
Committee on Sanitary and Phytosanitary Measures

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**NEW OR REVISED STANDARDS BEING PROPOSED FOR ADOPTION
AT THE 73RD OIE GENERAL SESSION (MAY 2005)**

Communication from the World Organization for Animal Health (OIE)

The following communication, dated 3 March 2005, is being circulated at the request of the OIE.

Terrestrial Animal Health Code

1. The OIE Terrestrial Animal Health Standards Commission (hereafter referred to as the Terrestrial Code Commission) met at the OIE Headquarters in Paris from 17-28 January 2005.

2. The following chapters and appendices from the Terrestrial Animal Health Code were modified and are being submitted for adoption:

- Evaluation of Veterinary Services

3. The Terrestrial Code Commission will respond to the recommendation on the quality of Veterinary Services arising from the OIE/AU-IBAR seminar held in Cairo in October 2004, requesting that the OIE develop more detailed guidelines for the establishment and functioning of the 'Veterinary Statutory Body' and some guidelines for community animal health workers. The Terrestrial Code Commission also noted the Cairo seminar recommendations on strengthening Veterinary Services and urged Member countries to implement fully the guidelines in the Terrestrial Code.

- Zoning and compartmentalization

4. The Terrestrial Code Commission drafted a revised chapter with the aim of providing more guidance to Member countries on zoning and compartmentalization, especially the procedures involved in setting up zones and compartments, and having them recognised for international trade. The revised text in English is attached.

- General Guidelines for Animal Health Surveillance

5. This text will serve as an introduction to the appendices dealing with surveillance of specific diseases, such as FMD, avian influenza and classical swine fever (which are also being proposed for adoption).

- Criteria for listing diseases

6. A revised list of the OIE terrestrial diseases has been developed by an ad hoc Group on disease/pathogen notification by assessing each disease against the agreed criteria.

- Foot and mouth disease

7. Among other recommendations, the Terrestrial Code Commission has proposed that maturation and deboning should not be required for meat exported from countries or zones free from foot and mouth disease with vaccination.

- Bluetongue

- Bovine tuberculosis

- BSE

8. As a result of the outcome of the discussion on BSE at the 2004 General Session and the universal support in comments received from Member countries, the Terrestrial Code Commission decided to prepare for adoption a revised BSE chapter based on the three category approach, according to BSE risk. The categories are: negligible BSE risk without commodity-specific risk mitigation measures; negligible BSE risk with commodity-specific risk mitigation measures and undetermined BSE risk.

9. The Terrestrial Code Commission has recommended that blood and blood products be placed in the list of commodities which require no BSE-specific risk mitigation measures. The Commission was also of the view that there was no scientific basis for considering that boneless skeletal muscle meat (excluding mechanically derived meat) was likely to contain BSE infectivity, and recommended that boneless skeletal muscle meat also be placed in the list of commodities which require no BSE-specific risk mitigation measures.

10. The Terrestrial Code Commission discussed the criteria listed for the determination of the BSE risk status of a country, zone or compartment, and considered that surveillance burdens should be commensurate with the BSE risk determined through a structured, formal science-based risk assessment. Accordingly, the Commission proposed that the formal surveillance requirements specified in the proposed new BSE surveillance appendix should not apply to those Member countries where the BSE risk has been assessed as negligible. However, other criteria would still apply, in particular the compulsory notification and investigation of all cattle showing clinical signs consistent with BSE. Maintenance surveillance for BSE will need to be considered further by the experts.

- Classical swine fever

- Avian influenza

11. During the 2004 General Session, a revised Terrestrial Code chapter on highly pathogenic avian influenza was adopted by the OIE International Committee, but incorporating many articles *under study* (ie not applicable until finalized). An expert group met in November 2004 to review all proposals received, and its recommendations were considered by the Terrestrial Code Commission in January.

12. Four groups of commodities were identified - live poultry, genetic material (hatching eggs, semen and day old poultry), products for human consumption (eggs and meat) and others (feathers etc). The Terrestrial Code Commission developed recommendations for commodities in each of these

groups based on the assessed risk of virus transmission. For example, as the risk of virus transmission via live poultry and genetic material is the highest, recommendations for trade in these commodities are the most restrictive; recommendations for trade in products for human consumption are less restrictive. The experts had noted that highly pathogenic AI viruses could be found in meat and the interior of eggs, and considered that poultry infected with highly pathogenic AI viruses not be used as a source of human food.

