

September 2009

CHAPTER 4.X.

APPLICATION OF COMPARTMENTALISATION

Article 4.X.1.

Introduction and objectives

The recommendations in this Chapter provide a structured framework for the application and recognition of *compartments* within countries or *zones*, based on the provisions of Chapter 4.1. with the objective to facilitate trade in *aquatic animals* and products of *aquatic animal* origin and as a tool for *disease* management.

Establishing and maintaining a disease free-status throughout the country should be the final goal for OIE Members. However, establishing and maintaining a *disease-free* status for an entire country may be difficult, especially in the case of *diseases* that can easily cross international boundaries. For many *diseases*, OIE Members have traditionally applied the concept of zoning to establish and maintain an animal *subpopulation* with a different animal health status within national boundaries.

The essential difference between zoning and compartmentalisation is that the recognition of *zones* is based on geographical boundaries whereas the recognition of *compartments* is based on management practices and biosecurity. However, spatial considerations and good management practices play a role in the application of both concepts.

The fundamental requirement for compartmentalisation is the implementation and documentation of management and biosecurity measures to create a functional separation of *subpopulations*.

For example, an *aquaculture establishment* in an infected country or *zone* might have biosecurity measures and management practices that result in negligible *risk* from *diseases* or agents. The concept of a *compartment* extends the application of a 'risk boundary' beyond that of a geographical interface and considers all epidemiological factors that can help to create an effective *disease-specific* separation between *subpopulations*.

In *disease-free* countries or *zones*, *compartments* preferably should be defined prior to the occurrence of a *disease outbreak*. In the event of an *outbreak* or in infected countries or *zones*, compartmentalisation may be used to facilitate trade.

For the purpose of *international trade*, *compartments* must be under the responsibility of the *Veterinary Authority* or other *Competent Authority* in the country. For the purposes of this Chapter, compliance by the Members with Chapters 1.1. and 3.1. is an essential prerequisite.

Article 4.X.2.

Principles for defining a compartment

A *compartment* may be established with respect of a specific *disease* or *diseases*. A *compartment* must be clearly defined, indicating the location of all its components including establishments, as well as related functional

units (such as brood stock facilities, hatcheries, nurseries, grow-out facilities, slaughterhouses, processing plants etc.), their interrelationships and their contribution to an epidemiological separation between the *aquatic animals* in a *compartment* and *subpopulations* with a different health status. The definition of *compartment* may revolve around *disease* specific epidemiological factors, production systems, biosecurity practices infrastructural factors and *surveillance*.

Article 4.X.3.

Separation of a compartment from potential sources of infection

The management of a *compartment* must provide to the *Competent Authority* documented evidence on the following:

1. Physical or spatial factors that affect the status of biosecurity in a compartment

While a *compartment* is primarily based on management and biosecurity measures, a review of geographical factors is needed to ensure that the functional boundary provides adequate separation of a *compartment* from adjacent animal populations with a different health status. The following factors should be taken into consideration in conjunction with biosecurity measures and, in some instances, may alter the degree of confidence achieved by general biosecurity and *surveillance* measures:

- a) disease status in adjacent areas and in areas epidemiologically linked to the *compartment*;
- b) location, disease status and biosecurity of the nearest *epidemiological units* or other epidemiologically relevant premises. Consideration should be given to the distance and physical separation from:
 - i) *aquatic animal* populations with a different health status in close proximity to the *compartment*, including wildlife and their migratory routes;
 - ii) slaughterhouses or processing plants;
 - iii) exhibitions, 'put and take' fisheries, fish markets, restaurants with live fish and other points of *aquatic animal* concentration.

2. Infrastructural factors

Structural aspects of the *establishments* within a *compartment* contribute to the effectiveness of its biosecurity. Consideration should be given to:

- a) water supply;
- b) effective means of physical separation;
- c) facilities for people entry including access control;
- d) vehicle and vessel access including washing and disinfection procedures;
- e) unloading and loading facilities;
- f) isolation facilities for introduced *aquatic animals*;
- g) facilities for the introduction of material and equipment;

- h) infrastructure to store feed and veterinary products;
- i) disposal of carcasses;
- j) measures to prevent exposure to living mechanical or biological vectors;
- k) feed supply/source.

3. Biosecurity plan

The integrity of the *compartment* relies on effective biosecurity. The management of the *compartment* should develop, implement and monitor a comprehensive *biosecurity plan*.

The *biosecurity plan* should describe in detail:

- a) potential pathways for introduction and spread into the *compartment* of the agents for which the *compartment* was defined, including *aquatic animal* movements, wild aquatic animals, potential vectors, *vehicles*, people, biological products, equipment, fomites, feed, waterways, drainage or other means. Consideration should also be given to the survivability of the agent in the environment;
- b) the critical control points for each pathway;
- c) measures to mitigate exposure for each critical control point;
- d) standard operating procedures including:
 - i) implementation, maintenance, monitoring of the measures,
 - ii) application of corrective actions,
 - iii) verification of the process,
 - iv) record keeping;
- e) contingency plan in the event of a change in the level of exposure;
- f) reporting procedures to the *Veterinary Authority* or other *Competent Authority*;
- g) the programme for educating and training workers to ensure that all persons involved are knowledgeable and informed on biosecurity principles and practices;
- h) the *surveillance* programme in place.

In any case, sufficient evidence should be submitted to assess the efficacy of the *biosecurity plan* in accordance with the level of *risk* for each identified pathway. This evidence should be structured in line with the principles of Hazard Analysis and Critical Control Point (HACCP). The biosecurity risk of all operations of the *compartment* should be regularly re-assessed and documented at least on a yearly basis. Based on the outcome of the assessment, concrete and documented mitigation steps should be taken to reduce the likelihood of introduction of the disease agent into the *compartment*.

