

SECTION 4.
DISEASE PREVENTION AND CONTROL
CHAPTER 4.3.
APPLICATION OF COMPARTMENTALISATION

Article 4.3.1.

Objective and introduction

This chapter provides recommendations for establishing and maintaining *compartments* that are free from specified *diseases* for the purpose of facilitating trade or for *disease* prevention and control.

Compartmentalisation provides a means of demonstrating that an *aquaculture establishment* is free from one or more specified *diseases* by establishing and maintaining functional epidemiological separation between the *aquatic animals* within the *compartment* and sources of *infection* outside the *compartment*. A *compartment* may comprise a single *aquaculture establishment* or a group of interrelated *aquaculture establishments* that operate under a common set of *risk management* measures in accordance with this chapter.

Compartmentalisation provides an opportunity for the private sector to demonstrate *disease* freedom at the enterprise level, including in circumstances where alternatives such as *country* or *zone* freedom may not be feasible or cost-effective. Investment by the private sector and oversight by the relevant *Competent Authorities* is essential.

Japan	<p>Category: deletion</p> <p>Proposed amended text: <i>Investment by the private sector and</i> oversight by the relevant <i>Competent Authorities</i> is essential.</p> <p>Rationale: To begin with, “investment” is not appropriate for the content of the WOAH Code. The Code should deal with the manner and methods of testing, harvesting and producing. In addition to it, the present draft is misleading, negatively implying that the high-cost investment is always necessary regardless of the effectiveness in disease prevention and control. The intent of the phrase “investment by the private sector” is unclear, and it seems unnecessary to mention in the introduction.</p> <p>Supporting evidence: not relevant</p>
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A *self-declaration of freedom from disease* for a *compartment* from specified *listed diseases* can be made if the requirements of this chapter to establish a *compartment* are met and the requirements for making a *self-declaration of freedom from disease* described in Chapter 1.4. and in the relevant disease-specific chapters have been met.

Article 4.3.2.

Purposes of compartments

Compartments provide an opportunity for trade of disease-free *commodities* from a *zone* or *country* not declared free. They can also be used to provide epidemiological separation for populations of valuable *aquatic animals* within a *free country* or *free zone* to protect them in the event of a *disease outbreak*.

There may be a range of *commodities* produced by a *compartment* and possible end-uses. The *commodity* types (e.g. *aquatic animals*, *aquatic animal products*) and end-uses (e.g. for *aquaculture*, stocking of natural water bodies, human consumption, *ornamental aquatic animals*) have implications for *risk management* and should be defined.

Article 4.3.3.

Principles for establishing a compartment

The following principles should be applied to establish and maintain a *free compartment*.

- 1) A *compartment* must ensure there are effective measures to prevent the entry or spread of *pathogenic agents* between the *compartment* and external environments (i.e. provide functional epidemiological separation);
- 2) the purpose of a *compartment* should be clearly defined (e.g. *disease(s)* for which freedom will be claimed, species and *commodities* produced, intended end-uses of *commodities*) as this will have implications for the design of *risk management* measures, as described in Article 4.3.2.;
- 3) *biosecurity* and *surveillance* measures should be appropriate for the category of *compartment*, i.e. those with disease-free status that is dependent on the *disease* status of the surrounding environment or those with disease-free status that is independent from the *disease* status of the surrounding environment, in Article 4.3.4.;
- 4) a *biosecurity plan* must be developed and maintained in accordance with Chapter 4.1. and applied consistently across all elements of the *compartment* as described in Article 4.3.5.;
- 5) *surveillance* measures to demonstrate that the *compartment* is free from specified *diseases*, and to maintain its free status, must be clearly described in accordance with Chapter 1.4., including elements of internal and external *surveillance* as appropriate, as described in Article 4.3.6.;
- 6) *surveillance* testing must be supported by reliable laboratory testing services which have independence from the *compartment* operator and which are approved by *Competent Authority*, as described in Article 4.3.7.;
- 7) traceability systems must provide assurance of provenance of *commodities* from the *free compartment*, as described in Article 4.3.8.;
- 8) record keeping must provide evidence of the ongoing application of all measures on which the *compartment* has been granted disease-free status, as described in Article 4.3.9.;
- 9) official oversight responsibilities must be clearly documented, including approval by the *Competent Authority*, an auditing schedule, underpinning regulatory instruments and authorising third parties within the *Aquatic Animal Health Services* for important roles, as described in Articles 4.3.10. and 4.3.11.;

10) notification and response measures must be in place in the event of detection of the *disease* for which the *compartment* has been declared free, or for other *diseases* relevant to trade from the *compartment*, as described in Article 4.3.12.;

Article 4.3.4.

