viscera)

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

1) comes from *animals* which:

   a) have remained in the *exporting country* for at least three months prior to *slaughter*;

   b) have remained, during this period, in a part of the country where cattle and buffaloes are regularly vaccinated against FMD and where official controls are in operation;

   c) have been vaccinated at least twice with the last *vaccination* not more than 12 months and not less than one month prior to *slaughter*;

   d) were kept for the past 30 days in an *establishment*, and that FMD has not occurred within a ten-kilometre radius of the *establishment* during that period;

   e) have been transported, in a *vehicle* which was cleansed and disinfected before the cattle and buffaloes were loaded, directly from the *establishment* of origin to the approved *abattoir* without coming into contact with other *animals* which do not fulfil the required conditions for export;

   f) have been slaughtered in an approved *abattoir*:

      i) which is officially designated for export;

      ii) in which no FMD has been detected during the period between the last *disinfection* carried out before *slaughter* and the shipment for export has been dispatched;

   g) have been subjected to ante- and post-mortem inspections for FMD with favourable results within 24 hours before and after *slaughter*;

2) comes from deboned carcasses:

   a) from which the major lymphatic nodes have been removed;

b) which, prior to deboning, have been submitted to maturation at a temperature above + 2°C for a minimum period of 24 hours following *slaughter* and in which the pH value was below 6.0 when tested in the middle of both the longissimus dorsi.

Article 8.5.23.~~26~~.

Recommendations for importation from FMD infected countries or zones

For meat products of ~~domestic ruminants and pigs~~ FMD susceptible animals

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

1) the entire consignment of *meat* comes from *animals* which have been slaughtered in an *approved abattoir* and have been subjected to ante- and post-mortem inspections for FMD with favourable results;

2) the *meat* has been processed to ensure the destruction of the FMD virus in conformity with one of the procedures referred to in Article 8.5.~~34~~31.;

3) the necessary precautions were taken after processing to avoid contact of the *meat products* with any potential source of FMD virus.

Article 8.5.24.~~27~~.

Recommendations for importation from FMD free countries~~,~~ ~~or~~ zones or compartments ~~(where vaccination either is or is not practised)~~ ~~or FMD free compartments~~

For milk and milk products intended for human consumption and for products of animal origin (from FMD susceptible animals) intended for use in animal feeding or for agricultural or industrial use

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that these products come from *animals* which have been kept in an FMD free country, *zone* or *compartment*, or which have been imported in accordance with Article 8.5.~~12~~10., Article 8.5.~~13~~11. or Article 8.5.~~14~~12.

Article 8.5.25.~~28~~.

Recommendations for importation from FMD infected countries or zones where an official control programme exists

For milk, cream, milk powder and milk products

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

1) these products:

   a) originate from *establishments* ~~*herds or flocks*~~ which were not infected or suspected of being infected with FMD at the time of *milk* collection;

   b) have been processed to ensure the destruction of the FMD virus in conformity with one of the procedures referred to in Article 8.5.~~38~~35. and in Article 8.5.~~39~~36.;

2) the necessary precautions were taken after processing to avoid contact of the products with any potential source of FMD virus.

Article 8.5.26.~~29~~.

Recommendations for importation from FMD infected countries

For blood and meat-meals from FMD susceptible animals ~~(from domestic or wild ruminants and pigs)~~

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that the manufacturing method for these products included heating to a minimum core temperature of 70°C for at least 30 minutes.

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Article 8.5.27.~~30~~.

Recommendations for importation from FMD infected countries

For wool, hair, bristles, raw hides and skins from FMD susceptible animals ~~(from domestic or wild ruminants and pigs)~~

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

1) these products have been processed to ensure the destruction of the FMD virus in conformity with one of the procedures referred to in Articles 8.5.~~35~~32., 8.5.~~36~~33. and 8.5.~~37~~34.;

2) the necessary precautions were taken after collection or processing to avoid contact of the products with any potential source of FMD virus.

Veterinary Authorities can authorise, without restriction, the import or transit through their territory of semi-processed hides and skins (limed hides, pickled pelts, and semi-processed leather – e.g. wet blue and crust leather), provided that these products have been submitted to the usual chemical and mechanical processes in use in the tanning industry.

Article 8.5.28.~~31~~.

Recommendations for importation from FMD infected countries or zones

For straw and forage

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

1) are free of grossly identifiable contamination with material of animal origin;

2) have been subjected to one of the following treatments, which, in the case of material sent in bales, has been shown to penetrate to the centre of the bale:

   a) either to the action of steam in a closed chamber such that the centre of the bales has reached a minimum temperature of 80°C for at least ten minutes,

   b) or to the action of formalin fumes (formaldehyde gas) produced by its commercial solution at 35–40 percent in a chamber kept closed for at least eight hours and at a minimum temperature of 19°C;

OR

3) have been kept in bond for at least three months (under study) before being released for export.

Article 8.5.29.~~32~~.

Recommendations for importation from FMD free countries or zones (where vaccination either is or is not practised)

For skins and trophies derived from FMD susceptible wild animals

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that these products are derived from *animals* that have been killed in such a country or *zone*, or which have been imported from a country or *zone* free of FMD (where *vaccination* either is or is not practised).

Article 8.5.30.~~33~~.

Recommendations for importation from FMD infected countries or zones

For skins and trophies derived from FMD susceptible wild animals

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that these products have been processed to ensure the destruction of the FMD virus in conformity with the procedures referred to in Article 8.5.~~40~~37.

Article 8.5.31.~~34~~.

Procedures for the inactivation of the FMD virus in meat and meat products

For the inactivation of viruses present in *meat* and *meat products*, one of the following procedures should be used:

1. Canning

   Meat and *meat products* ~~is~~ are subjected to heat treatment in a hermetically sealed container to reach an internal core temperature of at least 70°C for a minimum of 30 minutes or to any equivalent treatment which has been demonstrated to inactivate the FMD virus.

2. Thorough cooking

   Meat, previously deboned and defatted, and *meat products* shall be subjected to heating so that an internal temperature of 70°C or greater is maintained for a minimum of 30 minutes.

   After cooking, ~~it~~ they shall be packed and handled in such a way that it cannot be exposed to a source of virus.

3. Drying after salting

   When *rigor mortis* is complete, the *meat* must be deboned, salted with cooking salt (NaCl) and completely dried. It must not deteriorate at ambient temperature.

   'Drying' is defined in terms of the ratio between water and protein which must not be greater than 2.25:1.

Article 8.5.32.~~35~~.

Procedures for the inactivation of the FMD virus in wool and hair

For the inactivation of viruses present in wool and hair for industrial use, one of the following procedures should be used:

1) industrial washing, which consists of the immersion of the wool in a series of baths of water, soap and sodium hydroxide (soda) or potassium hydroxide (potash);

2) chemical depilation by means of slaked lime or sodium sulphide;

3) fumigation in formaldehyde in a hermetically sealed chamber for at least 24 hours. The most practical method is to place potassium permanganate in containers (which must NOT be made of plastic or polyethylene) and add commercial formalin; the amounts of formalin and potassium permanganate are respectively 53 ml and 35 g per cubic metre of the chamber;

4) industrial scouring which consists of the immersion of wool in a water-soluble detergent held at 60–70°C;

5) storage of wool at ~~18°C for four weeks, or~~ 4°C for four months, 18°C for four weeks or 37°C for eight days.

Annex XXXIX (contd)

Article 8.5.33.~~36~~.

Procedures for the inactivation of the FMD virus in bristles

For the inactivation of viruses present in bristles for industrial use, one of the following procedures should be used:

1) boiling for at least one hour;

2) immersion for at least 24 hours in a 1 percent solution of formaldehyde prepared from 30 ml commercial formalin per litre of water.

Article 8.5.34.~~37~~.

Procedures for the inactivation of the FMD virus in raw hides and skins

For the inactivation of viruses present in raw hides and skins for industrial use, the following procedure should be used: salting for at least 28 days in sea salt containing 2 percent sodium carbonate.

Article 8.5.35.~~38~~.

Procedures for the inactivation of the FMD virus in milk and cream for human consumption

For the inactivation of viruses present in *milk* and cream for human consumption, one of the following procedures should be used:

1) a sterilisation process applying a minimum temperature of 132°C for at least one second (ultra-high temperature [UHT]), or

2) if the milk has a pH less than 7.0, a sterilisation process applying a minimum temperature of 72°C for at least 15 seconds (high temperature – short time pasteurisation [HTST]), or

3) if the milk has a pH of 7.0 or over, the HTST process applied twice.

Article 8.5.36.~~39~~.

Procedures for the inactivation of the FMD virus in milk for animal consumption

For the inactivation of viruses present in *milk* for animal consumption, one of the following procedures should be used:

1) the HTST process applied twice;

2) HTST combined with another physical treatment, e.g. maintaining a pH 6 for at least one hour or additional heating to at least 72°C combined with dessication;

3) UHT combined with another physical treatment referred to in point 2 above.

Article 8.5.37~~40~~.

Procedures for the inactivation of the FMD virus in skins and trophies from wild animals susceptible to the disease

For the inactivation of viruses present in skins and trophies from *wild animals* susceptible to FMD, one of the following procedures should be used prior to complete taxidermal treatment:

1) boiling in water for an appropriate time so as to ensure that any matter other than bone, horns, hooves, claws, antlers or teeth is removed;

2) gamma irradiation at a dose of at least 20 kiloGray at room temperature (20°C or higher);

3) soaking, with agitation, in a 4 percent (w/v) solution of washing soda (sodium carbonate – Na_2CO_3) maintained at pH 11.5 or above for at least 48 hours;

4) soaking, with agitation, in a formic acid solution (100 kg salt [NaCl] and 12 kg formic acid per 1,000 litres water) maintained at below pH 3.0 for at least 48 hours; wetting and dressing agents may be added;

5) in the case of raw hides, salting for at least 28 days with sea salt containing 2 percent washing soda (sodium carbonate – Na_2CO_3).

Article 8.5.38. ~~41~~.

Procedures for the inactivation of the FMD virus in casings of ruminants and pigs

For the inactivation of viruses present in casings of ruminants and pigs, the following procedures should be used: salting for at least 30 days either with dry salt (NaCl) or with saturated brine (NaCl, ~~Aw~~ a_w< 0.80), or with phosphate supplemented ~~dry~~ salt containing 86.5 percent NaCl, 10.7 percent Na_2HPO_4 and 2.8 percent Na_3PO_4 (weight/weight/weight), either dry or as a saturated brine (a_w< 0.80), and kept at a temperature of greater than 12°C during this entire period.

EU comment

The EU agrees with the proposed amendments above. However, the EU suggests amending the temperature requirements as follows:

"[…] and kept at a temperature of ~~greater than 12~~20°C or above during this entire period.".

Indeed, the European Food Safety Authority, in its recent scientific opinion on animal health risk mitigation treatments as regards imports of animal casings (available on EFSA's website at http://www.efsa.europa.eu/it/efsajournal/pub/2820.htm), recommends that these treatments be made at 20°C or above (see conclusions and recommendations sections on p. 21-23).

Article 8.5.39.

OIE endorsed official control programme for FMD

The overall objective of an OIE endorsed *official control programme* for FMD is for countries to progressively improve the situation and eventually attain free status for FMD. The *official control programme* should be applicable to the entire country even if certain measures are directed towards defined *subpopulations.*

Members may, on a voluntary basis, apply for endorsement of their *official control programme* for FMD when they have implemented measures in accordance with this article.

For a Member's *official control programme* for FMD to be endorsed by the OIE, the Member should:

1) have a record of regular and prompt animal *disease* reporting according to the requirements in Chapter 1.1.;

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

EU comment

The second part of point 2 above is ambiguous, as it seems to imply that only countries following the OIE PVS Pathway can provide such evidence. Therefore, the EU suggests amending that sentence as follows:

"[…]; one way of providing this evidence ~~can be provided by countries following~~ is through the OIE PVS Pathway;".

3) submit a detailed plan on the programme to control and eventually eradicate FMD in the country or *zone* including:

   a) the timeline;

   b) the performance indicators to assess the efficacy of the control measures to be implemented;

   c) submit documentation indicating that the *official control programme* for FMD is applicable to the entire country;

4) submit a dossier on the epidemiology of FMD in the country describing the following:

   a) the general epidemiology 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 FMD *outbreaks* in order to reduce the incidence of FMD *outbreaks* and to eliminate virus circulation in domestic ruminants in at least one *zone* in the country;

   c) the main livestock production systems and movement patterns of FMD susceptible *animals* and their products within and into the country;

5) submit evidence that FMD *surveillance* is in place:

   a) taking into account provisions in Chapter 1.4. and the provisions on *surveillance* of this chapter;

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

6) where *vaccination* is practised as a part of the *official control programme* for FMD, provide:

   a) evidence (such as copies of legislation) that *vaccination* of selected populations is compulsory;

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

      i) target populations for *vaccination*;

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

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

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

EU comments

At the end of point iv) above, the words ", if applicable" should be added. Indeed, Members might already be using vaccines that are fully compliant with respective OIE standards.

Moreover, it may be desirable to add a further point v) concerning information on the matching of vaccines used with the FMDV strains circulating in the country.

7) provide an emergency preparedness and response plan to be implemented in case of *outbreaks*.

The Member's *official control programme* for FMD 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 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 according to the requirements in Chapter 1.1.

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

- non-compliance with the timelines or performance indicators of the programme; or
- significant problems with the performance of the *Veterinary Services*; or
- an increase in the incidence of FMD that cannot be addressed by the programme.

Article 8.5.40.42.

Surveillance: introduction

Articles 8.5.4240. to 8.5.4746. and Article 8.5.49. define the principles and provide a guide for the *surveillance* of FMD in accordance with Chapter 1.4. applicable to Members seeking establishment, maintenance and recovery of freedom from FMD at the country, *zone* or *compartment* level, either with or without the use of *vaccination* and Members seeking endorsement of their *official control programme* for FMD, in accordance with Article 8.5.39. *Surveillance* aimed at identifying *disease* and *infection*/virus circulation should cover all the susceptible species, including *wildlife*, if applicable, within the country, *zone* or *compartment*. Guidance is provided for Members seeking reestablishment of freedom from FMD for the entire country or for a *zone*, either with or without vaccination, or a *compartment*, following an *outbreak* and for the maintenance of FMD status.

The impact and epidemiology of FMD differ widely in different regions of the world and therefore it is impossible inappropriate to provide specific recommendations for all situations. *Surveillance* strategies employed for demonstrating freedom from FMD in the country, *zone* or *compartment* at an acceptable level of confidence will need to be adapted to the local situation. For example, the approach to proving freedom from FMD following an *outbreak* caused by a pig-adapted strain of FMD virus (FMDV) should differ significantly from an application designed to prove freedom from FMD for a country or *zone* where African buffaloes (*Syncerus caffer*) provide a potential reservoir of *infection*. *Surveillance* strategies employed for establishing and maintaining a *compartment* should also identify the prevalence, distribution and characteristics of FMD outside the *compartment* in the country or *zone. Surveillance* strategies employed in support of an OIE endorsed *official control programme* should show evidence of the effectiveness of any *vaccination* used and of the ability to rapidly detect all FMD *outbreaks*. There is therefore considerable latitude available to Members to design and implement *surveillance* on the one hand to establish that the whole territory or part of it is free from FMDV *infection*/circulation and on the other to understand the epidemiology of FMD as part of the official FMD control programmes.

It is incumbent upon the Member to submit a dossier to the OIE in support of its application that not only explains the epidemiology of FMD in the region concerned but also demonstrates how all the risk factors are identified and managed. This should include provision of scientifically based supporting data. There is therefore considerable latitude available to Members to provide a well-reasoned argument to prove that the absence of FMDV *infection* (in non-vaccinated populations) or circulation (in vaccinated populations) is assured at an acceptable level of confidence.

Surveillance for FMD should be in the form of a continuing programme. The design of *surveillance* programmes to prove the absence of FMDV *infection*/circulation needs to be carefully followed to avoid producing results that are either insufficiently reliable to be accepted by the OIE or international trading partners, or excessively costly and logistically complicated. The design of any *surveillance* programme, therefore, requires inputs from professionals competent and experienced in this field.