4. Traceability system

A prerequisite for assessing the integrity of a *compartment* is the existence of a valid *traceability* system. Although individual identification of *aquatic animals* may not be feasible, the *Veterinary Authority* or other *Competent Authority* should provide sufficient assurance of *traceability* in such a way that their history and movements can be documented and audited.

All *aquatic animal* movements into and out of the *compartment* should be recorded at the *compartment* level, and when needed, based on a *risk assessment*, certified by the *Veterinary Authority* or other *Competent Authority*. Movements within the *compartment* need not be certified but should be recorded at the *compartment* level.

Article 4.X.4.

Documentation

Documentation must provide clear evidence that the biosecurity, *surveillance*, *traceability* and management practices defined for a *compartment* are effectively and consistently applied. In addition to animal movement information, the necessary documentation should include production unit records (e.g. cage, pond), feed sources, laboratory tests, death records, the visitor logbook, morbidity history, medication and vaccination records, *biosecurity plans*, training documentation and any other criteria necessary for the evaluation of *disease* exclusion.

The historical status of a *compartment* for the *disease(s)* for which it was defined should be documented and demonstrate compliance with the requirements for freedom in the relevant *Aquatic Code* Chapter.

In addition, a *compartment* seeking recognition should submit to the *Veterinary Authority* or other *Competent Authority* a baseline *aquatic animal* health report indicating the presence or absence of OIE *listed diseases*. This report should be regularly updated to reflect the current *aquatic animal health status* of the *compartment*.

Vaccination records including the type of vaccine and frequency of administration must be available to enable interpretation of *surveillance* data.

The time period for which all records should be kept may vary according to the species and *disease(s)* for which the *compartment* was defined.

All relevant information must be recorded in a transparent manner and be easily accessible so as to be auditable by the *Veterinary Authority* or other *Competent Authority*.

Article 4.X.5.

Surveillance for the disease agent or disease

The *surveillance* system should comply with Chapter 1.4. on Surveillance and the specific recommendations for *surveillance* for the *disease(s)* for which the *compartment* was defined, if available.

If there is an increased *risk* of exposure to the agent for which the *compartment* has been defined, the detection level of the internal and external *surveillance* should be reviewed and, where necessary, raised. At the same time, biosecurity measures in place should be reassessed and increased if necessary.

1. Internal surveillance

Surveillance should involve the collection and analysis of *disease/infection* data so that the *Veterinary Authority* can certify that the animal *subpopulation* contained in all the *establishments* comply with the defined status of that *compartment*. A *surveillance* system that is able to ensure early detection in the event that the agent enters a *subpopulation* is essential. Depending on the *disease(s)* for which the *compartment* was defined, different *surveillance* strategies may be applied to achieve the desired confidence in *disease* freedom.

2. External surveillance

The biosecurity measures applied in a *compartment* must be appropriate to the level of exposure of the *compartment*. External *surveillance* will help identify a significant change in the level of exposure for the identified pathways for *disease* introduction into the *compartment*.

An appropriate combination of active and passive *surveillance* is necessary to achieve the goals described above. Based on the recommendations of Chapter 1.4., targeted *surveillance* based on an assessment of *risk* factors may be the most efficient *surveillance* approach. Targeted *surveillance* should in particular include *epidemiological units* in close proximity to the *compartment* or those that have a potential epidemiological link with it.

Article 4.X.6.

Diagnostic capabilities and procedures

Officially-designated laboratory facilities should be available for sample testing. All laboratory tests and procedures should comply with the recommendations of the *laboratory* for the specific *disease*. Each laboratory that conducts testing should have systematic procedures in place for rapid reporting of *disease* results to the *Veterinary Authority* or other *Competent Authority*. Where appropriate, results should be confirmed by an OIE Reference Laboratory.

Article 4.X.7.

Emergency response and notification

Early detection, diagnosis and notification of *disease* are critical to minimise the consequences of *outbreaks*.

In the event of suspicion of occurrence of the *disease* for which the *compartment* was defined, the free status of the *compartment* should be immediately suspended. If confirmed, the status of the *compartment* should be immediately revoked and *importing countries* should be notified following the provisions of Chapter 1.1.

In case of an occurrence of any infectious *disease* not present according to the baseline animal health report of the *compartment* referred to in Article 4.2.4., the management of the *compartment* should notify the *Veterinary Authority* or other *Competent Authority*, and initiate a review to determine whether there has been a breach in the biosecurity measures. If a significant breach in biosecurity, even in the absence of *outbreak*, is detected, export certification as a free *compartment* should be suspended. Disease free status of the *compartment* may only be reinstated after the *compartment* has adopted the necessary measures to re-establish the original biosecurity level and the *Veterinary Authority* or other *Competent Authority* re-approves the status of the *compartment*.

In the event of a *compartment* being at risk from a change, in the surrounding area, in the disease situation for which the *compartment* was defined, the *Veterinary Authority* should re-evaluate without delay the status of the *compartment* and any additional biosecurity measures needed to ensure that the integrity of the *compartment* is maintained.

Article 4.X.8.

Supervision and control of a compartment

The authority, organisation, and infrastructure of the *Veterinary Services*, including laboratories, must be clearly documented in accordance with the Chapter on the Evaluation of *Veterinary Services* of the *Aquatic Code*, to provide confidence in the integrity of the *compartment*.

The *Veterinary Authority* or other *Competent Authority* has the final authority in granting, suspending and revoking the status of a *compartment*. The *Veterinary Authority* or other *Competent Authority* should continuously supervise compliance with all the requirements critical to the maintenance of the *compartment* status described in this Chapter and ensure that all the information is readily accessible to the *importing countries*. Any significant change should be notified to the *importing country*.