13. In making its recommendations, the Commission weighed the evidence for the low likelihood of transmission of low pathogenicity virus against the possible negative effects onerous trade measures may have on Member countries' willingness to report low pathogenicity virus. Failure to report accurately would increase the likelihood of spread of the virus, nationally and internationally.

- Antimicrobial resistance

14. Revised recommendations on the prudent use of antimicrobials and risk assessment for antimicrobial resistance are being presented for adoption.

- Animal welfare

15. Draft animal welfare guidelines on land and sea transport, killing for disease control purposes and slaughter for human consumption are being proposed for adoption.

The following issues were also discussed:

- Animal identification and traceability

16. The aim of the work underway in the OIE is to provide the Working Group on Animal Production Food Safety with information on the current state of 'animal identification' in the different OIE regions. The data was collected from the responses to OIE questionnaires to Member countries. From this preliminary work, the lack of homogeneity of approach among OIE Member countries on this issue is evident.

17. Future guidelines will address both animal health and public health issues.

- Animal production food safety

18. The report of the April 2004 meeting of the Working Group on Animal Production Food Safety has been circulated for Member countries' comment. The next meeting of the Working Group is in March.

- The development of a chapter on the small hive beetle of honey bees.

19. The report of the Terrestrial Animal Health Standards Commission may be accessed at <http://www.oie.int>.

Aquatic Animal Health Code

20. The OIE Aquatic Animal Health Standards Commission met at the OIE Headquarters from 13 to 19 January 2005.

21. The following chapters and appendices from the Aquatic Animal Health Code were modified and are being submitted for adoption (subject to Member countries' comment):

- Disease listing and notification criteria
- Revision of the list of aquatic diseases

22. In revising the OIE list of aquatic diseases, the Aquatic Animals Commission stressed that the primary purpose of listing a disease was for the OIE to collate and disseminate information on the occurrence and control of that disease world-wide. The Commission noted that Member countries may still impose import restrictions addressing those diseases if this is justified on the basis of a science based import risk analysis and on their animal health situation.

- Notifications and epidemiological information

23. The Commission made a number of amendments to this chapter based on Member countries' comments.

- Harmonization of the structure of disease chapters for future editions of the Aquatic Code

24. The Commission received Member countries' comments on the draft chapters for three diseases, and prepared revised versions for consideration.

- General Recommendations on disinfection
- Continuing work on harmonization of horizontal chapters in the Aquatic and Terrestrial Codes

25. The work on harmonization will address initially the sections in Part 1 (General Provisions) of the Aquatic Code, including:

- Requirements for surveillance for declaration of freedom from disease;
- Compartmentalization;
- Listing criteria for emerging diseases.

26. The report of the Aquatic Animal Health Standards Commission may be accessed at <http://www.oie.int>.

Manual of Diagnostic Tests and Vaccines for Terrestrial Animals

27. The updating of the 5th (2004) edition of the Manual is underway, with a view to publishing in 2008. Prior to that date, individual chapters will be published on the OIE Web page as they are updated.

28. The following chapters have been identified for urgent revision with a view to submission for adoption in May 2005: the role of official bodies in the international regulation of veterinary biologicals; guidelines for international standards for vaccine banks (new chapter); foot and mouth disease; avian influenza; contagious equine metritis; and haemorrhagic septicaemia. Adopted chapters will be placed immediately on the OIE Web page.

Manual of Diagnostic Tests for Aquatic Animals

29. The preparation of the fifth edition of the Aquatic Manual is underway, with a view to publishing in 2006.

Appendix IV**CHAPTER 1.3.5.****ZONING, REGIONALISATION AND
COMPARTMENTALISATION**

Article 1.3.5.1.

Introduction

For the purposes of the *Terrestrial Code*, 'zoning' and 'regionalisation' have the same meaning.

Given the difficulty of establishing and maintaining a disease free status for an entire country, especially for diseases the entry of which is difficult to control through measures at national boundaries, there may be benefits to Member Countries in establishing and maintaining a subpopulation with a different animal health status within national boundaries. Subpopulations may be separated by natural or artificial geographical barriers, or in certain animal industries, by the application of appropriate management systems.