The strategy employed to establish the prevalence of FMDV *infection* or to demonstrate the absence of FMDV *infection*/circulation may be based on randomised or targeted clinical investigation or sampling at an acceptable level of statistical confidence. If an increased likelihood of *infection* in particular localities or species can be identified, targeted sampling may be an appropriate strategy. Clinical inspection may be targeted at particular species likely to exhibit clear clinical signs (e.g. cattle and pigs). The Member should justify the *surveillance* strategy chosen and the frequency of sampling as adequate to detect the presence of FMDV *infection*/circulation in accordance with Chapter 1.4. and the epidemiological situation.

The design of the sampling strategy will need to incorporate an epidemiologically appropriate design prevalence. The sample size selected for testing will need to be large enough to detect *infection*/circulation if it were to occur at a predetermined minimum rate. The sample size and expected *disease* prevalence determine the level of confidence in the results of the survey. The Member must justify the choice of design prevalence and confidence level based on the objectives of *surveillance* and the prevailing or historical epidemiological situation, in accordance with Chapter 1.4.

Irrespective of the survey design selected, the sensitivity and specificity of the diagnostic tests employed are key factors in the design, sample size determination and interpretation of the results obtained. Ideally, the sensitivity

and specificity of the tests used should be validated for the *vaccination/infection* history and production class of *animals* in the target population.

The *surveillance* design should anticipate the occurrence of false positive reactions. If the characteristics of the testing system are known, the rate at which these false positives are likely to occur can be calculated in advance. There needs to be an effective procedure for following-up positives to ultimately determine with a high level of confidence, whether or not they are indicative of *infection*/circulation. This should involve both supplementary tests and follow-up investigation to collect diagnostic material from the original *epidemiological unit* as well as *herds* which may be epidemiologically linked to it.

Laboratory results should be examined in the context of the epidemiological situation. Corollary information needed to complement the serological survey and assess the possibility of viral circulation includes but is not limited to:

- characterization of the existing production systems;
- results of clinical *surveillance* of the suspects and their cohorts;
- quantification of *vaccinations* performed on the affected sites;
- sanitary protocol and history of the *establishments* with positive reactors;
- control of *animal identification* and movements;
- other parameters of regional significance in historic FMDV transmission.

The entire investigative process should be documented as standard operating procedure within the *surveillance* programme.

All the epidemiological information should be substantiated, and the results should be collated in the final report.

~~*Surveillance* for FMD should be in the form of a continuing programme designed to establish that the whole territory or part of it is free from FMDV *infection*/circulation.~~

~~For the purposes of this chapter, virus circulation means transmission of FMDV as demonstrated by clinical signs, serological evidence or virus isolation.~~

Article 8.5.41.~~43~~.

Surveillance: ~~general conditions and methods~~ general principles

1) A *surveillance* system in accordance with Chapter 1.4. should be ~~under~~ the responsibility of the *Veterinary Authority*. A procedure should be in place for the rapid collection and transport of samples ~~from suspect cases of FMD~~ to a *laboratory* for FMD diagnose~~i~~s ~~as described in the *Terrestrial Manual*~~. This requires that sampling kits and other equipment are available for those responsible for *surveillance*. Personnel responsible for *surveillance* should be able to call for assistance from a team with expertise in FMD diagnosis and control.

2) The FMD *surveillance* programme should:

   a) include structured non-random *surveillance* activities as described in Article 1.4.5. with particular reference to an early warning system throughout the production, marketing and processing chain for reporting ~~suspicious~~ suspect *cases*. Farmers and workers who have day-to-day contact with livestock, as well as diagnosticians, should report promptly any suspicion of FMD. They should be supported directly or indirectly (e.g. through private *veterinarians* or *veterinary para-professionals*) by government information programmes and the *Veterinary Authority*. All suspect *cases* of FMD should be investigated immediately. ~~Where suspicion cannot be resolved by epidemiological and clinical investigation, s~~Samples should be taken and submitted for diagnostic testing a ~~*laboratory*~~, unless the suspect *case* can be confirmed or ruled out by epidemiological and clinical investigation. ~~This requires that sampling kits and other equipment are available for those responsible for *surveillance*. Personnel responsible for *surveillance* should be able to call for assistance from a team with expertise in FMD diagnosis and control.~~ Any *epidemiological unit* within which suspicious *animals* are detected should be classified as infected until contrary evidence is produced;

~~b) implement, when relevant, regular and frequent clinical inspection and serological testing of high-risk groups of *animals*, such as those adjacent to an FMD infected country or *infected zone* (for example, bordering a game park in which infected *wildlife* are present).~~

b) implement structured population-based surveys, when appropriate, as described in Article 1.4.4.

3) The *surveillance* programme above should:

a) identify the nature of risk factors, including the role of *wildlife*, to inform targeted *surveillance* strategies when appropriate;

b) implement, when relevant, an appropriate combination of clinical investigation and other diagnostic procedures in high risk groups.

~~3~~4) An effective *surveillance* system should ~~will~~ periodically identify ~~suspicious~~ suspect *cases* that require follow-up and investigation to confirm or exclude that the cause of the condition is FMDV. Details of the occurrence of suspect *cases* and how they were investigated and dealt with should be documented. ~~The rate at which such suspicious *cases* are likely to occur will differ between epidemiological situations and cannot therefore be predicted reliably~~. ~~Applications for freedom from FMDV *infection*/circulation should, in consequence, provide details of the occurrence of suspicious *cases* and how they were investigated and dealt with~~. This should include the results of diagnostic ~~*laboratory*~~ testing and the control measures to which the *animals* concerned were subjected during the investigation (quarantine, movement stand-still orders, etc.).

Article 8.5.42.~~44~~.

Surveillance: methods ~~strategies~~

~~1. Introduction~~

~~The target population for *surveillance* aimed at identifying *disease* and *infection* should cover all the susceptible species within the country, *zone* or *compartment*.~~

~~The design of *surveillance* programmes to prove the absence of FMDV *infection*/circulation needs to be carefully followed to avoid producing results that are either insufficiently reliable to be accepted by the OIE or international trading partners, or excessively costly and logistically complicated. The design of any *surveillance* programme, therefore, requires inputs from professionals competent and experienced in this field.~~

~~The strategy employed may be based on randomised sampling requiring *surveillance* consistent with demonstrating the absence of FMDV *infection*/circulation at an acceptable level of statistical confidence. The frequency of sampling should be dependent on the epidemiological situation. Targeted *surveillance* (e.g. based on the increased likelihood of *infection* in particular localities or species) may be an appropriate strategy. The Member should justify the *surveillance* strategy chosen as adequate to detect the presence of FMDV *infection*/circulation in accordance with Chapter 1.4. and the epidemiological situation. It may, for example, be appropriate to target clinical *surveillance* at particular species likely to exhibit clear clinical signs (e.g. cattle and pigs). If a Member wishes to apply for recognition of a specific *zone* within the country as being free from FMDV *infection*/circulation, the design of the survey and the basis for the sampling process would need to be aimed at the population within the *zone*.~~

~~For random surveys, the design of the sampling strategy will need to incorporate an epidemiologically appropriate design prevalence. The sample size selected for testing will need to be large enough to detect *infection*/circulation if it were to occur at a predetermined minimum rate. The sample size and expected *disease* prevalence determine the level of confidence in the results of the survey. The Member must justify the choice of design prevalence and confidence level based on the objectives of *surveillance* and the epidemiological situation, in accordance with Chapter 1.4. Selection of the design prevalence in particular clearly needs to be based on the prevailing or historical epidemiological situation.~~

~~Irrespective of the survey design selected, the sensitivity and specificity of the diagnostic tests employed are key factors in the design, sample size determination and interpretation of the results obtained. Ideally, the sensitivity and specificity of the tests used should be validated for the vaccination/*infection* history and production class of *animals* in the target population.~~

~~Irrespective of the testing system employed, *surveillance* design should anticipate the occurrence of false positive reactions. If the characteristics of the testing system are known, the rate at which these false positives are likely to occur can be calculated in advance. There needs to be an effective procedure for~~

~~following-up positives to ultimately determine with a high level of confidence, whether they are indicative of *infection*/circulation or not. This should involve both supplementary tests and follow-up investigation to collect diagnostic material from the original sampling unit as well as *herds* which may be epidemiologically linked to it.~~

1~~2~~. Clinical surveillance

The detection of clinical signs by farmers, *veterinary para-professionals* and *veterinarians* is the foundation of an early warning system and of clinical *surveillance*. Clinical *surveillance* ~~aims at detecting clinical signs of FMD by~~ requires close physical examination of susceptible *animals*. Whereas significant emphasis is placed on the diagnostic value of mass serological screening, *surveillance* based on clinical inspection should not be underrated~~. .~~ ~~It may~~ as it can ~~be able to~~ provide a high level of confidence of detection of *disease* if a sufficient~~ly large~~ number of clinically susceptible *animals* is examined at an appropriate frequency.

Clinical *surveillance* and ~~*laboratory*~~ diagnostic testing should ~~always~~ be applied in series to clarify the status of FMD suspects detected by either of these complementary diagnostic approaches. ~~*Laboratory*~~ Diagnostic testing may confirm clinical suspicion, while clinical *surveillance* may contribute to confirmation of positive ~~serology~~ laboratory tests. ~~Any sampling unit within which suspicious *animals* are detected should be classified as infected until contrary evidence is produced.~~ Clinical *surveillance* may be insufficient in case of species that usually do not show clinical signs or husbandry systems that do not permit sufficient observations. In such cases, sero-surveillance should be used.

~~A number of issues must be considered in clinical *surveillance* for FMD. The often underestimated labour intensity and the logistical difficulties involved in conducting clinical examinations should not be underestimated and should be taken into account.~~

~~Identification of clinical *cases* is fundamental to FMD *surveillance*. Establishment of the molecular, antigenic and other biological characteristics of the causative virus, as well as its source, is dependent upon disclosure of such *animals*. It is essential that FMDV isolates are sent regularly to the regional reference *laboratory* for genetic and antigenic characterization.~~

~~3~~2. Virological surveillance

Establishment of the molecular, antigenic and other biological characteristics of the causative virus, as well as its source, is mostly dependent upon clinical *surveillance* to provide materials. It is essential that FMDV isolates are sent regularly to an OIE Reference Laboratory.

Virological *surveillance* ~~using tests described in the *Terrestrial Manual* should be conducted~~ aims to:

~~a)~~ ~~to monitor at risk populations;~~

~~b)~~a) ~~to~~ confirm clinically suspect *cases*;

~~c~~b) ~~to~~ follow up positive serological results;

c) characterize isolates for epidemiological studies and vaccine matching;

~~d) to test 'normal' daily mortality, to ensure early detection of *infection* in the face of vaccination or in *establishments* epidemiologically linked to an *outbreak*.~~

d) monitor at risk populations.

~~4~~3. Serological surveillance

Serological *surveillance* aims at detecting antibodies against FMDV caused by *infection* or *vaccination* using either, non-structural protein (NSP) tests that detect all FMD types or type-specific tests that detect structural proteins. ~~Positive FMDV antibody test results can have four possible causes:~~

Serological *surveillance* ~~with tests described in the *Terrestrial Manual*~~ is used to:

a) estimate the prevalence or demonstrate the absence of FMDV *infection*/circulation;

b) monitor population immunity.

a) natural *infection* with FMDV;

b) *vaccination* against FMD;

c) maternal antibodies derived from an immune dam (maternal antibodies in cattle are usually found only up to six months of age but in some individuals and in some species, maternal antibodies can be detected for considerably longer periods);

d) heterophile (cross) reactions.

It is important that serological tests, where applicable, contain antigens appropriate for detecting antibodies against viral variants (types, subtypes, lineages, topotypes, etc.) that have recently occurred in the region concerned. Where the probable identity of FMDVs is unknown or where exotic viruses are suspected to be present, tests able to detect representatives of all serotypes should be employed (e.g. tests based on nonstructural viral proteins – see below).

It may be possible to use sSerum collected for other survey purposes can be used for FMD *surveillance*., provided However, the principles of survey design described in this chapter are met. and the requirement for a statistically valid survey for the presence of FMDV should not be compromised.

The discovery of clustering of seropositive reactions should be foreseen. It may reflect any of a series of events, including but not limited to the demographics of the population sampled, vaccinal exposure or the presence of field strain *infection*. As clustering may signal field strain *infection*, the investigation of all instances must be incorporated in the survey design. If *vaccination* cannot be excluded as the cause of positive serological reactions, diagnostic methods should be employed that detect the presence of antibodies to nonstructural proteins (NSPs) of FMDVs as described in the *Terrestrial Manual*.

The results of random or targeted serological surveys are important in providing reliable evidence that FMDV *infection* is not present in a country, *zone* or *compartment* of the FMD situation in a country, *zone* or *compartment*. It is therefore essential that the survey be thoroughly documented.

Article 8.5.43.45.

Members applying for recognition of freedom from FMD for the whole a country, or a zone or compartment where vaccination is not practised: additional surveillance procedures

The strategy and design of the *surveillance* programme will depend on the historical epidemiological circumstances including whether or not *vaccination* has been used. In addition to the general conditions described in the above-mentioned articles, a A Member applying for recognition of FMD freedom for the country, or a *zone* or *compartment* where *vaccination* is not practised should provide evidence for the existence of an effective *surveillance* programme. The strategy and design of the *surveillance* programme will depend on the prevailing epidemiological circumstances will be planned and implemented according to general conditions and methods in this chapter, to demonstrate absence of FMDV circulation in previously vaccinated *animals* and absence of FMDV *infection* in non-vaccinated *animals*., during the preceding 12 months in susceptible populations. This requires the support of a national or other *laboratory* able to undertake identification of FMDV *infection* through virus/antigen/genome detection and antibody tests described in the *Terrestrial Manual*.

Article 8.5.44.46.

Members applying for recognition of freedom from FMD for the whole a country, or a zone or compartment where vaccination is practised: additional surveillance procedures

In addition to the general conditions described in the above-mentioned articles, a Member applying for recognition of country or *zone* freedom from FMD with *vaccination* should show evidence of an effective *surveillance* programme planned and implemented according to general conditions and methods in this chapter. Absence of clinical *disease* in the country or *zone* for the past two years should be demonstrated. Furthermore, s*Surveillance* should demonstrate that FMDV has not been circulating in any susceptible populations during the past 12 months. This will require serological *surveillance* incorporating tests able to detect antibodies to NSPs as described in the *Terrestrial Manual*. Serological surveys to demonstrate the absence of FMDV circulation should target within vaccinated populations, unvaccinated *animals* or *animals* that are less likely to show vaccine-derived antibodies to NSPs, such as young *animals* vaccinated a limited number of times, or unvaccinated *subpopulations*. Vaccination to prevent the transmission of FMDV may be part of a disease control programme. The level of *herd* immunity required to prevent transmission will depend on the size, composition (e.g. species) and density of the susceptible population. It is therefore impossible to be prescriptive. However, the aim should be for at least 80 percent of the *animals* in each vaccinated population to have protective immunity. The vaccine must comply with the *Terrestrial Manual*. Evidence to show the effectiveness of the *vaccination* programme such as adequate *vaccination* coverage and population immunity should be provided.

EU comment

In the paragraph above, the word "NSPs" should be replaced by "non-structural proteins (NSPs)", as that abbreviation is used for the first time in this chapter.

In designing serosurveys to estimate population immunity, blood sample collection should be stratified by age to take account of the number of *vaccinations* the *animals* have received. The interval between last *vaccination* and sampling depends upon the intended purpose. Sampling at one or two months after *vaccination* provides information on the efficiency of the *vaccination* campaign, while sampling before or at the time of revaccination provides information on the duration of immunity. When multivalent vaccines are used, tests should be carried out to determine the antibody level at least for each serotype, if not for each antigen blended into the vaccine. The test cut-off for an acceptable level of antibody should be selected with reference to protective levels demonstrated by vaccine-challenge test results for the antigen concerned. Where the threat from circulating virus has been characterised as resulting from a field virus with significantly different antigenic properties to the vaccine virus, this should be taken into account when interpreting the protective effect of population immunity. Figures for population immunity should be quoted with reference to the total of susceptible *animals* in a given *subpopulation* and in relation to the subset of vaccinated *animals*.

