

CHAPTER 4.2.

APPLICATION OF COMPARTMENTALISATION

Article 4.2.1.

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 ultimate goal for Member Countries. However, establishing and maintaining a *disease-free* status for an entire country may be difficult, especially in the case of *diseases* that exist in wild *aquatic animal* species or can easily cross international boundaries. For many *diseases*, Member Countries 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 and *biosecurity* practices. 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 *infected 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 *free zones*, it is preferable that *compartments* are defined prior to the occurrence of a *disease outbreak*. In the event of an *outbreak* or in infected countries or *infected zones*, compartmentalisation may be used to facilitate trade.

For the purpose of *international trade*, *compartments* should be under the responsibility of the *Competent Authority* in the country. For the purposes of this chapter, compliance by the Member Countries with Chapters 1.1. and 3.1. is an essential prerequisite.

Article 4.2.2.

Principles for defining a compartment

A *compartment* may be established with respect to a specific *disease* or *diseases*. A *compartment* should be clearly defined. This should indicate, *inter alia*, 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.). It should also describe their interrelationships and their contribution to an epidemiological separation between the *aquatic animals* in a *compartment* and *subpopulations* elsewhere with a different health status. The definition of *compartment* should encompass *disease-specific* epidemiological factors, the *aquatic animal* species in the *compartment*, production systems, *biosecurity* practices, infrastructural factors and *surveillance*.

Article 4.2.3.

Separation of a compartment from potential sources of infection

The management of a *compartment* should provide to the *Aquatic Animal Health Service* 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 an *establishment* or *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 *aquatic animal* waste;
- j) measures to prevent exposure to fomites, 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 compliance with the *risk* mitigation 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 *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 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 *pathogenic 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 *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*, approved by the *Competent Authority*. Movements within the *compartment* need not be certified but should be recorded and documented at the *compartment* level.

Article 4.2.4.

Documentation

Documentation should 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, mortality records, visitor logbook, morbidity history, water supply and effluent treatments, 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 chapter of the *Aquatic Code*.

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

Vaccination records including the *aquatic animal* groups vaccinated, type of vaccine and frequency of administration should be available to enable interpretation of *surveillance* data.

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

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

Article 4.2.5.

Surveillance for the pathogenic 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 sensitivity of the internal and external *surveillance* system should be reviewed, documented and, where necessary, increased. 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 *Competent 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* should 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 targeted 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 4.2.6.

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 *Aquatic Manual* for the specific *disease*. Each laboratory that conducts testing should have systematic procedures in place for rapid reporting of *disease* results to the *Competent Authority*. Where appropriate, results should be confirmed by an OIE Reference Laboratory.

Article 4.2.7.

Emergency response and notification

Early detection, *diagnosis*, *notification* of *disease* and rapid response 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 the detection of any *disease* not present in accordance with the baseline animal health report of the *compartment* referred to in Article 4.2.4., the management of the *compartment* should notify the *Competent Authority*, and initiate a review to determine whether there has been a breach in the *biosecurity* measures and notify the *Competent Authority*. 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 *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 *Competent Authority* should re-evaluate without delay the status of the *compartment* and consider whether any additional *biosecurity* measures are needed to ensure that the integrity of the *compartment* is maintained.

Article 4.2.8.

Supervision and control of a compartment

The authority, organisation, and infrastructure of the *Aquatic Animal Health Services*, including laboratories, should be clearly documented in accordance with Chapter 3.1., to provide confidence in the integrity of the *compartment*.

The *Competent Authority* has the final authority in granting, suspending and revoking the status of a *compartment*. The *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*.