Dependent and independent compartments

There are two categories of *compartments* that are determined by the degree of epidemiological separation from the surrounding environment. Independent *compartments* have complete epidemiological separation from the surrounding environment and are characterised by appropriate levels of physical and management measures to maintain effective *biosecurity*. Dependent *compartments* do not have complete epidemiological separation from the surrounding environment and require the application of appropriate *risk* mitigation measures to achieve and maintain disease-free status despite epidemiological links to the surrounding environment. If such *risk* mitigation measures cannot be applied successfully, a dependent *compartment* cannot be approved by the *Competent Authority*.

The concept of dependent *compartments* enables compartmentalisation to be applied to more types of production systems and more establishments, increasing opportunities to trade in disease-free *commodities* where these *compartment* types provide an appropriate level of *risk management*.

Independent and dependent *compartments* have the following characteristics:

1) Independent *compartments*:

- a) are closed production system types only (as described in Chapter 4.1);
- b) have control over all transmission pathways and complete epidemiological separation from surrounding environments;
- c) have appropriate levels of physical and management measures to maintain effective *biosecurity* for all pathways;
- d) provide levels of *risk* mitigation suitable for all purposes, *commodity* types and end-uses;
- e) are often preferred for high value *aquatic animals* (e.g. genetically improved lines, brood stock).

2) Dependent compartments:

- a) are semi-closed production system types only (as described in Chapter 4.1.);
- b) are dependent on the health status of the surrounding waters;
- c) have appropriate levels of physical and management measures to maintain effective *biosecurity* for all pathways;
- d) meet the additional *biosecurity* criteria and *risk* mitigation measures for transmission via intake water which the *Competent Authority* may approve in accordance with Article 4.3.5.;
- e) may not provide sufficient *risk* mitigation for all purposes, *commodity* types and end-uses (e.g. supplying live *aquatic animals* for *aquaculture* or restocking, for high value *aquatic animals* such as genetically improved lines).

Japan	Category: deletion
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	<p>Proposed amended text: may not provide sufficient <i>risk</i> mitigation for all purposes, <i>commodity</i> types and end-uses (e.g. supplying live aquatic animals for aquaculture or restocking, for high value aquatic animals such as genetically improved lines).</p> <p>Rationale: Japan opposes indicating “live aquatic animals for aquaculture” as possible inappropriate example in 2) e). The current text is misleading that the dependent compartment cannot be applied for supplying “live aquatic animals for aquaculture”. However, Japan thinks it may be applicable to such case if appropriate risk mitigation measures are implemented in accordance with Article 4.3.5.</p> <p>If examples are absolutely necessary in 2) e), Japan requests the Commission to make clear for each example in what respects sufficient risk mitigation may not be achieved, so that bilateral discussions on the application of dependant compartment for such inappropriate examples will be facilitated.</p> <p>Supporting evidence: not relevant</p>
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The suitability of a dependent *compartment* to achieve the required level of *risk* mitigation should be determined following consideration of the purpose of the *compartment* (refer to Article 4.3.2.), the *commodities* produced (e.g. *aquatic animal products* or *aquatics animals*), and their end-uses (e.g. products for human consumption versus *aquatic animals* for stocking in semi-open systems).

Japan	<p>Category: change</p> <p>Proposed amended text: ..., and their end-uses (e.g. products for human consumption versus <i>aquatic animals</i> for <u>aquaculture stocking</u> in semi-open systems).</p> <p>Rationale: Japan requests the Commission to clarify the difference between “<i>aquatic animals</i> for stocking in semi-open systems” and “<i>aquatic animals</i> for aquaculture in semi-open systems”, since the assumed situation is equal.</p> <p>Supporting evidence: not relevant</p>
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Based on a *risk analysis*, approved by the *Competent Authority*, dependent *compartments* may require specific measures to mitigate the *risk of disease* transmission from the environment to the *compartment*. The *risk* mitigation measures should be developed in accordance with Article 4.1.8. and may include the application of specific *biosecurity* measures, post-production testing, auditing within the production cycle, a higher level of internal *targeted surveillance*, external *surveillance* to monitor for change in *disease risk*, and external *disease* control measures to mitigate the *risk of disease* transmission into the environment adjacent to the *compartment*.