~~Based on the epidemiology of FMD in the country or *zone*, it may be that a decision is reached to vaccinate only certain species or other subsets of the total susceptible population. In that case, the rationale should be contained within the dossier accompanying the application to the OIE for recognition of status.~~

~~Evidence to show the effectiveness of the vaccination programme should be provided.~~

Article 8.5.45.~~47~~.

Members re-applying for recognition of freedom from FMD for ~~the whole~~ a country, ~~or a~~ zone or compartment where vaccination is either practised or not practised, following an outbreak: additional surveillance procedures

~~In addition to the general conditions described in the above-mentioned articles, a~~A country re-applying for country, ~~or~~ *zone* or *compartment* freedom from FMD where *vaccination* is practised or not practised should show evidence of an active *surveillance* programme for FMD as well as absence of FMDV *infection*/circulation. This will require serological *surveillance* incorporating, in the case of a country or a *zone* practising *vaccination*, tests able to detect antibodies to NSPs ~~as described in the *Terrestrial Manual*~~.

~~Four strategies are recognised by the OIE in a programme to eradicate FMDV *infection*/circulation following an *outbreak*:~~

~~1. *slaughter* of all clinically affected and in-contact susceptible *animals*;~~

~~2. *slaughter* of all clinically affected and in-contact susceptible *animals* and vaccination of at-risk *animals*, with subsequent *slaughter* of vaccinated *animals*;~~

~~3. *slaughter* of all clinically affected and in-contact susceptible *animals* and vaccination of at-risk *animals*, without subsequent *slaughter* of vaccinated *animals*;~~

~~4. vaccination used without *slaughter* of affected *animals* or subsequent *slaughter* of vaccinated *animals*.~~

~~The time periods before which an application can be made for re-instatement of freedom from FMD depends on which of these alternatives is followed. The time periods are prescribed in Article 8.5.9.~~

Additional *surveillance* using NSP tests is required to reduce the time period from six to three months in case of *slaughter* of all clinically affected and in-contact susceptible *animals* and *vaccination* of at-risk *animals*, without subsequent *slaughter* of vaccinated *animals* as mentioned in point 1c) of Article 8.5.7. This includes serosurveillance of all *herds* with vaccinated *animals* by sampling all vaccinated ruminants and their non-vaccinated offspring and a representative number of *animals* of other species based on an acceptable level of confidence.

~~In all circumstances, a Member re-applying for country or *zone* freedom from FMD with vaccination or without vaccination should report the results of an active *surveillance* programme implemented according to general conditions and methods in this chapter.~~

~~Article 8.5.48.~~

~~**OIE endorsed official control programme for FMD**~~

~~The overall objective of an OIE endorsed *official control programme* for FMD is for countries to progressively improve the situation and eventually attain free status for FMD.~~

~~Members may, on a voluntary basis, apply for endorsement of their *official control programme* for FMD when they have implemented measures in accordance with this article.~~

~~For a Member's *official control programme* for FMD to be endorsed by the OIE, the Member should:~~

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

~~2. submit documentation indicating that the *official control programme* for FMD is applicable to the entire territory;~~

~~3. have a record of regular and prompt animal *disease* reporting according to the requirements in Chapter 1.1.;~~

~~4. submit a dossier on the epidemiology of FMD in the country describing the following:~~

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

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

~~c) the main livestock production systems and movement patterns of FMD susceptible animals and their products within and into the country;~~

~~5. submit a detailed plan on the programme to control and eventually eradicate FMD in the country or *zone* including:~~

~~a) the timeline;~~

~~b) the performance indicators to assess the efficacy of the control measures to be implemented;~~

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

~~7. have diagnostic capability and procedures, including regular submission of samples to a laboratory that carries out diagnosis and further characterisation of strains in accordance with the *Terrestrial Manual*;~~

~~8. where vaccination is practised as a part of the *official control programme* for FMD, provide evidence (such as copies of legislation) that vaccination of selected populations is compulsory;~~

~~9. if applicable, provide detailed information on vaccination campaigns, in particular on:~~

~~a) target populations for vaccination;~~

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

~~c) technical specification of the vaccines used and description of the licensing procedures in place;~~

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

Annex XXXIX (contd)

~~10. provide an emergency preparedness and response plan to be implemented in case of *outbreaks*.~~

~~The Member's *official control programme* for FMD 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 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 according to the requirements in Chapter 1.1.~~

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

- ~~non-compliance with the timelines or performance indicators of the programme; or~~
- ~~significant problems with the performance of the *Veterinary Services*; or~~
- ~~an increase in the incidence of FMD that cannot be addressed by the programme.~~

Article 8.5.46.~~49~~.

The use and interpretation of serological tests (see Figure ~~1~~2)

The recommended serological tests for FMD *surveillance* are described in the *Terrestrial Manual*. Information should be provided on the protocols, reagents, performance characteristics and validation of all tests used. Where combinations of tests are used, the overall test system performance characteristics should be known. The selection and interpretation of serological tests should be considered in the context of the epidemiological situation.

Animals infected with FMDV produce antibodies to both the structural proteins (SP) and the nonstructural proteins (NSP) of the virus. ~~Tests for SP antibodies to include SP-ELISAs and the virus neutralisation test (VNT).~~ Vaccinated *animals* produce antibodies mainly or entirely to the SP of the virus depending upon vaccine purity. The SP tests are serotype specific and for optimal sensitivity should utilise an antigen or virus closely related to the field strain against which antibodies are being sought. ~~Tests for NSP antibodies include NSP I-ELISA 3ABC and the electro-immunotransfer blotting technique (EITB) as recommended in the *Terrestrial Manual* or equivalent validated tests.~~ In unvaccinated populations, SP tests may be used to screen sera for evidence of FMDV *infection*/circulation or to detect the introduction of vaccinated *animals*. In areas where *animals* have been vaccinated, SP antibody tests may be used to monitor the serological response to the *vaccination* and can help to identify *infection* since vaccinated-and-infected *animals* may have higher SP antibody titres than vaccinated-only *animals*.

~~In contrast to SP tests,~~ NSP tests can detect antibodies due to *infection*/circulation for ~~to~~ all serotypes of FMD virus regardless of the *vaccination* status of the *animals* provided the vaccines comply with the standards of the *Terrestrial Manual* insofar as purity is concerned. However, although *a~~A~~nimals* vaccinated and subsequently infected with FMD virus develop antibodies to NSPs, ~~but in some,~~ the ~~titre~~ levels may be lower than ~~that~~ those found in infected *animals* that have not been vaccinated. To ensure that all *animals* that had contact with the FMDV have seroconverted it is recommended to take samples for NSP antibody testing not earlier than 30 days after the last case and in any case not earlier than 30 days after the last *vaccination*.

~~Both the NSP I-ELISA 3ABC and EITB tests have been extensively used in cattle. Validation in other species is ongoing. Vaccines used should comply with the standards of the *Terrestrial Manual* insofar as purity is concerned to avoid interference with NSP antibody testing.~~

~~Serological testing is a suitable tool for FMD *surveillance*. The choice of a serosurveillance system will depend on, amongst other things, the vaccination status of the country. A country, which is free from FMD without vaccination, may choose serosurveillance of high-risk subpopulations (e.g. based on geographical risk for exposure to FMDV). SP tests may be used in such situations for screening sera for evidence of FMDV *infection*/circulation if a particular virus of serious threat has been identified and is well characterised. In other cases, NSP testing is recommended in order to cover a broader range of strains and even serotypes. In both cases, serological testing can provide additional support to clinical *surveillance*. Regardless of whether SP or NSP tests are used in countries that do not vaccinate, a diagnostic follow-up protocol should be in place to resolve any presumptive positive serological test results. In areas where *animals* have been vaccinated, SP antibody tests may be used to monitor the serological response to the vaccination. However,~~

~~NSP antibody tests should be used to monitor for FMDV *infection*/circulation. NSP ELISAs may be used for screening sera for evidence of *infection*/circulation irrespective of the vaccination status of the *animal*.~~

Positive FMDV antibody test results can have five possible causes:

a) *infection* with FMDV;

b) *vaccination* against FMD;

c) maternal antibodies derived from an immune dam (maternal antibodies in cattle are usually found only up to six months of age but in some individuals and in some species, maternal antibodies can be detected for longer periods);

d) non-specific reactivity of the serum;

e) lack of specificity of the diagnostic tests used.

Procedure in case of positive test results

All seropositive reactors should be retested in the *laboratory* using repeat and confirmatory tests. Tests used for confirmation should be of high diagnostic specificity to minimize false positive test reactors. The diagnostic sensitivity of the confirmatory test should approach that of the screening test. The number and strength of sero reactors should be taken into account.

All *herds* with ~~seropositive~~ at least one *laboratory* confirmed reactor~~s~~ should be investigated immediately. ~~Epidemiological and supplementary *laboratory* investigation results should document the status of FMDV *infection*/circulation for each positive *herd*.~~ The investigation should examine all evidence, including the results of virological tests that might confirm or refute the hypothesis that the positive results to the serological tests employed in the initial survey were due to virus circulation and should document the status of FMDV *infection*/circulation for each positive *herd*. Epidemiological investigation should be continued in parallel.

Clustering of seropositive reactions should be investigated as it may reflect any of a series of events, including but not limited to the demographics of the population sampled, vaccinal exposure or the presence of *infection*/circulation. As clustering may signal *infection*/circulation, the investigation of all instances must be incorporated in the survey design.

Paired serology can be used to identify virus circulation by demonstrating an increase in the number of seropositive *animals* or an increase in antibody titre at the second sampling.

The investigation should include the reactor *animal(s)*, susceptible *animals* of the same *epidemiological unit* and susceptible *animals* that have been in contact or otherwise epidemiologically associated with the reactor *animal(s)*. The *animals* sampled should remain in the holding pending test results, should be clearly identifiable, accessible and should not be vaccinated during the investigations, so that they can be retested after an adequate period of time. Following clinical examination, a second sample should be taken from the *animals* tested in the initial survey with emphasis on *animals* in direct contact with the reactor(s) after an adequate interval of time has lapsed. If the *animals* are not individually identified, a new serological survey should be carried out in the holding(s) after an adequate period of time, repeating the application of the primary survey design. The magnitude and prevalence of antibody reactivity observed should not differ in a statistically significant manner from that of the primary sample if virus is not circulating.

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Sentinel *animals* can also be used. These can be young, unvaccinated *animals* or *animals* in which maternally conferred immunity has lapsed and preferably belonging to the same species resident within the initial positive sampling units. If other susceptible, unvaccinated *animals* are present, they could act as sentinels to provide additional serological evidence. The sentinels should be kept in close contact with the *animals* of the *epidemiological* unit under investigation for at least two *incubation periods* and should remain serologically negative if virus is not circulating.

~~Tests used for confirmation should be of high diagnostic specificity to eliminate as many false positive screening test reactors as possible. The diagnostic sensitivity of the confirmatory test should approach that of the screening test. The EITB or another OIE-accepted test should be used for confirmation.~~

~~Information should be provided on the protocols, reagents, performance characteristics and validation of all tests used.~~

~~1. The follow-up procedure in case of positive test results if no vaccination is used in order to establish or re-establish FMD free status without vaccination country or, zone where vaccination is not practised~~

~~Any positive test result (regardless of whether SP or NSP tests were used) should be followed up immediately using appropriate clinical, epidemiological, serological and, where possible, virological investigations of the reactor *animal* at hand, of susceptible *animals* of the same *epidemiological unit* and of susceptible *animals* that have been in contact or otherwise epidemiologically associated with the reactor *animal*. If the follow-up investigations provide no evidence FMDV infection, the reactor *animal* shall be classified as FMD negative. In all other cases including the absence of such follow-up investigations, the reactor *animal* should be classified as FMD positive.~~

If circulation is proved then the *outbreak* is declared.

In the absence of FMDV circulation, an *outbreak* can be ruled out, but the significance of FMD positive *animals* is difficult to classify. Such findings can be an indication of acute *infection* followed by recovery or by the development of the carrier state, in ruminants, or due to non-specific reaction or lack of specificity of the diagnostic tests used. Antibodies to NSP may be induced by repeat *vaccination* with vaccines that do not comply with the requirements for purity. However the use of such vaccines is not permissible for countries, *zones* or *compartments* applying for an official status.

In the case of a vaccinated *herd* in a country, *zone* or *compartment* trying to establish or re-establish the status of an FMD free country, *zone* or *compartment* where *vaccination* is practised, the follow-up investigations may be considered completed where the *herd* can be declared free of FMDV circulation. In the case of a number of FMD positive *animals* at a level above the expected number of non-specific test system findings, susceptible *animals* that have been in contact or otherwise epidemiologically associated with the reactor *animal(s)* should be investigated.

In all other cases, when a small number of FMD positive *animals* are found, at a level consistent with the expected number of non-specific test system findings, it is recommended that such reactor *animals* should be slaughtered, and then the *herd* declared free of FMDV *infection*. In the case of a number of FMD positive *animals* at a level above the expected number of non-specific test system findings, it is recommended that the *herd* should be slaughtered and susceptible *animals* that have been in contact or otherwise epidemiologically associated with the reactor *animal(s)* should be investigated.

~~2. The follow-up procedure in case of positive test results if vaccination is used in order to establish or re-establish FMD free country or zone where vaccination is practised status with vaccination~~

~~In case of vaccinated populations, one has to exclude that positive test results are indicative of virus circulation. To this end, the following procedure should be followed in the investigation of positive serological test results derived from *surveillance* conducted on FMD vaccinated populations.~~

~~The investigation should examine all evidence that might confirm or refute the hypothesis that the positive results to the serological tests employed in the initial survey were not due to virus circulation. All the epidemiological information should be substantiated, and the results should be collated in the final report.~~

~~It is suggested that in the primary sampling units where at least one *animal* reacts positive to the NSP test, the following strategy(ies) should be applied:~~

~~a) Following clinical examination, a second serum sample should be taken from the *animals* tested in the initial survey after an adequate interval of time has lapsed, on the condition that they are individually identified, accessible and have not been vaccinated during this period. The number of *animals* with antibodies against NSP in the population at the time of retest should be statistically either equal to or less than that observed in the initial test if virus is not circulating.~~

~~The *animals* sampled should remain in the holding pending test results and should be clearly identifiable. If the three conditions for retesting mentioned above cannot be met, a new serological survey should be carried out in the holding after an adequate period of time, repeating the application of the primary survey design and ensuring that all *animals* tested are individually identified. These *animals* should remain in the holding and should not be vaccinated, so that they can be retested after an adequate period of time.~~

~~b) Following clinical examination, serum samples should be collected from representative numbers of susceptible *animals* that were in physical contact with the primary sampling unit. The magnitude and prevalence of antibody reactivity observed should not differ in a statistically significant manner from that of the primary sample if virus is not circulating.~~

~~c) Following clinical examination, epidemiologically linked *herds* should be serologically tested and satisfactory results should be achieved if virus is not circulating.~~

~~d) Sentinel *animals* can also be used. These can be young, unvaccinated *animals* or *animals* in which maternally conferred immunity has lapsed and belonging to the same species resident within the positive initial sampling units. They should be serologically negative if virus is not circulating. If other susceptible, unvaccinated *animals* are present, they could act as sentinels to provide additional serological evidence.~~