Zoning and compartmentalisation are procedures implemented by a country under the provisions of this Chapter with a view to defining *subpopulations* of different *animal health status* within its territory for the purpose of disease control and/or international trade. ~~and in accordance with the recommendations stipulated in the relevant Chapters in the *Terrestrial Code*.~~ Compartmentalisation applies to a *subpopulation* when management ~~criteria~~ systems related to biosecurity are applied, while zoning applies when a *subpopulation* is defined on a geographical basis.

This chapter is to assist OIE Member Countries to establish and maintain different subpopulations within their national boundaries using the procedures of compartmentalisation and zoning. It also outlines a process for trading partners to follow in achieving recognition of such subpopulation. These procedures are best implemented by trading partners through establishing parameters and gaining agreement on the necessary measures prior to disease outbreaks.

Separate requirements will be developed for each disease for which the application of zoning or compartmentalisation is considered appropriate.

Article 1.3.5.2.

General considerations

Before trade in animals or their products may occur, an importing country needs to be satisfied that its animal health status will be appropriately protected. In most cases, the import regulations developed will rely in part on judgements made about the effectiveness of sanitary procedures undertaken by the exporting country, both at its boundaries and within its territory.

The benefits of zoning and compartmentalisation may include a contribution to disease control or eradication within Member Countries, and to the safety of *international trade*. Zoning may encourage the more efficient use of resources within certain parts of a country to allow trade in certain *commodities* from that *zone* in accordance with the *Terrestrial Code*. Compartmentalisation may allow safe trade due to the functional separation of a *sub-population* from other domestic or wild animals through biosecurity measures, which a *zone* (through geographical separation alone) would not achieve. Following a *disease outbreak*, compartmentalisation may be able to take advantage of epidemiological linkages despite diverse geographical locations, to facilitate disease control.

Appendix IV (contd)

An exporting country which is establishing a zone or compartment within its territory for international trade purposes should clearly define the subpopulation in accordance with the measures stipulated in the relevant Chapters in the Terrestrial Code and should be able to explain to an importing country the basis for its claim of a distinct animal health status for the zone or compartment in such terms. Animals and herds belonging to a sub-population need to be clearly recognisable as such. The Veterinary Administration should document in detail the measures taken to ensure the identification of the animals and herds belonging to a sub-population, and the recognition and maintenance of its health status.

The requirements necessary to preserve procedures used to establish and maintain the distinct health status of a zone or compartment should be appropriate to the particular circumstances disease, and will depend on the epidemiology of the disease, environmental factors, applicable biosecurity measures, (including movement controls, use of natural and artificial boundaries, and measures, commercial management and husbandry practices), and surveillance and monitoring. The exporting country should be able to demonstrate, through detailed documentation published through official channels, that it has implemented the measures stipulated in the Terrestrial Code for establishing and maintaining such a zone or compartment.

The extent of a zone and its limits should be established by the Veterinary Administration on the basis of natural, artificial or legal boundaries, and made public through official channels. The requirements regarding a compartment should be established by the Veterinary Administration on the basis of relevant criteria such as management and husbandry practices, and made public through official channels.

Thus defined, the zones and compartments constitute the relevant sub-populations for the application of the recommendations in Part 2 of the Terrestrial Code.

Article 1.3.5.3.

When an exporting country has defined a zone or compartment within its territory in respect of one or more of the diseases covered by the Terrestrial Code, it needs to implement the measures stipulated in the Terrestrial Code for establishing and maintaining such a zone or compartment.

An importing country should recognise the existence of this zone or compartment and accept the application of the appropriate measures recommended in the Terrestrial Code corresponding to the animal health status of the zone or compartment with regard to the importation, or transit through its territory, of commodities from the zone or compartment.

Article 1.3.5.3.**Prerequisite considerations in defining a zone or compartment**

The exporting country should conduct a practical assessment of the resources needed and available to establish and maintain a zone or compartment for international trade purposes. These include the human and financial resources, and the technical capability of the Veterinary Services (and of the relevant industry, in the case of a compartment).