Japan	<p>Category: deletion</p> <p>Proposed amended text: Based on a risk analysis approved by the Competent Authority, dependent compartments may require specific measures to mitigate the risk of disease transmission from the environment to the compartment. The risk mitigation measures should be developed in accordance with Article 4.1.8. and may include the application of specific biosecurity measures, post-production testing, auditing within the production cycle, a higher level of internal targeted surveillance, external surveillance to monitor for change in disease risk, and external disease control measures to mitigate the risk of disease transmission into the environment adjacent to the compartment.</p> <p>Rationale: This paragraph should be in the next article 4.3.5. based on the content.</p>
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	Supporting evidence: not relevant
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Table 1. A summary of the characteristics of independent and dependent compartments

Independent	Dependent
Only closed systems are a suitable production system type	Only semi-closed systems are a suitable production system type
<i>Biosecurity</i> across all pathways in accordance with Chapter 4.1.	<i>Biosecurity</i> across most pathways in accordance with Chapter 4.1.
Disease-free status not dependent on the status of the surrounding waters	Disease-free status dependent on the status of the surrounding waters
External <i>surveillance</i> generally not required to maintain freedom (but may be useful to inform biosecurity measures)	Ongoing external <i>surveillance</i> may be required to maintain freedom in accordance with Chapter 1.4.
Suitable for all <i>commodities</i> and pathways	May not meet the required level of <i>risk</i> mitigation for all <i>commodities</i> and pathways

Article 4.3.5.

Biosecurity and other risk mitigation measures

The integrity of a *compartment* relies on *biosecurity* to mitigate the *risk* of introduction of specific *pathogenic agents* into the *compartment* and to maintain its disease-free status. A *biosecurity plan* for the *compartment* should be developed and maintained in accordance with Chapter 4.1.

For *compartments* comprising more than one *aquaculture establishment*, the *biosecurity plan* should provide a common set of management and physical measures to provide a consistent level of *risk* mitigation across all elements of the *compartment*.

For dependent *compartments*, the *risk analysis* described in Article 4.1.8. should include the assessment of risks within the environment surrounding the *compartment* and the development of appropriate *risk management* and *surveillance* measures to mitigate the identified *risks*. The *Competent Authority* should consider in the *risk analysis*:

- 1) characteristics of the *pathogenic agent*;
- 2) absence of *susceptible species* and pathways of *infection* in the surrounding environment due to geographical location, environmental conditions or the application of *biosecurity* measures. Specific consideration should be given to:
 - a) the hydrological conditions in the water body;
 - b) the geographical location of each *aquaculture establishment* comprising the dependent *compartment* and the nature of the water supply;
 - c) the health status of other *aquaculture establishments* within the shared water body system;
 - d) the location of the *aquaculture establishments* referred to in point (c) or processing facilities and their proximity to the dependent *compartment*;
 - e) the method of production and the source of the *aquatic animals* used in the *aquaculture establishments* referred to in point (c);

- f) the presence and abundance of wild *susceptible species* in the water body and their health status;
- g) the details of whether the *susceptible species* referred to in point (f) are sedentary or migratory;
- h) the exclusion of the wild *aquatic animals* referred to in point (f) from entering the *compartment*;
- i) the general *biosecurity* measures applied in *aquaculture establishments* and processing facilities in the shared water body;

3) absence of *infection* in any nearby populations of *susceptible species* demonstrated by appropriate *external surveillance*;

4) additional internal *surveillance* (i.e. in the *aquaculture establishment(s)* that comprise the *compartment*).

Japan	<p>Category: addition</p> <p>Proposed amended text: <u>Based on a risk analysis, approved by the Competent Authority, dependent compartments may require specific measures to mitigate the risk of disease transmission from the environment to the compartment. The risk mitigation measures should be developed in accordance with Article 4.1.8. and may include the application of specific biosecurity measures, post-production testing, auditing within the production cycle, a higher level of internal targeted surveillance, external surveillance to monitor for change in disease risk, and external disease control measures to mitigate the risk of disease transmission into the environment adjacent to the compartment.</u></p> <p>Rationale: This paragraph should be in the article 4.3.5., not in the article 4.3.4, based on the content.</p> <p>Supporting evidence: not relevant</p>
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For some semi-closed aquaculture establishments, it may not be possible to mitigate identified *risks* from the surrounding environment (e.g. presence of *disease* in adjacent wild populations of *susceptible species*) and the *aquaculture establishment* would not be eligible to be recognised as a dependent *compartment*.

Article 4.3.6.

Surveillance requirements to demonstrate and maintain freedom

For recognition of a *free compartment*, a *self-declaration of freedom from disease* should be made which complies with the requirements of Article 1.4.4. The *surveillance* requirements to make a *self-declaration of freedom from disease* for a *compartment*, and to maintain a *free compartment*, should comply with Chapter 1.4.