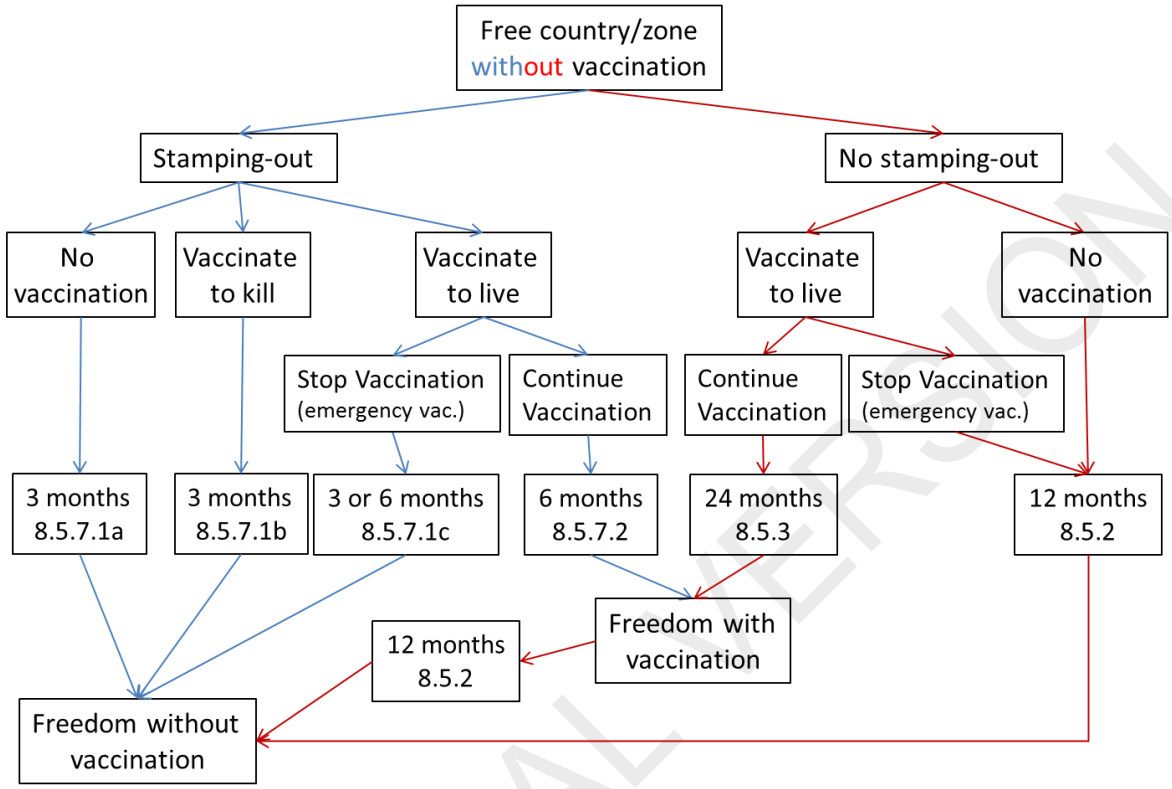
~~*Laboratory* results should be examined in the context of the epidemiological situation. Corollary information needed to complement the serological survey and assess the possibility of viral circulation includes but is not limited to:~~

- ~~characterization of the existing production systems;~~
- ~~results of clinical *surveillance* of the suspects and their cohorts;~~
- ~~quantification of *vaccinations* performed on the affected sites;~~
- ~~sanitary protocol and history of the *establishments* with positive reactors;~~
- ~~control of *animal identification* and movements;~~
- ~~other parameters of regional significance in historic FMDV transmission.~~

~~The entire investigative process should be documented as standard operating procedure within the *surveillance* programme.~~

Annex XXXIX (contd)

Figure 1: Schematic representation of the minimum waiting periods and pathways for recovery of FMD free status



**Waiting periods are minima depending upon outcome of surveillance specified in respective Articles*

EU comments

For clarity and consistency, the EU suggests slightly amending the text in two of the boxes in the Figure above as follows:

1) replace "Freedom with vaccination" by "Free country/zone with vaccination";

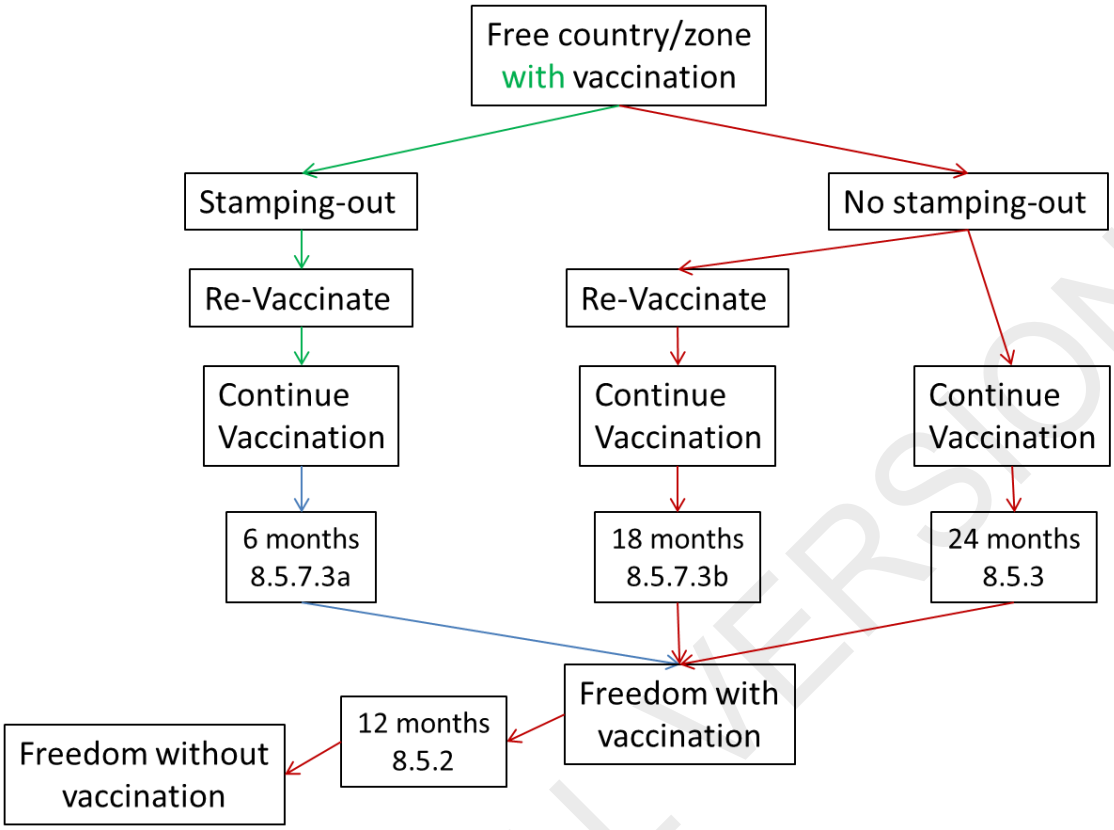
2) replace "Freedom without vaccination" by "Free country/zone without vaccination ".

Furthermore, for clarity reasons, it is suggested to add the word "Art." in front of the numbers in the boxes where reference is made to the respective Articles in the chapter, and to put this reference in parenthesis, e.g. as follows:

"3 months

(Art. 8.5.7.1a)"

Annex XXXIX (contd)



**Waiting periods are minima depending upon outcome of surveillance specified in respective Articles*

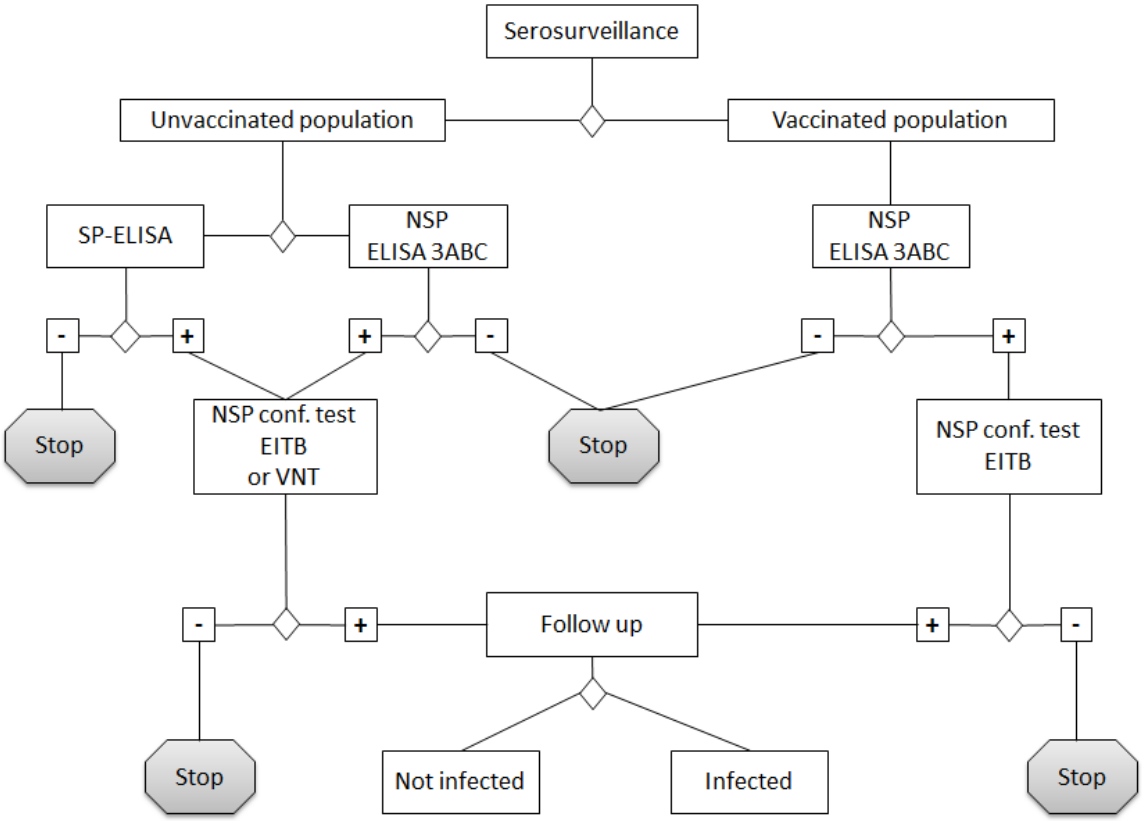
EU comments

The comments made above as to the first part of Figure 1 apply mutatis mutandis to the second part of the Figure above.

Furthermore, to avoid confusion, the word "Re-Vaccinate" in the two boxes in the Figure above should be replaced by "Emergency vaccination", as this is the term used in points 3 a) and b) of Article 8.5.7.

Annex XXXIX (contd)

Figure ~~1~~2: Schematic representation of laboratory tests for determining evidence of FMDV infection through or following serological surveys



— Text deleted.

Annex XL

CHAPTER 8.X.

INFECTION WITH *BRUCELLA ABORTUS, MELITENSIS* AND *SUIS*

EU comments

The EU thanks the OIE for its work and for having taken many of its comments into account, and in general supports the proposed changes to this draft new chapter.

The title of the chapter should be changed into "INFECTION WITH *BRUCELLA ABORTUS*, *B. MELITENSIS* AND *B. SUIS*".

Moreover, the word "animal" should not be italicised in this chapter, as that term is specifically defined for this chapter in Art. 8.x.1. and thus the glossary definition does not apply.

Further specific comments are inserted in the text below.

Article 8.X.1.

General provisions

The aim of this chapter is to mitigate the risk of spread of, and the risk to human health from, *B. abortus, B. melitensis* and *B. suis* in *animals*.

For the purpose of this chapter:

– '*Brucella'* means *B. abortus, B. melitensis* or *B. suis,* excluding vaccine strains.

– ~~For the purpose of this chapter,~~ 'Animals' means domestic and *captive wild* animal populations of the following categories:

1) ~~Bovidae~~ bovids ; this term means cattle (*Bos taurus*, *B. indicus, B. frontalis*, ~~and~~ *B. javanicus*~~), yak (~~ and *B. grunniens*), bison (*Bison bison* and *B. bonasus*) and water buffalo (*Bubalus bubalis*);

2) ~~Ovidae and Capridae mean~~ sheep (*Ovis aries*) and goats (*Capra aegagrus*);

3) pigs ~~means domestic pigs and *wild* boars~~ (*Sus scrofa*);

4) ~~*Camelidae*~~ camelids; this term means dromedary camel (*Camelus dromedarius*), Bactrian camel (*Camelus bactrianus*), llama (*Lama glama*), alpaca (*Lama pacos*), guanaco *(Lama guanicoe*) and vicuna (*Vicugna vicugna*);

5) ~~*Cervidae*~~ cervids means roe deer (*Capreolus capreolus),* red deer *(Cervus elaphus elaphus),* wapiti/elk *(C. elaphus canadensis),* sika*(C. nippon)*, samba*(C. unicolor unicolor)*, rusa *(C. timorensis),* fallow deer *(Dama ~~dama~~ dama,)*, white-tailed, black-tailed, mule deer (*Odocoileus* spp.) and reindeer (~~*Cervus elaphus elaphus, C. elaphus canadensis, C. nippon, C. unicolor unicolor, C. timorensis, Dama dama dama, Odocoileus virginianus borealis, O.docoileus hemionus columbianus, O.docoileus hemionus hemionus*~~ and *Rangifer tarandus*);

6) European hare (*Lepus europaeus*).

For the purpose of the *Terrestrial Code*, a *case* is an *animal* infected with *Brucella*.

EU comment

To avoid confusion, the word "animal" should not be italicised in the sentence above (nor throughout the rest of the chapter), so as not to refer to the glossary definition but rather to the specific definition of "animal" provided for in this Article.

The chapter deals not only with the occurrence of clinical signs caused by *Brucella infection*, but also with the presence of *Brucella infection* in the absence of clinical signs.

~~A *case* is an animal infected with *Brucella*.~~

The following defines ~~a *case of*~~ *Brucella infection*:

– *Brucella* has been ~~isolated and/or~~ identified ~~as such~~ from an *animal* or a product derived from that *animal*;

OR

– positive results to ~~one or more~~ a diagnostic test~~s~~ have been obtained and there is an epidemiological link to a confirmed *case* ~~evidence of *Brucella infection*~~.

Standards for diagnostic tests and vaccines are described in the *Terrestrial Manual*. ~~In the absence of sufficient scientific information, the prescribed tests for bovines, except bovine specific indirect ELISAs, may be applied to *Cervidae* and *Camelidae*.~~

EU comment

For consistency with other Code chapters, the sentence above relating to the Terrestrial Manual should be moved to the end of this article.

When authorising import or transit of *commodities* listed in this chapter, with the exception of those listed in Article 8.x.2., *Veterinary Authorities* should require the conditions prescribed in this chapter relevant to the *Brucella infection* status of the animal population of the *exporting country*, *zone*, *herd* or *flock*.

Article 8.X.2.

Safe commodities

When authorising import or transit of the following *commodities*, *Veterinary Authorities* should not require any *Brucella*-related conditions, regardless of the *Brucella* *infection* status of the animal population of the *exporting country*, *zone*, *herd* or *flock*:

1) skeletal muscle *meat*, brain and spinal cord, digestive tract, thymus, thyroid and parathyroid glands and derived products~~, provided that they are accompanied by an *international veterinary certificate* attesting that they are originating from animals that have been subjected to ante-mortem and post-mortem inspections as described in Chapter 6.2.~~;

2) cured hides and skins;

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

~~When authorising import or transit of other *commodities* listed in this chapter, *Veterinary Authorities* should require the conditions prescribed in this chapter relevant to the *Brucella* status of the animal population of the *exporting country*, *zone* or *herd* or *flock*.~~

Article 8.X.3.

Country or zone free from *Brucella* infection ~~in animals~~ without vaccination in bovids

~~A country or *zone* can be qualified free from *Brucella infection* without *vaccination* either in one or several of the animal categories listed in Article 11.3.1.~~

1) To qualify as free from *Brucella infection* without *vaccination* in bovids, a country or *zone* should satisfy ~~for each relevant category of animals~~ the following requirements:

~~1.~~a) *Brucella infection* in *animals* is a *notifiable disease* in the country or *zone*;

~~2.~~b) regulatory measures for the early detection ~~a programme should be in place to ensure effective reporting of all *cases* suggestive~~ of *Brucella infection* in bovids, ~~particularly abortions, and~~ including the regular submission of abortion material to diagnostic laboratories for investigation, have been implemented;

~~3.~~c) ~~neither domestic nor *captive wild* animals~~ no bovids have been vaccinated against *Brucella infection* for at least the past three years, and bovids that are introduced in the country or *zone* have not been vaccinated during the past three years;

~~4.~~d) no *case* of ~~abortion due to~~ *Brucella infection* ~~and no isolation of *Brucella*~~ has been recorded in ~~animals~~ bovids for at least the past three years;

~~5)~~ ~~except for pigs:~~

e) bovids and their genetic materials introduced in the country or *zone* ~~should~~ comply with the recommendations in Articles 8.X.13., 8.X.15. to 8.X.17.;

~~a~~f) regular and periodic testing of all *herds* ~~or *flocks*~~ has been in place for the past three years; and this testing has demonstrated that *Brucella infection* was not present in at least 99.8% of the *herds* ~~or *flocks*~~ ~~and~~ representing at least 99.9% of ~~animals~~ bovids in the country or *zone* ~~three consecutive years;~~.