Appendix IV (contd)

Article 1.3.5.4.**Principles for defining a zone or compartment**

In conjunction with the above considerations, defining a *zone* or *compartment* should be based on the application of the following principles:

- 1) The extent of a *zone* and its limits should be established by the *Veterinary Administration* on the basis of natural, artificial or legal boundaries, and made public through official channels.
- 2) The requirements regarding a *compartment* should be established by the *Veterinary Administration* on the basis of relevant criteria such as biosecurity management and husbandry practices, and made public through official channels.
- 3) Animals and herds belonging to *subpopulations* need to be clearly recognizable as such. The *Veterinary Administration* must document in detail the measures taken to ensure the identification of the *subpopulation* and the recognition and maintenance of its health status.
- 4) The requirements necessary to preserve the distinct health status of a *zone* or *compartment* must be appropriate to the particular *disease* and will depend on the epidemiology of the *disease*, environmental factors, control measures and surveillance.
- 5) Thus defined, the *zones* and *compartments* constitute the relevant *subpopulations* for the application of the recommendations in Part 2 of the *Terrestrial Code*.

Article 1.3.5.5.**Sequence of steps to be taken in defining a zone/compartment**

There is no single sequence of steps which must be followed in defining a *zone* or a *compartment*. The steps that trading partners choose will generally depend on the circumstances existing within a country and at its borders. The recommended steps are:

1. For zoning:
 - a) the *exporting country* identifies a geographical area within its territory which it considers to contain an animal *subpopulation* with a distinct health status with respect to a specific disease/specific diseases, based on surveillance and monitoring;
 - b) the *exporting country* identifies the procedures which are being, or could be, employed to distinguish such an area epidemiologically from other parts of its territory, in accordance with the measures stipulated in the *Terrestrial Code*;
 - c) the *exporting country* provides the information above to the *importing country*, and explains that the area can be treated as an epidemiologically separated zone for *international trade purposes*;
 - d) the *importing country* determines whether it may accept such an area as a *zone* for the importation of animals and animal products, taking into account:
 - i) an evaluation of the *exporting country's Veterinary Services*;

Appendix IV (contd)

- ii) the result of a *risk assessment* based on the information provided by the *exporting country* and its own research;
 - iii) its own animal health situation with respect to the disease(s) concerned; and
 - iv) other relevant OIE standards;
 - e) the *importing country* notifies the *exporting country* of the result of its determination and the underlying reasons, within a reasonable period of time, being either:
 - i) recognition of the *zone*;
 - ii) request for further information; or
 - iii) rejection of the area as a *zone* for *international trade* purposes;
 - f) an attempt should be made to resolve any differences of opinion over the definition of the *zone*, either in the interim or finally, by using an agreed mechanism to reach consensus (such as the OIE dispute settlement mechanism);
 - g) the *importing country* and the *exporting country* may enter into a formal agreement defining the *zone*.
- 2) For compartmentalisation:
- a) based on discussions with the relevant enterprise/industry, the *exporting country* identifies within its territory one or more *establishments* or other premises owned by an enterprise(s) which operates under a common biosecurity management system, and which it considers contains an animal *subpopulation* with a distinct health status with respect to a specific disease/specific diseases;
 - b) the *exporting country* jointly examines the 'biosecurity management manual' produced by the enterprise/industry for such *establishment(s)*, and confirms through an audit that:
 - i) such *establishment(s)* is(are) epidemiologically closed throughout its routine operating procedures as a result of effective implementation of its 'biosecurity management manual' and;
 - ii) the surveillance and monitoring programme in place is appropriate to verify the free status of such *establishment(s)* with respect to such disease(s);
 - c) the *exporting country* identifies such an enterprise to be a free *compartment*, in accordance with the measures stipulated in the *Terrestrial Code*;
 - d) the *exporting country* provides the information above to the *importing country*, and explains that such an enterprise can be treated as an epidemiologically separated *compartment* for *international trade* purposes;
 - e) the *importing country* determines whether it may accept such an enterprise as a *compartment* taking into account:
 - i) an evaluation of the *exporting country's Veterinary Services*;

Appendix IV (contd)

- ii) the result of a *risk assessment* based on the information provided by the *exporting country* and its own research;
- iii) its own animal health situation with respect to the disease(s) concerned; and
- iv) other relevant OIE standards;
- f) the *importing country* notifies the *exporting country* of the result of its examination and the underlying reasons, within a reasonable period of time, being either:
 - i) recognition of the *compartment*;
 - ii) request for further information; or
 - iii) rejection of such an enterprise as a *compartment* for *international trade* purposes;
- g) an attempt should be made to resolve any differences of opinion over the definition of the *compartment*, either in the interim or finally, by using an agreed mechanism to reach consensus (such as the OIE dispute settlement mechanism);
- h) the *importing country* and the *exporting country* may enter into a formal agreement defining the *compartment*.

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