Basic biosecurity conditions for a *compartment* must be in place and continuously met prior to the commencement of *targeted surveillance* to demonstrate freedom. The relevant disease-specific chapters provide the required periods that *basic biosecurity conditions* must be in place prior to commencement of *targeted surveillance*, and the period that *targeted surveillance* should be conducted prior to making a *self-declaration of freedom from disease*.

Surveillance requirements should be developed in accordance with factors as described in Article 4.3.5.

If there is an increased *risk* of exposure to the *disease* from 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, the *biosecurity plan* should be reviewed in accordance with Article 4.1.9 and revised if necessary.

1. Internal surveillance

Internal surveillance (i.e. for populations of *susceptible species* within a *compartment*) is required to make a *self-declaration of freedom from disease* for both independent and dependent *compartments*. The surveillance requirements to maintain freedom are described in the relevant disease specific chapters and Article 1.4.15.

2. External surveillance

External surveillance (i.e. for populations of *susceptible species* in the environment outside a *compartment*) can be used to identify a significant change in the level of exposure for the identified pathways for *disease* introduction into the *compartment*. External surveillance is required for dependent *compartments* if populations of *susceptible species* are present in the environment surrounding the *compartment*.

Article 4.3.7.

Laboratory testing

Laboratories providing testing services for a *compartment* should be approved by the relevant *Competent Authority*. In providing approval, the *Competent Authority* should ensure that the laboratory:

- 1) has a quality management system that meets requirements of Chapter 1.1.1. of the *Aquatic Manual*, or can demonstrate quality through another means in accordance with Chapter 3.1.;
- 2) is required to conduct testing in accordance with the recommendations of the *Aquatic Manual*;
- 3) can confirm or exclude cases of *disease* as described in Article 1.4.18.;
- 4) is independent from management and ownership structures of the *compartment*;
- 5) has a legal obligation to report positive test results to the *Competent Authority* in accordance with the requirements of *basic biosecurity conditions* specified in Article 1.4.6.

Article 4.3.8.

Traceability

Traceability systems should apply throughout the supply chain and are required to reliably differentiate *commodities* that originate from a *free compartment* from those that originate from outside a *free compartment*. The traceability system should:

- 1) be appropriate for the *aquatic animal* species and for application to individual or groups of *aquatic animals* or *aquatic animal products*, as necessary;

Japan	<p>Category: addition</p> <p>Proposed amended text: be appropriate for the nature of supply chains of the <i>aquatic animal</i> species and for application to individual or groups of <i>aquatic animals</i> or <i>aquatic animal products</i>, as necessary;</p> <p>Rationale: When applied aiming for disease control, the traceability “appropriate” in terms of “species” is unclear. Japan requests the Commission to clarify the meaning by adding some phrase as proposed, or if not possible, delete “for the <i>aquatic animal species</i>”.</p> <p>Rationale: Supporting evidence: not relevant</p>
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- 2) ensure that all movements of disease-free *aquatic animals* into a *free compartment* originate from a *free country, free zone or free compartment*, and in the case of international movements are certified in accordance with Chapter 5.1.;
- 3) be reflected in the *biosecurity plan* that is developed in accordance with Article 4.3.5. and which provides appropriate *risk management*;
- 4) comprise record keeping requirements in accordance with Article 4.3.9.;
- 5) be approved by the *Competent Authority* in accordance with Article 4.3.10.

Article 4.3.9.

Record keeping

A system of record keeping by the operator of a *compartment* should provide clear evidence that the *biosecurity, surveillance, traceability* and management practices that form the basis of a *self-declaration of freedom from disease* are effectively and continuously applied.

Records should be maintained consistently by the operator of the *free compartment* and be accessible on request for the purposes of an audit or in response to queries from the *Competent Authority* of an *importing country*. The record keeping system should:

- 1) substantiate that the *compartment's biosecurity plan* is maintained in accordance with Chapter 4.1., including the maintenance of records associated with all relevant pathways described in Article 4.1.7.;
- 2) substantiate that the *surveillance* required to declare and maintain *free compartment* status has been conducted in accordance with Chapter 1.4. and the provisions of relevant disease-specific chapters;
- 3) document any changes to *biosecurity, surveillance, traceability* or management practices, the rationale for the changes and substantiation that they continue to meet *risk management* requirements;
- 4) in addition to the points above, maintain any external reports, certificates or approvals associated with the requirements of this chapter, including but not limited to audit reports, laboratory reports, health certificates, and health investigations;
- 5) maintain records for sufficient period of time to inform tracing, recall or emergency response at any point in the supply chain if a *disease* were detected within the *compartment* or in *commodities* originating from the *compartment*. The required period should be meet requirements for *surveillance, the biosecurity plan, auditing, and traceability*. It may vary depending on the *disease, aquatic animal species and commodity types* produced and the duration of production cycles.