2) To maintain the status as free from *Brucella infection* without *vaccination* in bovids, a country or *zone* should satisfy the following requirements:

a) the requirements in points 1a) to 1e) above are met;

b) a *surveillance* programme based on regular and periodic testing of ~~animals should be~~ bovids is in place in the country or *zone* to detect *Brucella infection* in accordance with Chapter 1.4.;

c) if ~~a~~ the *surveillance* programme described ~~in Points 2 and 5 a) and~~ b) above has not detected *Brucella infection* for ~~the past five~~ two consecutive years, *surveillance* ~~should~~ may be maintained in accordance with Chapter 1.4.

~~6.~~3) ~~vaccinated animals should not be introduced. Unvaccinated animals and genetic materials should comply with the recommendations in Articles 11.3.8. to 11.3.12.~~ The free status without *vaccination* of the country or *zone* ~~for~~ in bovids ~~a specified animal category~~ is not affected by the occurrence of *Brucella infection* in other animal categories or *feral* ~~and~~ or *wild animals* provided that effective measures have been implemented to prevent transmission of *Brucella infection* to ~~the relevant animal population~~ bovids ~~belonging to the specified animal category free from *Brucella infection* is effectively separated from the potential source of *infection*~~.

Article 8.X.4.

Country or zone free from *Brucella* infection ~~in animals~~ with vaccination in bovids

~~A country or *zone* can be qualified free from *Brucella infection* with *vaccination* either in bovines or ovidae and capridae as listed in Article 11.3.1.~~

1) To qualify as free from *Brucella infection* with *vaccination* in bovids, a country or *zone* should satisfy ~~for each relevant category of animals~~ the following requirements:

~~1.~~a) *Brucella infection* in *animals* is a *notifiable disease* in the country or *zone*;

~~2.~~b) regulatory measures for the early detection ~~a programme should be in place to ensure effective reporting of all *cases* suggestive~~ of *Brucella infection* in bovids, ~~particularly abortions, and~~ including the regular submission of abortion material to diagnostic laboratories for investigation, have been implemented;

~~3.~~c) vaccinated ~~animals~~ bovids should be identified with a permanent mark;

~~4.~~d) no *case* of ~~abortion due to~~ *Brucella infection* ~~and no isolation of *Brucella*~~ has been recorded in ~~animals~~ bovids for at least the past three years;

~~5~~e) bovids and their genetic materials introduced in the country or *zone* comply with the recommendations in

Articles 8.X.13., 8.X.15. to 8.X.17.;

f) regular and periodic testing of all *herds* ~~or *flocks*~~ has been in place for the past three years; and this testing has demonstrated that *Brucella infection* was not present in at least 99.8% of the *herds* ~~or *flocks* and~~ representing at least 99.9% of ~~animals~~ bovids in the country or *zone*. ~~three consecutive years;~~

2) To maintain the status as free from *Brucella infection* with *vaccination* in bovids, a country or *zone* should satisfy the following requirements:

a) the requirements in points 1a) to 1e) above are met;

~~6.~~b) a *surveillance* programme based on regular and periodic testing of ~~animals should be~~ bovids is in place in the country or *zone* to detect *Brucella infection* in accordance with Chapter 1.4.;

c) if ~~a~~ the *surveillance* programme described in ~~Points 2 and 5 a) and~~ b) above has not detected *Brucella infection* for ~~the past five~~ two consecutive years, *surveillance* ~~should~~ may be maintained in accordance with Chapter 1.4.

~~7. 8. animals and genetic materials introduced should comply with the recommendations in Articles 11.3.8. to 11.3.12~~.

3) The free status with *vaccination* of the country or *zone* for bovids ~~a specified animal category~~ is not affected by the occurrence of *Brucella infection* in other animal categories or *feral* ~~and~~ or *wild animals* provided that effective measures have been implemented to prevent transmission of *Brucella infection* to ~~the relevant animal population~~ bovids ~~belonging to the specified animal category free from *Brucella infection* is effectively separated from the potential source of *infection*~~.

4) In addition, if a country or *zone* free from *Brucella infection* with *vaccination* in bovids wishes to change its status to country or *zone* free from *Brucella infection* without *vaccination*, the status of this country or *zone* remains unchanged for a period of at least three years after *vaccination* has ceased, provided that the requirements in point 1c) of Article 8.X.3. are met during that period.

Article 8.X.5.

Country or zone free from *Brucella* infection without vaccination in sheep and goats

1) To qualify as free from *Brucella infection* without *vaccination* in sheep and goats, a country or *zone* should satisfy the following requirements:

a) *Brucella infection* in *animals* is a *notifiable disease* in the country or *zone*;

b) regulatory measures for the early detection of *Brucella infection* in sheep and goats, including the regular submission of abortion material to diagnostic laboratories for investigation, have been implemented;

c) no sheep and goats have been vaccinated against *Brucella infection* for at least the past three years and sheep and goats that are introduced in the country or *zone*, have not been vaccinated during the past three years;

d) no *case* of *Brucella infection* has been recorded in sheep and goats for at least the past three years;

e) sheep and goats and their genetic materials introduced in the country or *zone* comply with the recommendations in Articles 8.X.13., 8.X.15. to 8.X.17.;

f) regular and periodic testing of all *flocks* has been in place for the past three years; and this testing has demonstrated that *Brucella infection* was not present in at least 99.8% of the *flocks* representing at least 99.9% of sheep and goats in the country or *zone*.

2) To maintain the status as free from *Brucella infection* without *vaccination* in sheep and goats, a country or *zone* should satisfy the following requirements:

a) the requirements in points 1a) to 1e) above are met;

b) a *surveillance* programme based on regular and periodic testing of sheep and goats is in place in the

country or *zone* to detect *Brucella infection* in accordance with Chapter 1.4.;

c) if the *surveillance* programme described in b) above has not detected *Brucella infection* for two consecutive years, *surveillance* may be maintained in accordance with Chapter 1.4.

3) The free status without *vaccination* of the country or *zone* in sheep and goats is not affected by the occurrence of *Brucella infection* in other animal categories or *feral* or *wild animals* provided that effective measures have been implemented to prevent transmission of *Brucella infection* to sheep and goats.

Article 8.X.6.

Country or zone free from *Brucella* infection with vaccination in sheep and goats

1) To qualify as free from *Brucella infection* with *vaccination* in sheep and goats, a country or *zone* should satisfy the following requirements:

a) *Brucella infection* in *animals* is a *notifiable disease* in the country or *zone*;

b) regulatory measures for the early detection of *Brucella infection* in sheep and goats, including the regular submission of abortion material to diagnostic laboratories for investigation, have been implemented;

c) vaccinated sheep and goats should be identified with a permanent mark;

d) no *case* of *Brucella infection* has been recorded in sheep and goats for at least the past three years;

e) sheep and goats and their genetic materials introduced in the country or *zone* comply with the recommendations in Articles 8.X.13., 8.X.15. to 8.X.17.;

f) regular and periodic testing of all *flocks* have been in place for the past three years; and this testing has demonstrated that *Brucella infection* was not present in at least 99.8% of the f*locks* representing at least 99.9% of sheep and goats in the country or *zone*.

2) To maintain the status as free from *Brucella infection* with *vaccination* in sheep and goats, a country or *zone* should satisfy the following requirements:

a) the requirements in points 1a) to 1e) above are met;

b) a *surveillance* programme based on regular and periodic testing of sheep and goats is in place in the country or *zone* to detect *Brucella infection* in accordance with Chapter 1.4.;

c) if the *surveillance* programme described in b) above has not detected *Brucella infection* for two consecutive years, *surveillance* may be maintained in accordance with Chapter 1.4.

3) The free status with *vaccination* of the country or *zone* in sheep and goats is not affected by the occurrence of *Brucella infection* in other animal categories or *feral* or *wild animals* provided that effective measures have been implemented to prevent transmission of *Brucella infection* to sheep and goats.

4) In addition, if a country or *zone* free from *Brucella infection* with *vaccination* in sheep and goats wishes to change its status to country or *zone* free from *Brucella infection* without *vaccination*, the status of this country or *zone* remains unchanged for a period of at least three years after *vaccination* has ceased, provided that the requirements in point 1c) of Article 8.X.5. are met during that period.

Article 8.X.7.

Country or zone free from *Brucella* infection in camelids

1) To qualify as free from *Brucella infection* in camelids, a country or *zone* should satisfy the following requirements:

a) *Brucella infection* in *animals* is a *notifiable disease* in the country or *zone*;

Annex XL (contd)

b) regulatory measures for the early detection of *Brucella infection* in camelids, including the regular submission of abortion material to diagnostic laboratories for investigation, have been implemented;

c) no camelids have been vaccinated against *Brucella infection*;

EU comment

For consistency, the EU suggests adding the following to point c) above:

"[…] for at least the past three years and camelids that are introduced in the country or zone have not been vaccinated during the past three years;".

d) no *case* of *Brucella infection* has been recorded in camelids for at least the past three years;

e) camelids and their genetic materials introduced in the country or *zone* comply with the recommendations in Articles 8.X.13., 8.X.15. to 8.X.17.;

f) regular and periodic testing of all *herds* has been in place for the past three years; and this testing has demonstrated that *Brucella infection* was not present in at least 99.8% of the *herds* representing at least 99.9% of camelids in the country or *zone*.

2) To maintain the status as free from *Brucella infection* in camelids, a country or *zone* should satisfy the following requirements:

a) the requirements in points 1a) to 1e) above are met;

b) a *surveillance* programme based on regular and periodic testing of camelids is in place in the country or *zone* to detect *Brucella infection* in accordance with Chapter 1.4.;

c) if the *surveillance* programme described in b) above has not detected *Brucella infection* for two consecutive years, *surveillance* may be maintained in accordance with Chapter 1.4.

3) The free status of the country or *zone* in camelids is not affected by the occurrence of *Brucella infection* in other animal categories or *feral* or *wild animals* provided that effective measures have been implemented to prevent transmission of *Brucella infection* to camelids.

Article 8.X.8.

Country or zone free from *Brucella* infection in cervids

1) To qualify as free from *Brucella infection* in cervids, a country or *zone* should satisfy the following requirements:

a) *Brucella infection* in *animals* is a *notifiable disease* in the country or *zone*;

b) regulatory measures for the early detection of *Brucella infection* in cervids, including the regular submission of abortion material to diagnostic laboratories for investigation, have been implemented;

c) no cervids have been vaccinated against *Brucella infection*;

EU comment

For consistency, the EU suggests adding the following to point c) above:

"[…] for at least the past three years and cervids that are introduced in the country or zone have not been vaccinated during the past three years;".

d) no *case* of *Brucella infection* has been recorded in cervids for at least the past three years;

e) cervids and their genetic materials introduced in the country or *zone* comply with the recommendations

in Articles 8.X.13., 8.X.15. to 8.X.17.;

f) regular and periodic testing of all *herds* has been in place for the past three years; and this testing has demonstrated that *Brucella infection* was not present in at least 99.8% of the *herds* representing at least 99.9% of cervids in the country or *zone*;

2) To maintain the status as free from *Brucella infection* in cervids, a country or *zone* should satisfy the following requirements:

a) the requirements in Points 1.a) to 1.e) above are met;

b) a *surveillance* programme based on regular and periodic testing of cervids is in place in the country or *zone* to detect *Brucella infection* in accordance with Chapter 1.4.;

c) if the *surveillance* programme described in b) above has not detected *Brucella infection* for two consecutive years, *surveillance* may be maintained in accordance with Chapter 1.4.;

3) The free status of the country or *zone* in cervids is not affected by the occurrence of *Brucella infection* in other animal categories or *feral* or *wild animals* provided that effective measures have been implemented to prevent transmission of *Brucella infection* to cervids.

Article 8.X.9.

Herd or flock free from *Brucella* infection without vaccination in bovids, sheep and goats, camelids or cervids

1) To qualify as free from *Brucella infection* without *vaccination*, a *herd* or *flock* of ~~the relevant animal category~~ bovids, sheep and goats, camelids or cervids should satisfy the following requirements:

a) the *herd* or *flock* is in a country or *zone* free from *Brucella infection* without *vaccination* for the relevant animal category and is certified free without *vaccination* by the *Veterinary Authority*;

OR

b) the *herd* or *flock* is in a country or *zone* free from *Brucella infection* with *vaccination* for the relevant animal category and is certified free without *vaccination* by the *Veterinary Authority*; and no *animal* of the *herd* or *flock* has been vaccinated in the past three years;

OR

c) the *herd* or *flock* met the following conditions:

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

ii) no *animal* of the relevant category of the *herd* or *flock* has been vaccinated during the past three years;

iii) no *case* of *Brucella infection* has been detected in the *herd* or *flock* ~~has not shown evidence of *Brucella infection*~~ for at least the ~~past~~ ~~nine~~ past 12 months;

iv) *animals* showing clinical signs consistent with *Brucella infection* ~~all suspect cases~~ (such as ~~animals which have aborted~~ abortions) have been subjected to the necessary ~~clinical~~ ~~and laboratory investigations~~ diagnostic tests ~~with negative results~~;

EU comment

For reasons of clarity, the words "with negative results" should not be deleted at the end of the point above.

v) for at least the past 12 months, there has been no evidence of *Brucella infection* in other susceptible *animals* of the same *epidemiological unit*, or measures have been implemented to prevent any transmission of the *Brucella infection* from other susceptible *animals*;

~~v~~vi) all sexually mature *animals* of the relevant category, except castrated males were subjected to a

prescribed ~~serological~~ test for *Brucella infection* with negative results on two occasions, at an interval of more than 6 and less than 12 months between each test, the first test being performed not before 3 months after the *slaughter* of the last *case*.

2) To maintain the free status, the following conditions should be met:

a) the requirements in points 1a) or 1b) or 1c) i) to v) above are met;

~~a~~b) regular prescribed tests, at a frequency depending on the prevalence of *herd* or *flock infection* in the country or *zone*, demonstrate the continuing absence of *Brucella infection*;

~~b~~c) *animals* of the relevant category introduced into the *herd* or *flock* are ~~should be~~ accompanied by a certificate from an *Official Veterinarian* attesting that they come from:

i) a country or *zone* free from *Brucella infection* without *vaccination*;

EU comment

For clarity reasons, the EU suggests adding the following to point i) above:

"[…] for the relevant category;".

OR

ii) a country or *zone* free from *Brucella infection* with *vaccination* and the *animals* of the relevant category have not been vaccinated during the past three years;

OR

iii) a *herd* or *flock* free from *Brucella infection* with or without *vaccination*~~,~~ and ~~provided~~ that the *animals* have not been vaccinated in the past 3 years and were subjected ~~negative results were shown~~ to a prescribed test for *Brucella infection* ~~during~~ within ~~the~~ 30 days prior to shipment with negative results; in the ~~*case*~~ case of post-parturient females ~~which have given birth during the past 30 days~~, the test is ~~should be~~ carried out at least 30 days after giving ~~the~~ birth. This test is not required for sexually immature *animals* or vaccinated *animals* less than 18 months of age.

~~c) There is no evidence of *infection* in other epidemiologically relevant animal species kept in the same *establishment*, or measures have been implemented to prevent any transmission of the *Brucella infection* from other species kept in the same *establishment*.~~

Article 8.X.10.