Article 4.3.10.

Official oversight

A *Competent Authority* must have the authority to approve the operation of the *aquaculture establishment(s)* that compromise the *compartment*. A *Competent Authority* must also have the authority to make a *self-declaration of freedom from disease* as described in Chapter 1.4., as well as grant, suspend and revoke the status of a *compartment*. It should supervise compliance with all of the requirements critical to the maintenance of the *compartment* status described in this chapter and ensure that all relevant information (as described in Article 4.3.9) is readily accessible to *importing countries*. The *Competent Authority* should ensure appropriate auditing of the *compartment* is completed by trained officials or accredited third party auditors.

The *Veterinary Authority* should ensure that any changes to the health status of the *compartment* should be notified to the *Veterinary Authority* of *importing countries*.

Article 4.3.11.

Quality of aquatic animal health services

The quality of *Aquatic Animal Health Services* relevant to the self-declaration of *compartment* freedom should be documented, including how they meet the requirements of Chapter 3.1.

Article 4.3.12.

Notification and response measures

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 and *importing countries* should be notified following the provisions of Chapter 1.1.

In the event of detection of any *disease* which may indicate a breach of *biosecurity* measures, the management of the *compartment* should notify the *Competent Authority*. A review should be initiated to determine whether a breach of *biosecurity* measures has occurred.

If a significant breach in *biosecurity* is identified, even in the absence of the *disease(s)* for which the *compartment* was declared free, the *compartment*'s free status should be suspended. There should be an immediate suspension of trade to disease-free areas if a *disease* for which the *compartment* has been declared disease-free, is suspected or confirmed, and trading partners should be notified in accordance with Article 5.1.4.

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*. If the health status of the *compartment* is at risk, the *Competent Authority* should immediately re-evaluate the status of the *compartment* and consider whether any additional *biosecurity* measures are needed to ensure that the integrity of the *compartment* is maintained.

FORM A**COMMENTS ON THE WORK PROGRAMME OR ITEMS DOCUMENTED IN THE REPORT THAT DO NOT INCLUDE ANNEXES**

Japan	Aquatic Animal Health Standards Commission February 2025
	<p>Title of the item in the report or item in the work programme annex:</p> <p>Work Programme – New proposal. Chapter 2.2.3. Infection with Decapod iridescent virus 1 in Aquatic Manual</p> <p>Proposal/Comment:</p> <p>Japan requests the Commission to consider reviewing Chapter 2.2.3 Infection with Decapod iridescent virus 1. Apparently, there is an issue in the cycling parameters for DIV1 real-time PCR (incorrect incubation time). We recommend correcting it to avoid confusion.</p> <p>Rationale:</p> <p>In the DIV1 manual, there is a section for Real-Time PCR (4.4.1) and all details regarding real-time PCR assays are listed in Table 4.4.1.1 (Primers and probes and cycling conditions for DIV1 real-time PCR). Among the three assays in the Table, the cycling parameters for Method 1 (Qiu et al., 2018a) targeting ATPase seems to be incorrect. The cycling parameter for the assay is stated as follows: 40 cycles of 95°C for 100 sec and 60°C for 30 sec. We believe that the incubation time for the denaturation step is too long (95°C for 100 sec) and should be corrected to 95°C for 10 sec.</p> <p>Apparently, the information originates from the paper published by Qiu LM et al. (2018), which also states 100 sec. This is considerably longer than the typical real-time PCR program. Additionally, we checked the manual for the qPCR enzyme mentioned in the original paper and confirmed that it recommends 10 sec.</p> <p>Just in case, we performed an evaluation experiment to confirm it. As expected, 10 sec incubation produced significantly better results than 100 sec and the detection limit of 10 sec was higher than that of 100 sec (See Supporting evidence).</p> <p>Given the reasons above, we believe that the 100 sec in the WOAH DIV1 manual and the original paper was simply a typo. Therefore, we suggest that the program for detecting DIV1 ATPase by real-time PCR method should consist of 40 cycles of 95°C for 10 sec and 60°C for 30 sec.</p> <p>References: Qiu, L., M et al. (2018): Detection and quantification of shrimp hemocyte iridescent virus by TaqMan probe based real-time PCR. J. Invertebr. Pathol., 154, 95-101</p>