Herd or flock free from *Brucella* infection with vaccination in bovids, sheep and goats

~~A *herd* or *flock* can be qualified free from *Brucella infection* with *vaccination* either in bovines or ovidae and capridae as listed in Article 11.3.1.~~

1) To qualify as free from *Brucella infection* with *vaccination*, a *herd* of bovids or *flock* of sheep and goats ~~the relevant animal category~~ should satisfy the following requirements:

a) the *herd* or *flock* is in a country or *zone* free from *Brucella infection* with *vaccination* for the relevant animal category and is certified free with *vaccination* by the *Veterinary Authority*;

OR

b) the *herd* or *flock* met the following conditions:

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

ii) vaccinated *animals* of the relevant categories ~~should be~~ are permanently identified;

iii) no *case* of *Brucella infection* has been detected in the *herd* or *flock* ~~has not shown evidence of *Brucella infection*~~ for at least the past ~~nine~~ 12 months;

iv) *animals* of the relevant category showing clinical signs consistent with *Brucella infection* ~~all suspect cases~~ (such as ~~animals which have aborted~~ abortions) have been subjected to the necessary ~~clinical and laboratory investigations~~ diagnostic tests ~~with negative results~~;

EU comment

For reasons of clarity, the words "with negative results" should not be deleted at the end of the point above.

v) for at least the past 12 months, there has been no evidence of *Brucella infection* in other susceptible *animals* of the same *epidemiological unit*, or measures have been implemented to prevent any transmission of the *Brucella infection* from other susceptible *animals*;

~~v~~vi) all sexually mature *animals* of the relevant category except castrated males were subjected to a prescribed ~~serological~~ test for *Brucella infection* with negative results on two occasions, at an interval of more than 6 and less than 12 months between each test, the first test being performed not before 3 months after the *slaughter* of the last *case*.

EU comment

All current prescribed tests for Brucellosis in the Terrestrial Manual (Chapters 2.4.3., 2.7.2. and 2.8.5.), and mentioned in the table of Chapter 1.3. of the Terrestrial Code (i.e. Brucella-Buffered Antigen Test, Complement Fixation test, Enzyme-Linked Immunosorbent Assay, Fluorescence Polarisation Assay), are serological tests. These tests would therefore be expected to yield positive results in animals vaccinated with conventional (non-DIVA) vaccines used against Brucellosis. The point above should therefore be clarified or deleted.

2) To maintain the free status, the following conditions should be met:

a) the requirements in points 1 a) or 1b) i) to v) above are met;

~~a~~b) regular prescribed tests, at a frequency depending on the prevalence of *herd* or *flock infection* in the country or *zone*, demonstrate the continuing absence of *Brucella infection*;

~~b~~c) *animals* of the relevant category introduced into the *herd* or *flock* should be accompanied by a certificate from an *Official Veterinarian* attesting that they come from either:

i) a country or *zone* free from *Brucella infection* with or without *vaccination*;

EU comment

For clarity reasons, the EU suggests adding the following to point i) above:

"[…] for the relevant category;".

OR

ii) a *herd* or *flock* free from *Brucella infection* with or without *vaccination*~~,~~ and ~~provided~~ that the *animals* have not been vaccinated in the past 3 years and were subjected ~~negative results were shown~~ to a prescribed test for *Brucella infection* within ~~during the~~ 30 days prior to shipment with negative results; in the ~~*case*~~ case of post-parturient females ~~which have given birth during the past 30 days~~, the test is ~~should be~~ carried out at least 30 days after giving ~~the~~ birth. This test is not required for sexually immature *animals* or vaccinated *animals* less than 18 months of age.

~~c) There is no evidence of *infection* in other epidemiologically relevant animal species kept in the same *establishment*, or measures have been implemented to prevent any transmission of the *Brucella infection* from other species kept in the same *establishment*.~~

Article 8.X.11.

Herd free from *Brucella* infection in pigs

1) To qualify as free from *Brucella infection*, a *herd* of pigs should satisfy the following requirements:

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

b) no pigs of the *herd* have been vaccinated;

EU comment

For consistency, the EU suggests adding the following to point b) above:

"[…] for at least the past three years and pigs that are introduced in the herd have not been vaccinated during the past three years;".

c) no *case* of *Brucella infection* has been detected in the *herd* for at least the past three years;

d) *animals* showing clinical signs consistent with *Brucella infection* (such as abortions or orchitis) have been subjected to the necessary diagnostic tests;

EU comment

For reasons of clarity, the words "with negative results" should be added after "diagnostic tests" at the end of the point above.

e) for at least the past three years, there has been no evidence of *Brucella infection* in other susceptible *animals* of the same *epidemiological unit*, or measures have been implemented to prevent any transmission of the *Brucella infection* from other susceptible *animals*.

2) To maintain the free status, the following conditions should be met:

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

b) *animals* introduced into the *herd* are accompanied by a certificate from an *Official Veterinarian* attesting that:

i) they come from a *herd* free from *Brucella infection*;

OR

ii) they come from a *herd* in which a statistically valid sample of the breeding pigs, selected in accordance with the provisions of Chapter 1.4., was subjected to a prescribed test within 30 days prior to shipment, demonstrating the absence of *Brucella infection;*

OR

iii) they were subjected to a prescribed test within 30 days prior to shipment with negative results.

Article 8.X.12.

Recovery of the *Brucella* infection free status in a country or a zone

Should a *case* of *Brucella infection* in one or more animal categories occur in a free country or *zone* as described in Articles 8.X.3. to 8.X.8., ~~the status is suspended~~ the free status ~~and~~ may ~~not~~ be recovered ~~until~~ once the following requirements are met:

1) all infected *animals* of the relevant category ~~were~~ are slaughtered or destroyed as soon as *Brucella infection* is confirmed ~~the result of the diagnostic test was known~~;

2) an epidemiological investigation is performed within 60 days of *Brucella infection* confirmation in the *herd* or *flock*, aiming at identifying the likely source and the distribution of the *infection,* and shows that *Brucella infection* has spread to less than 0.2% of *herds* or *flocks*;

3) in the *herds* or *flocks* identified by the epidemiological investigation:

a) depopulation is practised; or,

~~2~~.b) depopulation is not practised ~~in animal categories other than pigs~~, and all remaining sexually mature *animals* ~~in the *herd* or *flocks*~~ except castrated males have been subjected to a ~~serological~~ prescribed test, with negative results, on three occasions, at an interval of not less than two months, then a ~~further~~ fourth test six months later and a final fifth test a year later;

c) no *animals* are moved from the *herds* or *flocks* except for direct *slaughter* until the processes in point a) or b) above are completed;

~~3.~~4) ~~in pig *herds*, where *cases* of *Brucella infection* have occurred, all pigs were slaughtered or destroyed~~ cleansing and *disinfection* procedures have been applied at the end of the *slaughter* process and before new *animals* are introduced.

When these requirements are not met, Articles 8.X.3. to 8.X.8. apply as relevant.

Article 8.X.13.

Recommendations for the importation of ~~animals~~ bovids, sheep and goats, camelids or cervids for breeding or rearing

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

1) showed no clinical signs of *Brucella infection* on the day of shipment;

2) originate from:

a) a country or *zone* free from *Brucella infection* as relevant;

EU comment

For clarity, the EU suggests inserting the words "for the relevant category" after the words "Brucella infection".

OR

b) a *herd* or *flock* free from *Brucella infection* and all sexually mature *animals* were subjected to a prescribed ~~serological~~ test for *Brucella infection* with negative results ~~during~~ within ~~the~~ 30 days prior to shipment.

~~This test is not required for:~~

- ~~pigs;~~
- ~~young bovines before the age of 12 months;~~
- ~~young ovidae and capridae before the age of 6 months;~~
- ~~young *Camelidae* and *Cervidae* before the age of sexual maturity;~~

OR

c) ~~with the exception of pigs,~~ a *herd* or *flock* not qualified free from *Brucella infection*:

i) in which no *Brucella infection* has been reported during the nine 12 months prior to shipment;

EU comment

For consistency, the word "nine" in point i) above should be deleted.

ii) the *animals* were isolated for 30 days prior to shipment and subjected ~~during~~ within that period to a prescribed ~~serological~~ test for *Brucella infection* with negative results; in the ~~case~~ case of post-

parturient females ~~which have given birth during the past 30 days~~, the test is ~~should be~~ carried out at least 30 days after giving ~~the~~ birth. ~~This test is not required for sexually immature animals or vaccinated animals less than 18 months of age~~.

Article 8.X.14.

Recommendations for the importation of pigs for breeding or rearing

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

1) showed no clinical signs of *Brucella infection* on the day of shipment;

2) either:

   a) originate from a *herd* free from *Brucella infection*;

   OR

   b) originate from a *herd* in which a statistically valid sample of the breeding pigs, selected in accordance with the provisions of Chapter 1.4., was subjected to a prescribed test within 30 days prior to shipment, demonstrating the absence of *Brucella infection*;

   OR

   c) were subjected to a prescribed test for *Brucella infection* within 30 days prior to shipment with negative results.

Article 8.X.15.

Recommendations for the importation of animals for slaughter

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

1) showed no clinical signs of *Brucella infection* on the day of shipment;

2) originate from a country, *zone, herd* or *flock* free from *Brucella infection* ~~with or without *vaccination*~~;

   OR

3) are not being eliminated as part of an eradication programme against *Brucella infection* and in the case of sexually mature bovids, sheep and goats, camelids or cervids, were subjected to a prescribed test for *Brucella infection* with negative results ~~during~~ within ~~the~~ 30 days prior to shipment ~~and are not being~~ eliminated as part of an eradication programme against *Brucella infection*.

EU comment

In point 3) above, the EU suggests replacing the word "eliminated" by the word "slaughtered" (clarity and style).

~~Article 11.3.10.~~

~~**Recommendations for the importation of captive European hares (*Lepus europaeus*) for restocking**~~

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

~~1) the animals showed no clinical signs of *Brucella infection* on the day of shipment;~~

~~2) a programme is in place to ensure effective investigation and reporting of all *cases* suggestive of *Brucella infection* in *establishments* keeping hares.~~

Article 8.X.16.

Recommendations for the importation of semen

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

1) the donor *animals* showed no clinical signs of *Brucella infection* on the day of collection of the semen;

2) the donor *animals* were not vaccinated against *Brucella infection* and either:

   a) were kept in an *artificial insemination centre* ~~free from *Brucella infection*~~;

EU comment

For reasons of clarity, the words "free from Brucella infection" should not be deleted at the end of the point above. Alternatively, a reference could be made to Chapter 4.6., as follows:

"a) were kept in an artificial insemination centre ~~free from Brucella infection~~ which complies with the recommendations of Chapter 4.6."

OR

   b) were kept in a *herd* or *flock* free from *Brucella infection* and ~~are~~ subjected every six months to a prescribed test for *Brucella infection* with negative results, and the semen was collected, processed and stored in conformity with the provisions of Articles 4.5.3. to 4.5.5. and Articles 4.6.5. to 4.6.7.

~~3) the semen was collected, processed and stored in conformity with the provisions of Chapter 4.5. and Chapter 4.6.~~

Article 8.X.17.

Recommendations for the importation of embryos and oocytes

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

1) the donor *animals* showed no clinical signs of *Brucella infection* on the day of collection;

2) the donor *animals* were not vaccinated against *Brucella infection* during the past three years and either:

   a) were kept in a country or *zone* free from *Brucella infection,* as relevant;

EU comment

For clarity, the EU suggests inserting the words "for the relevant category" after the words "Brucella infection" in point a) above.

OR

   b) were kept in a *herd* or *flock* free from *Brucella infection* and ~~are~~ subjected every six months to a prescribed test for *Brucella infection* with negative results;

3) the embryos and oocytes were collected, processed and stored in conformity with the provisions of Chapter 4.7. to Chapter 4.9.

Article 8.X.18.

Recommendations for the importation of fresh meat and meat products other than mentioned in Article 8.X.2.

Veterinary Authorities of *importing countries* should require the presentation of an *international veterinary*

certificate attesting that the *meat* and *meat products* come from *animals*:

1) which have been subjected to ante-~~mortem~~ and post-mortem inspections as described in Chapter 6.2.;

2) which:

a) originate from a country or *zone* free from *Brucella infection,* as relevant;

EU comment

For clarity, the EU suggests inserting the words "for the relevant category" after the words "Brucella infection" in point a) above.

OR

~~a~~b) originate from a *herd* or *flock* free from *Brucella infection*;

OR

~~b~~c) have not been eliminated as part of an eradication programme against *Brucella infection* ~~have not tested positive to a prescribed test for *Brucella infection*~~.

EU comment

In point 3) above, the EU suggests replacing the word "eliminated" by the word "slaughtered" (clarity and style).

Article 8.X.19.

Recommendations for the importation of milk and milk products

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

1) have been derived from *animals* in a country, *zone, herd* or *flock* free ~~of a *herd* or *flock* free~~ from *Brucella infection*;

EU comment

For clarity reasons, the EU suggests adding the following to point 1) above:

"[…] for the relevant category;".

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.

Article 8.X.20.

Recommendations for importation of wool and hair

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

1) have not been derived from ~~*Brucella* infected~~ *animals* eliminated as part of an eradication programme against *Brucella infection*;

EU comment

In point 1) above, the EU suggests replacing the word "eliminated" by the word "slaughtered" (clarity and style).

OR

2) have been processed to ensure the destruction of the *Brucella*.

Article 8.X.21.

Procedures for the inactivation of *Brucella* in casings of bovids, sheep and goats, and pigs

For the inactivation of *Brucella* in casings of bovids, sheep and goats, and pigs, the following procedures should be used: salting for at least 30 days either with dry salt (NaCl) or with saturated brine (Aw < 0.80), and kept at a temperature of greater than 20°C during this entire period.

EU comment

The EU agrees with the proposed new article above. However, the EU suggests amending the temperature requirement as follows:

"[…] (~~Awa~~a_w < 0.80), and kept at a temperature of ~~greater than~~ 20°C or above during this entire period.".

Indeed, the European Food Safety Authority, in its recent scientific opinion on animal health risk mitigation treatments as regards imports of animal casings (available on EFSA's website at http://www.efsa.europa.eu/it/efsajournal/pub/2820.htm), recommends that the treatment be made at 20°C or above (see conclusions and recommendations sections on p. 21-23).

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— Text deleted.

Annex XLI

CHAPTER X.X.

INFECTION WITH EPIZOOTIC HEMORRHAGIC DISEASE VIRUS

EU comments

The EU thanks the OIE for having taken its comments into account and in general supports the proposed changes to this draft new chapter.

However, the EU is of the opinion that the concept of seasonally free zones should not be deleted from this draft chapter, but rather be kept, just as in the chapter on bluetongue. Indeed, this concept has successfully been used in the EU for many years to allow safe trade of animals during the vector free period, as demonstrated by appropriate surveillance. Therefore, Articles X.X.4., X.X.7., X.X.10. and X.X.13., and the references to seasonally free in Articles X.X.5. and X.X.16. should be retained.

Further comments are inserted in the text below.

Article X.X.1.

General provisions

For the purposes of the *Terrestrial Code*, epizootic hemorrhagic disease (EHD) is defined as an *infection* of cervids and bovids ~~cattle~~ with one of several serotypes of epizootic hemorrhagic disease virus (EHDV). *Outbreaks* of *disease* due to EHDV are sporadic and geographically restricted. Although EHDV is not regarded as a significant pathogen of livestock in many countries in which it is present, *outbreaks* of *disease* have caused significant economic loss to the cattle industry in some countries.

The following defines the occurrence of EHDV *infection*:

1) EHDV has been isolated and identified as such from a cervid or bovid or a product derived from it; or

EU comments

In the point above, the EU suggests replacing the words "from it" by the words "from such animals" (clarity).

2) viral antigen or viral ribonucleic acid (RNA) specific to one or more of the serotypes of EHDV has been identified in samples from a cervid or bovid showing clinical signs consistent with EHD, or epidemiologically linked to a confirmed or suspected *case*, or giving cause for suspicion of previous association or contact with EHDV; or

3) antibodies to structural or nonstructural proteins of EHDV that are not a consequence of *vaccination* have been identified in a cervid or bovid that either shows clinical signs consistent with EHD, or is epidemiologically linked to a confirmed or suspected *case*, or gives cause for suspicion of previous association or contact with EHDV.

For the purposes of *international trade*, a distinction is made between a *case* as defined above and an *animal* that is potentially infectious to *vectors*.

For the purposes of the *Terrestrial Code*, the *infective period* for EHDV shall be 60 days.

For countries that do not meet the provisions of point 1 of Article 1.4.6. and in the absence of clinical *disease* in a country or *zone*, its EHDV status should be determined by an ongoing *surveillance* programme (in accordance with Article x.x.~~16~~12.). The programme may need to be adapted to target parts of the country or *zone* at a higher risk due to historical, geographical and climatic factors, ruminant population data and *Culicoides* ecology.

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

Article X.X.2.

Safe commodities

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

1) *milk* and *milk products*;

2) *meat* and *meat products*;

3) hides, skins, antlers and hooves;

4) wool and fibre.

Article X.X.3.

EHDV free country or zone

1) A country or a *zone* may be considered free from EHDV when EHD ~~epizootic haemorrhagic disease~~ is notifiable in the whole country and either:

   a) historical freedom has been demonstrated as described in Article 1.4.6.; or

   b) a *surveillance* programme in accordance with Article X.X.~~16~~12. has demonstrated no evidence of EHDV transmission in the country or *zone* during the past two years; or

   c~~b~~) an ongoing *surveillance* programme has demonstrated no evidence of *Culicoides* in the country or *zone*.

2) An EHDV free country or *zone* in which ongoing *vector surveillance* has found no evidence of *Culicoides* will not lose its free status through the importation of seropositive or infective *animals*, or semen, embryos or ova from infected countries or *infected zones*.

3) An EHDV free country or *zone* in which *surveillance* has found evidence that *Culicoides* are present will not lose its free status through the importation of seropositive *animals,* provided that they were imported in accordance with Article X.X.6.

~~Article X.X.4.~~

~~**EHDV seasonally free zone**~~

~~An EHDV seasonally free *zone* is a part of an infected country or an *infected zone* for which for part of a year *surveillance* demonstrates no evidence either of EHDV transmission or of adult *Culicoides*.~~

Article X.X.~~5~~4.

EHDV infected country or zone

For the purpose of this chapter, an EHDV infected country or *infected zone* is a clearly defined area where evidence of EHDV transmission has been reported during the past two years. ~~Such a country or *zone* may contain an EHDV seasonally free *zone*.~~

Article X.X.~~6~~5.

Recommendations for importation from EHDV free countries or zones

For cattle and cervids

Where EHDV is of concern, *Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that:

1) the *animals* were kept in an EHDV free country or *zone* since birth or for at least 60 days prior to shipment; or

2) the *animals* were kept in an EHDV free country or *zone* for at least 28 days, then were subjected, with negative results, to a serological test to detect antibody to the EHDV group and remained in the EHDV free country or *zone* until shipment; or

3) the *animals* were kept in an EHDV free country or *zone* for at least seven days, then were subjected, with negative results, to an agent identification test and remained in the EHDV free country or *zone* until shipment;

AND

4) if the *animals* were exported from a free *zone* within an *infected country* either:

   a) did not transit through an *infected zone* during transportation to the *place of shipment*; or

   b) were protected from attacks by *Culicoides* at all times when transiting through an *infected zone.*

~~Article X.X.7.~~

~~**Recommendations for importation from EHDV seasonally free zones**~~

~~For cattle and cervids~~

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

~~1) were kept during the seasonally free period in an EHDV seasonally free *zone* since birth or for at least 60 days prior to shipment; or~~

~~2) were kept during the EHDV seasonally free period in an EHDV seasonally free *zone* for at least 28 days prior to shipment, and were subjected during the residence period in the *zone* to a serological test to detect antibody to the EHDV group with negative results, carried out at least 28 days after the commencement of the residence period; or~~

~~3) were kept during the EHDV seasonally free period in an EHDV seasonally free *zone* for at least 14 days prior to shipment, and were subjected during the residence period in the *zone* to an agent identification test with negative results, carried out at least 14 days after the commencement of the residence period;~~

~~AND~~

~~4) either:~~

~~a) did not transit through an *infected zone* during transportation to the *place of shipment*; or~~

~~b) were protected from attacks by *Culicoides* at all times when transiting through an *infected zone.*~~

Article X.X.~~8~~6.

Recommendations for importation from EHDV infected countries or zones

For cattle and cervids

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

1) were protected from attacks by *Culicoides* in a *vector*-protected *establishment* for at least 60 days prior to shipment and during transportation to the *place of shipment*; or

2) were protected from attacks by *Culicoides* in a *vector*-protected *establishment* for at least 28 days prior to shipment and during transportation to the *place of shipment*, and were subjected during that period to a serological test to detect antibody to the EHDV group, with negative results, carried out at least 28 days after introduction into the *vector*-protected *establishment*; or

3) were protected from attacks by *Culicoides* in an *vector*-protected *establishment* for at least 14 days prior to shipment and during transportation to the *place of shipment*, and were subjected during that period to an agent identification test with negative results, carried out at least 14 days after introduction into the *vector*-protected *establishment*; or

4) were demonstrated to have antibodies for at least 60 days prior to dispatch against all serotypes whose presence has been demonstrated in the source population through a *surveillance* programme in accordance with Article x.x.~~16~~12.

Article X.X.~~9~~7.

Recommendations for importation from EHDV free countries or zones

For semen of cattle and cervids

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

1) the donor *animals*:

   a) were kept in an EHDV free country or *zone* for at least 60 days before commencement of, and during, collection of the semen; or

   b) were subjected to a serological test to detect antibody to the EHDV group, between 21 and 60 days after the last collection for this consignment, with negative results; or

   c) were subjected to an agent identification test on blood samples collected at commencement and conclusion of, and at least every 7 days (virus isolation test) or at least every 28 days (PCR test) during, semen collection for this consignment, with negative results;

2) the semen was collected, processed and stored in conformity with the provisions of Chapters 4.5. and 4.6.

~~Article X.X.10.~~

~~**Recommendations for importation from EHDV seasonally free zones**~~

~~For semen of cattle and cervids~~

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

~~1) the donor *animals*:~~

~~a) were kept during the EHDV seasonally free period in a seasonally free *zone* for at least 60 days before commencement of, and during, collection of the semen; or~~

~~b) were subjected to a serological test to detect antibody to the EHDV group, with negative results, at least every 60 days throughout the collection period and between 21 and 60 days after the final collection for this consignment; or~~

~~c) were subjected to an agent identification test on blood samples collected at commencement and conclusion of, and at least every 7 days (virus isolation test) or at least every 28 days (PCR test) during, semen collection for this consignment, with negative results;~~

~~2) the semen was collected, processed and stored in conformity with the provisions of Chapters 4.5. and 4.6.~~

Article X.X.~~11~~8.

Recommendations for importation from EHDV infected countries or zones

For semen of cattle and cervids

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

1) the donor *animals*:

   a) were kept in a *vector*-protected *establishment* for at least 60 days before commencement of, and during, collection of the semen; or

   b) were subjected to a serological test to detect antibody to the EHDV group, with negative results, at least every 60 days throughout the collection period and between 21 and 60 days after the final collection for this consignment; or

   c) were subjected to an agent identification test on blood samples collected at commencement and conclusion of, and at least every 7 days (virus isolation test) or at least every 28 days (PCR test) during, semen collection for this consignment, with negative results;

2) the semen was collected, processed and stored in conformity with the provisions of Chapters 4.5. and 4.6.

Article X.X.~~12~~9.

Recommendations for importation from EHDV free countries or zones

For embryos or oocytes of cattle and cervids

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

1) the donor females:

   a) were kept in an EHDV free country or *zone* for at least the 60 days prior to, and at the time of, collection of the embryos or oocytes; or

   b) were subjected to a serological test ~~t~~o detect antibody to the EHDV group, between 21 and 60 days after collection, with negative results; or

   c) were subjected to an agent identification test on a blood sample taken on the day of collection, with negative results;

2) the embryos or oocytes were collected, processed and stored in conformity with the provisions of Chapters 4.7., 4.8. and 4.9., as relevant.

~~Article X.X.13.~~

~~**Recommendations for importation from EHDV seasonally free zones**~~

~~For embryos or oocytes of cattle and cervids~~

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

~~1) the donor females:~~

   ~~a) were kept during the seasonally free period in a seasonally free *zone* for at least 60 days before commencement of, and during, collection of the embryos or oocytes; or~~

   ~~b) were subjected to a serological test to detect antibody to the EHDV group, between 21 and 60 days after collection, with negative results; or~~

Annex XLI (contd)

~~c) were subjected to an agent identification test on a blood sample taken on the day of collection, with negative results;~~

~~2) the embryos or oocytes were collected, processed and stored in conformity with the provisions of Chapters 4.7., 4.8. and 4.9., as relevant.~~

Article X.X.~~14~~10.

Recommendations for importation from EHDV infected countries or zones

For embryos or oocytes of cattle and cervids

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

1) the donor females:

   a) were kept in a *vector*-protected *establishment* for at least 60 days before commencement of, and during, collection of the embryos or oocytes; or

   b) were subjected to a serological test to detect antibody to the EHDV group, between 21 and 60 days after collection, with negative results; or

   c) were subjected to an agent identification test on a blood sample taken on the day of collection, with negative results;

2) the embryos or oocytes were collected, processed and stored in conformity with the provisions of Chapters 4.7., 4.8. and 4.9., as relevant.

Article X.X.~~15~~11.

Protecting animals from Culicoides attacks

1. Vector-protected establishment or facility

   Where movement of *animals* or collection of genetic material requires a vector-protected facility, the *establishment* or facility should be approved by the *Veterinary Authority* and the following criteria apply:

   a) appropriate physical barriers at entry and exit points, for example, double-door entry-exit system;

   b) openings of the building are *vector* screened with mesh of appropriate gauge impregnated regularly with an approved insecticide according to the manufacturer's instructions;

   c) *vector* surveillance and control within and around the building;

   d) measures to limit or eliminate breeding sites for *vectors* in the vicinity of the *establishment* or facility;

   e) standard operating procedures, including description of back-up and alarm systems, for operation of the *establishment* or facility and transport of *animals* to the place of *loading*.

2. During transportation

When transporting *animals* through EHDV infected countries or *infected zones*, *Veterinary Authorities* should require strategies to protect *animals* from attacks by *Culicoides* during transport.

Risk management strategies may include:

a) *loading*, transporting and *unloading animals* at times of low *vector* activity (i.e. bright sunshine, low temperature);

b) ensuring *vehicles* do not stop en route during times of high *vector* activity (i.e. dawn or dusk, or overnight).

EU comment

The EU suggests adding a point c) as follows:

"c) treating animals or vehicles with insect repellents prior to and during transportation."

Article X.X.~~16~~12.

Surveillance

This article is complementary to Chapters 1.4. and 1.5. and outlines the principles for EHDV *surveillance* applicable to Members seeking to determine the EHDV status of a country or a *zone*.

The impact and epidemiology of EHD differ widely in different regions of the world and therefore it is impossible to provide specific recommendations for all situations. It is incumbent upon Members to provide scientific data that explain the epidemiology of EHD in the region concerned and adapt the *surveillance* strategies for defining their infection status (free ~~, seasonally free~~ or infected country or *zone*) to the local conditions. There is considerable latitude available to Members to justify their infection status at an acceptable level of confidence.

Surveillance for EHD should be in the form of a continuing programme.

General provisions on surveillance for arthropod *vectors* are in Chapter 1.5.

More specific approaches to *surveillance* for *Culicoides* transmitted *Orbivirus infections* are described in Chapters 8.3. and 12.1. Passive *surveillance* for clinical *cases* of EHD in susceptible wild ruminants can be a useful tool for detecting *disease*, based on lesions of haemorrhagic disease combined with viral detection techniques.

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— Text deleted.

Annex XLII

CHAPTER 4.X.

GENERAL PRINCIPLES FOR ANIMAL DISEASE CONTROL

EU comments

The EU thanks the OIE for its work on this draft new text.

However, this draft chapter is very general and the value added by including such a text in the Code is not clear. The way the text is drafted, making numerous references to existing concepts and chapters in the OIE Code and Manual, makes it appear more like a guidance document than a standard, which aims to explain how to implement the OIE standards. Indeed, a very similar text is already present on the OIE website (cf. http://www.oie.int/fileadmin/Home/eng/Our_scientific_expertise/docs/pdf/A_Guidelines_for_Animal_Disease_Control_final.pdf).

Therefore, the EU cannot support including this text as a standard in the OIE Terrestrial Code.

If at all, and as it might be useful for certain people or OIE member countries only, this text might be published as a guideline on the OIE website e.g. under "Support to OIE members".

As to the contents of the chapter itself, it is not clear what the scope of the chapter is – the principles are generally sound but if it is to include non-listed non-notifiable diseases (which do not require a legislative framework but may be supported by the veterinary authority) that should be clearly stated in the introduction and objectives.

Some specific comments are inserted in the text below.

Article 4.X.1.

Introduction and objectives

This chapter is intended to help Member Countries identify priorities, objectives and the desired goal of *disease* control programmes in endemic, *outbreak* or emergency situations. *Disease* control programmes are often established with the aim of eventual eradication of agents at a country, *zone* or *compartment* level. While this approach is desirable, the needs of stakeholders may require a broader range of outcomes. For some *diseases*, eradication may not be economically or practically feasible and options for sustained mitigation of *disease* impacts may be needed. It is important to clearly describe the programme goals and these may range from simple mitigation of *disease* impacts to progressive control or eradication. The chapter highlights the importance of *disease* intervention options in the design of programmes, taking into consideration effectiveness, feasibility of implementation, and costs and benefits. The purpose is to provide a conceptual framework that can be adapted to a particular national and epidemiological context.

It is assumed that the country should have determined its *disease* control priorities and this chapter should help in the development and implementation of a specific programme that includes objectives, policies and strategies adapted to the full range of national needs. Specific outputs of this process will include the rationale for establishing a *disease* control programme, strategic goal and objectives, a control programme plan and implementation.

These general recommendations may be refined by the approaches described in the specific *disease* chapters. Where specific information on an *official control programme* is not available, suitable approaches should be based on the recommendations in this chapter.

EU comment

The EU suggests adding a reference to the concept of progressive control of certain transboundary animal diseases, as is already the case e.g. for FMD and PPR.

Article 4.X.2.

Rationale for establishing a disease control programme

The country should clearly state the rationale for establishing a *disease* control programme. In addition to animal health, consideration should be given to public health, food safety, food security, biodiversity and socioeconomic aspects.

The justification for the *disease* control programme should include a summary of the current knowledge of the epidemiological situation in the country, providing for example detailed information on:

1) description of the *disease* situation;

EU comment

The disease epidemiology (risk factors, transmission rates etc.) is critical to control as well the epidemiological situation that the country is in. Therefore the EU suggests inserting the following wording into point 1 above :

"1) description of the disease situation <u>including the important epidemiological characteristics of the disease</u>;".

2) description of *disease* impacts (animal and public health, food safety, food security and socioeconomic impact) and how these are distributed among stakeholders;

3) identification, level of interest and involvement of stakeholders.

Article 4.X.3.

Control programme goal and objectives

The goal of a control programme should be defined. Although eradication has traditionally been the goal for many *disease* control programmes, it may not always be achievable within a reasonable time frame or at an acceptable cost. The epidemiology of the *disease,* along with the availability of technical tools as well as social, environmental and economic considerations, should dictate if eradication is achievable or if control at a certain prevalence level is the desired outcome. For some *diseases*, or in certain situations, the emphasis of a programme may be limited to reducing health and economic impacts. In other cases a programme may not be feasible or cost-beneficial. Specific objectives and indicators leading to achievement of the programme goal should be established.

EU comments

In general, when setting the goal and objectives there is no mention of official recognition or self-declaration of the status, whereas this is the main goal for most of the control/eradication programmes. Moreover, the effect of the disease control programmes and activities on trade is not sufficiently highlighted. The EU is of the opinion that these essential aspects need to be added to the text.

Furthermore, the zoonotic potential of an animal pathogen should be emphasised more, as it is an essential factor guiding control policies. Therefore, the EU suggests amending the second sentence in the paragraph above as follows:

"The epidemiology of the disease <u>including its zoonotic potential</u>, along with the availability of technical tools as well as <u>Public Health,</u> social, environmental and economic considerations, should dictate if eradication is achievable or if control at a certain prevalence level is the desired outcome."

Some of the factors to define the goal of *disease* control programmes are listed (Table 1). An assessment of these factors should guide in the strategic planning and programme implementation.

Table 1 – Factors to consider in setting achievable goals for disease control programmes

EU comments
As stated in the text above, Table 1 does not provide a complete list of factors to consider, therefore the EU suggests adding the word 'some' into the title for Table 1, as follows:
"<u>Some</u> factors to consider in setting achievable goals for disease control programmes".
Furthermore, the following amendments are suggested for the specific boxes of Table 1:
1. Biological Factors section:
- in line with the EU comment above, the words "<u>Zoonotic potential</u>" should be added, as a separate bullet point after "Species affected" and "Genetic stability and diversity of the agent";
- the following wording should be added to existing points :
- <u>Distribution and</u> Density of susceptible species
- <u>Modes of transmission including</u> Vector transmission
2. Control Measures section:
- the following wording should be added to the existing point on vaccination to cover propylactic treatments:
- Vaccination <u>and other permitted medical measures</u>
3. Socioeconomic Considerations section:
- the following wording should be added to existing points, and an additional point added as follows:
- Structure of livestock production systems <u>and production chains</u>
- <u>Governance and</u> Institutional arrangements
- <u>Roles and responsibilities</u>

Biological factors	**Availability of technical tools**
- Species affected - Genetic stability and diversity of the agent - Density of susceptible species - Wildlife reservoir - Vector transmission - Transmissibility - Current extent of disease - Survival in the environment - Carrier state - Ease of clinical recognition	- Diagnostic tests - Vaccines - Treatment - Disinfectants and insecticides - Disposal facilities

Control measures	Socioeconomic considerations
- Movement control - Stamping-out, slaughter or pre-emptive slaughter - Import or export restrictions - Zoning or compartmentalisation - Herd accreditation - Isolation and quarantine - Cleaning and disinfection - Vector and reservoir control - Treatment of products and by-products - Vaccination	- Cost and benefits of intervention - Availability of resources - Structure of livestock production systems - Public health implications - Logistics and ease of implementation, - Stakeholder engagement - Environmental impact - Political will - Incentives and compensation - Acceptance of the public (e.g. animal welfare implications, culling of animals, destruction of food) - Safe commodities for trade - Institutional arrangements

Article 4.X.4.

Programme planning

The *Veterinary Authority,* in collaboration with stakeholders, should develop a plan based on the goal of the programme. Intervention options should be based on biological effectiveness, ease and cost of implementation, as well as the expected benefits. Tools such as value chain analysis may be used to help understand the role of different players within the production system, identify critical control points to target measures and provide an indication on the incentives for and feasibility of implementation of the programme.

EU comment

When developing and implementing plans for zoonotic diseases, close collaboration and coordination with Public health Authorities is necessary. Therefore, the EU suggests adding the following sentence after the paragraph above:

"<u>In case of zoonotic diseases, close collaboration and coordination with Public health Authorities is necessary during programme planning and implementation</u>."

The decision on the most appropriate intervention options should take into account cost-benefit considerations, in conjunction with the likelihood of success of a particular set of *disease* control measures.

Institutional analysis examines the organisations involved in delivering services and the processes that govern their interaction. This type of analysis would be helpful to inform the strategic planning process and identify areas where a change would enable better programme implementation and facilitate effective collaboration.

EU comment

Critical path methods are also used to improve project management through work breakdown structures and identifying dependencies between activities; these should also be considered in the paragraph above.

The programme should include a continued review process to assess the effectiveness of the interventions being applied, identify gaps in knowledge and adapt the goals, objectives and methods or actions as required.

The programme should take into consideration the distribution of costs and benefits among different stakeholders and understand the factors limiting stakeholder participation in programme activities. These factors can affect the optimal selection of interventions. Programme policies need to include incentives for engagement including additional services for the holder or producer, appropriate compensation schemes, adding value to the final product and protecting public health. In addition, it may be necessary to include measures to raise awareness and ensure compliance including movement restrictions and fines. *Disease* control programmes should take into consideration non-financial factors (social, cultural, religious, etc.) affecting the livelihoods and well-being of animal owners such as pastoralists, indigenous communities or

small-scale backyard holders or producers. These factors can be important incentives for participation or non-compliance and ultimately impact the success of the programme.

Article 4.X.5.

Implementation plan

A *disease* control programme should be based on an efficient and effective *Veterinary Services* and holder or producer participation. Countries are encouraged to follow the provisions of Chapter 3.1., as well as to undergo a Performance of Veterinary Services (PVS) evaluation and address the gaps that may be identified. In addition, the programme should have political support, and sustainable sources of funding, including government and private stakeholder contributions.

EU comment

Since it is a general obligation resulting from membership for OIE Member Countries to comply with OIE Standards, the wording of the second sentence of the paragraph above, merely encouraging countries to follow the provisions of Chapter 3.1 "Veterinary services" is confusing. Furthermore, Chapter 3.2 "Evaluation of veterinary services" should duly be mentioning. Therefore, the EU suggests amending that sentence as follows:

"Member Countries should ensure good quality of Veterinary Services by following the provisions of Chapter 3.1. . An evaluation of Veterinary Services following the provisions of Chapter 3.2., for instance by requesting an OIE Performance of Veterinary Services (PVS) evaluation, will be valuable to identify possible gaps that should consequently be addressed."

The implementation plan should address the following:

1. Regulatory framework

   The *disease* control programme should be supported by effective legislation at the primary and secondary levels. Countries are encouraged to follow the OIE standards on Veterinary Legislation (Chapter 3.4.). The *disease* should be notifiable throughout the country. The regulatory framework for the *disease* control programme should be adapted to evolving programme needs.

EU comments

Similar as explained in the comment above, the EU suggests amending the point above by replacing the words "are encouraged to" by the word "should".

Furthermore, relating to the scope of the chapter, the sentence "The disease should be notifiable throughout the country" in the paragraph above implies that the only means of developing a control programme is by making the disease notifiable which is not necessarily the case. If this chapter is only applicable to notifiable diseases, it needs to be made explicit in the introduction and thereafter.

2. Programme management

   Disease control measures to be applied in the programme may be implemented by the *Veterinary Authority*, or private or community entities or a combination of all. In any event, the overall responsibility for oversight of the programme remains with the *Veterinary Authority*.

EU comment

The reference to the overall responsibility of the Veterinary Authority also links to the overall question regarding the scope of this chapter – there are excellent programmes

initiated and led by the industry for non-listed non-notifiable diseases. If the scope of the chapter extends to them then this statement would not be applicable.

The management of the application of *disease* control measures should follow standard operating procedures including:

a) implementation, maintenance, monitoring of the measures;

b) application of corrective actions;

c) verification of the process;

EU comment

Point c) above should be amended as follows, to ensure on-going development of the quality of the programme as required:

"c) evaluation and verification of the process".

d) record keeping including information systems and data management.

3. Epidemiological situation

The implementation of the programme needs to take into consideration:

a) distribution and density of susceptible species including *wildlife*, if applicable;

b) knowledge of animal production and marketing systems;

c) spatial and temporal distribution of *disease;*

d) zoonotic potential;

e) risk factors and critical control points;

f) *vectors*;

g) carriers;

h) reservoirs;

i) impact of *disease* control measures;

j) specific *disease* situation in neighbouring country(ies), if applicable;

k) evaluation of appropriateness of establishing *disease zones* or *compartments.*

4. Disease surveillance

The underpinning of the *disease* control programme activities is an effective *surveillance* system that provides guidance on priorities and targets for the application of interventions. The *surveillance* system should consist of general *surveillance* activities reinforced by pathogen specific activities. A clear *case* definition and *outbreak* investigation and response procedures are required. The provisions of Chapters 1.1., 1.4. and 1.5. should be referred to and specific *surveillance* guidelines where applicable for particular *diseases*.

5. Diagnostic capability

The programme should be supported by diagnostic facilities with adequate capability and capacity. Samples for diagnosis should be collected and shipped in accordance with Chapter 1.1.1. of the *Terrestrial Manual.* The choice of diagnostic tests should ensure detection and confirmation of the *disease*. The tests should follow the specific requirements in Chapter 1.1.5. and the *disease* specific recommendations in the *Terrestrial Manual.* Diagnostic facilities, either official or accredited, should be under a quality

assurance scheme coordinated by the designated national reference laboratory. The latter should establish communication with an OIE Reference Laboratory for the particular *disease*. National and sub-national laboratories need to ensure that diagnostic results are communicated to the *Veterinary Authority* as appropriate to the situation. National laboratories are also needed to provide independent and impartial quality control of vaccines. When appropriate, national laboratories are encouraged to submit samples to OIE Reference Laboratories for confirmation of findings and more detailed analysis.

EU comment

The provisions in the point above relating to the relations between national reference laboratories and OIE Reference Laboratories are overly prescriptive and do not match the particular situation in the EU. Indeed, in the EU, at the supranational level and for certain diseases, the national reference laboratories of EU Member States interact with EU reference laboratories, which are not necessarily OIE Reference Laboratories.

6. Vaccination and other control measures

Vaccination is one of the essential tools in the control of many *diseases*, if an effective vaccine is available. However, *vaccination* on its own will not usually achieve the desired results unless the *vaccination* programme is part of an integrated control strategy utilising a combination of control measures as outlined in Table 1. If *vaccination* is applied the following points should be considered:

a) Role of vaccination

Depending on the epidemiological situation, the pattern of animal movements, population density and production systems within the country, the occurrence of *wildlife* reservoirs, targeted *vaccination* may be more effective than systematic mass *vaccination*. *Vaccination* campaigns should be serologically monitored for their effectiveness to ensure that immunity objectives are being met. When a validated strategy to differentiate infected and vaccinated animals (DIVA) is available, its use should be considered.

b) Vaccine quality

A vaccine quality assurance programme ensures the purity, safety, potency of vaccines as well as measures their efficacy in relation to the circulating strains. Vaccines used within control programmes should be licensed under the authority of the official *Veterinary Services* in accordance to the provisions of the *Terrestrial Manual* and preferably tested by an independent authority for safety and potency.

c) Vaccine delivery

Effective delivery of vaccine, including preservation of the cold chain requirements and proper administration, is essential for reaching an adequate level of population immunity. This could require the implementation of governmental or private schemes that include quality assurance controls of vaccine distribution.

EU comment

In the paragraph above, the need to adequately and permanently mark vaccinated animals (as appropriate) in order to easily identify them and allow traceability should be mentioned.

d) Vaccine and antigen banks

Vaccine and antigen banks may be useful to ensure that sufficient stocks are available. These may be held at national or regional level and should comply with the provisions of Chapter 1.1.10. of the *Terrestrial Manual.*

e) Other measures

Regardless of whether *vaccination* is used or not, a disease control programme should utilise a mix of control measures and tools. Several measures frequently applicable in a disease control programme are listed in Table 1.

7. Traceability

An effective traceability system facilitates the identification of affected individual *animals*, *herds* or *flocks*. The design of the traceability system should follow the provisions of Chapter 4.1. and Chapter 4.2.

8. Regional integration

Many diseases are considered transboundary animal diseases and require a regional control approach. Regional and inter-sectorial agreements, including the *Veterinary Authority* in each country and representatives from international and other relevant regional organisations, should be established to ensure proper coordination. Where possible, Member Countries should cooperate on a regional basis to harmonise disease control programmes.

9. Social participation

Communication, awareness programmes and programme ownership need to be in place. Stakeholders should be involved in the development, planning, implementation, management and revision of the programme. This should be an on-going process.

10. Role of research in support of disease control programmes

During the strategic planning and assessment of programmes certain areas needing further research may be identified. Communication with national and international research institutions should be established to address programme needs.

11. Training and capacity building

Institutional capacity building is important in the development of systems and infrastructure. The personnel in charge of implementing the measures within the programme need to be adequately trained and updated on the current knowledge of the *disease*. Veterinary accreditation schemes of private *veterinarians* and *veterinary para-professionals* can be a useful tool to increase the veterinary presence in the field; however, training and supervision coordinated by the *Veterinary Authority* is required.

Article 4.X.6.

Outbreak investigation

An *outbreak* investigation is a systematic procedure to help identify the cause and source of *cases* with a view to control and prevent possible future occurrence. *Outbreak* investigation is an important responsibility of the *Veterinary Services* to ensure that preventive and control measures are applied. Investigations also help recognise intervention strategy failures and successes, identify changes in the agent, environment or events that may be beyond the scope of a disease control programme. It is important to maintain records of *outbreak* investigations including those which were not confirmed as this will help demonstrate the effectiveness of the *surveillance* system.

The main steps of outbreak investigation include:

1) preparation for field work;

2) establishment of the validity of the report triggering the investigation;

3) confirmation of diagnosis;

4) intensive follow-up and tracing;

5) collection and analysis of data including the characterisation of the event describing the *animals* involved and the spatial and temporal distribution;

6) implementation of control and preventive measures;

7) documentation and reporting.

A field investigation often entails doing several of these steps simultaneously. Two pathways are possible after the clinical investigation. If in the context of the disease control programme, clinical and epidemiological

information may be sufficient to take action and no further laboratory investigation may be required. On the other hand, if the information is inconclusive, further laboratory and epidemiological investigation are needed. Control measures are usually implemented from the beginning of the investigation and modified as appropriate during the process. Laboratory characterisation of the agent may be important to the long term management of the programme.

Article 4.X.7.

Emergency preparedness and contingency planning

1) Member Countries should develop emergency preparedness and contingency plans for immediate action for *listed* and *emerging diseases*. Emergency response plans should be up to date, tested in a simulation exercise and embedded in the legal framework. Emergency funds should be available to cover operational costs and indemnities. The chain of command and coordination with all key participants and relevant support services, when necessary, should be well established to ensure control efforts are executed rapidly and with success.

2) A contingency plan is a set of activities, including immediate actions and longer term measures, for responding to *disease outbreaks*. The process in developing a contingency plan is important to ensure successful implementation when an emergency occurs. It involves organising a team representing relevant authorities and stakeholders, identifying critical resources and functions, and establishing a plan for recovery. The plan should be simple and implementable. It should be documented, tested and updated regularly.

   The plan should be put together by the *veterinary authority*, involving representatives from local government, different relevant agencies and private sector representatives. Key components in a contingency plan include:

   a) established chain of command;

   b) systems for rapid detection and confirmation;

   c) *outbreak* investigation procedures;

   d) rapid containment measures (e.g. movement control, *disinfection*, *vaccination*, culling);

   e) communication strategy.

3) Notification of disease confirmation should be sent immediately to appropriate ministries, trading partners, stakeholders and should generally be made available to the general public. In addition, notification to the OIE should follow the provisions of Chapter 1.1.

4) Following the official confirmation of an *outbreak*, control areas may be established around the affected premises. The extent of these areas depends on a number of factors, in particular, the epidemiology of the *disease* in question. The measures imposed will often include movement restrictions, intensified *surveillance* as well as specific measures applied to affected premises. In addition, for ease of management and for trade purposes, a larger area surrounding the control areas may be designated corresponding to administrative boundaries, geographical or other appropriate features.

5) Disease control measures usually have a significant economic impact; therefore, appropriate compensation mechanisms are needed to ensure cooperation by farmers. Lack of compensation could result in non-compliance. Partnerships between government and the private sector have proven effective to develop sustainable contingency funds in several parts of the world.

6) It is important that this plan be coordinated on a regional level, particularly for transboundary animal diseases.

Where possible, Member Countries should act on a regional basis to ensure that funds and resources are available in an emergency and to protect the region from disease incursion and spread.

Detailed guidance and examples of contingency plans are available on the OIE web site: (http://www.oie.int/en/animal-health-in-the-world/the-world-animal-health-information-system/national-disease-contingency-plans).

EU comment

The above reference to the OIE web site should be removed, as referencing web sites is not usual practice in the Code.

Article 4.X.8.

Monitoring, evaluation and review

The programme should include a continued review process to assess the effectiveness of the interventions applied, identify gaps in knowledge and adapt the goals, objectives and methods or actions as required. This process should begin with the establishment of baseline data on the epidemiological, economic and social impact of the *disease*. The programme should collect data on process and impact indicators. This enables measurement of the effectiveness of interventions on epidemiological indicators such as incidence and prevalence, and identify areas needing strengthening.

EU comment

The EU suggests adding the following wording to the paragraph above to reflect the importance of defining the outcome in assessing effectiveness of the control measures:

"The programme should include a continued review process to assess the effectiveness of the interventions applied <u>against defined outcomes</u>, […]".

— Text deleted.