

UNITED STATES OF AMERICA – COMMENTS

Annex 13. Item 6.3. – Draft new Chapter 4.3. ‘Application of Compartmentalisation’

SECTION 4.

DISEASE PREVENTION AND CONTROL

CHAPTER 4.3.

APPLICATION OF COMPARTMENTALISATION

United States	Category: general It is our understanding that the impetus for establishing a compartment is to demonstrate a distinct health status to support trade, and is especially relevant when the surrounding zone or country is unable (or simply hasn't yet) to claim freedom. This understanding seems to be substantiated by the description provided in the February 2026 Report of the Meeting of the WOAHA Aquatic Animal Health Standards Commission (“The Commission highlighted that compartmentalisation provides an opportunity to trade disease-free aquatic animal commodities from zones or countries that are not declared free from the diseases of concern.”), and Article 4.3.3. (“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.”). If the principles above remain the intent of the standards we are developing/revising for compartmentalization, then there are several misleading, contradictory, and/or false statements in the proposed chapter below. We believe it is paramount that these standards clearly communicate 1) the intent of compartmentalization [i.e., to facilitate trade of disease-free aquatic animal commodities with a distinct health status regardless of the health status of the surrounding environment (i.e., country or zone) for a given disease(s) of concern]; and 2) the steps/considerations that should be undertaken to establish, maintain, and regain compartment status based on risk analysis. We greatly appreciate the work of the Commission and Members for their ongoing dedication to revising this chapter so that it meets the objectives stated above. We hope that our comments and recommendations on Chapter 4.3. assist with achieving these objectives to support all Members and global trade of disease-free aquatic animal commodities.
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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 and ~~or~~ for *disease* prevention and control. It

provides a framework for the development of requirements for *compartments* and to support bilateral negotiation between Member Countries that is based on *risk analysis*.

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 under the control of a single operator in accordance with this chapter.

United States	Category: addition Proposed amended texts (or precise suggested deletion): Please see the proposed addition in blue – “...<i>aquaculture establishments</i> (i.e. <i>enterprise</i>) that operate under a common set of <i>risk management</i> measures <u>under the control of a single operator</u> in accordance with this chapter.” Rationale: The term “enterprise” appears in the following paragraph but is not defined elsewhere in this chapter or in the glossary. To avoid ambiguity, it should be clarified that, in this context, an enterprise refers to a group of aquaculture establishments.
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Compartmentalisation provides an opportunity for the operator ~~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 operator~~private sector~~ and oversight by the relevant *Competent Authorities* ~~are~~ essential.

The Veterinary Authority-A Competent Authority can make a *self-declaration of freedom from disease* for a *compartment* from specified *listed disease(s)* ~~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* including compliance with basic biosecurity conditions and surveillance requirements as described in Chapter 1.4. and in the relevant disease-specific chapters have been met.

Article 4.3.2.

Principles for establishing and maintaining a compartment

The following principles should be applied to establish and maintain a *free compartment*. The principles should be addressed in a *self-declaration of freedom from disease* as described in Chapter 1.4.

- 1) A *compartment* must ~~have~~ ensure there are effective measures (established through *risk analysis*) to prevent the entry or spread of *pathogenic agents* ~~from the external environments~~ into the *compartment* (i.e. to provide functional epidemiological separation between the *compartment* and infected populations);
- 2) The purpose and scope of a *compartment* should be clearly defined (e.g. *disease(s)* for which freedom will be claimed species produced and *aquaculture establishments* that comprise the *compartment*) as described in Article 4.3.3.;

United States	Category: editorial Proposed amended texts (or precise suggested deletion): Please see the proposed change in blue –
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	“...freedom will be claimed, species produced and” Rationale: Editorial as this is a list of items.
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- 3) There are two categories of *compartments* (i.e. those with disease-free status that is independent from dependent on the disease status of the surrounding water body environment or those with disease-free status that is dependent on independent from the disease status of the surrounding water body environment, as described in Article 4.3.4.) and *biosecurity* and *surveillance* measures should be appropriate for the category of *compartment*.

United States	Category: change Proposed amended texts (or precise suggested deletion): Please see the proposed changes in blue – <u>“There are two categories of <i>compartments</i> based on the hydrological connection with the surrounding water body (i.e. those with disease-free status that is independent from dependent on the disease status of the surrounding water body environment or those with disease free status that is dependent on independent from the disease status of the surrounding water body environment; independent and dependent, as described in Article 4.3.4.) All categories of compartment must demonstrate a distinct health status from the surrounding environment, and <i>biosecurity</i> and <i>surveillance</i> measures should be appropriate for the category of <i>compartment</i>.”</u> Rationale: The glossary definition of a compartment (regardless of the category) specifies it must have a distinct health status with respect to a specific disease(s). Therefore, if the aquaculture establishment or enterprise cannot demonstrate and uphold this distinct health status regardless of the health status of its surroundings, then it doesn't meet the WOAHP definition of a compartment. These recommended changes help to clarify that all compartments (independent and dependent) must have a distinct health status from their environment and carry out risk evaluation, biosecurity, and surveillance activities. The extent of risk evaluation, biosecurity, surveillance, and other disease mitigation measures will depend on the level of risk for disease introduction as outlined later in this chapter. It is our understanding that the intent of this paragraph in Article 4.3.2. is to highlight that there are 2 categories of compartment (which are later described in Article 4.3.4.) and that while risk evaluation, biosecurity, and surveillance are required for all compartments, there may be variations based on the category of compartment.
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- 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 disease-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 the *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) ~~Competent Authority–Official oversight~~ responsibilities must be clearly documented, including approval by the *Competent Authority*, an auditing schedule, underpinning regulatory instruments and ~~approving/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 ~~a~~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 4.3.32.

Purposes and scope 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*. The *disease(s)* for which freedom will be claimed, ~~and~~ the species produced ~~and~~ *aquaculture establishments that comprise the compartment* should be clearly defined.

~~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.

Independent and dependent ~~Dependent and independent~~ compartments

There are two categories of *compartments* that are determined by the degree of epidemiological separation from the surrounding **water bodyenvironment**: independent and dependent *compartments*. 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 may 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 compartments

Independent *compartments* have **complete** epidemiological separation from the surrounding **water body environment** and are characterised by appropriate levels of physical and management measures to maintain effective *biosecurity*.

~~Independent and dependent *compartments* and have the following characteristics:~~

- 4) Independent *compartments* have the following characteristics:
 - 1a) are closed production system types only (as described in Chapter 4.1.);
 - 2b) have control over all transmission pathways **identified through *risk analysis*** and **complete** epidemiological separation from the surrounding **water bodyenvironments**;
 - 3e) have appropriate levels of *biosecurity* and *surveillance* to mitigate the *risk* of introduction of specific *pathogenic agents* into the *compartment* in accordance with Article 4.3.5. ~~physical and management measures to maintain effective *biosecurity* for all pathways;~~

United States	Category: change
	Proposed amended texts (or precise suggested deletion):

	Please see the proposed changes in blue – “2b) have control over all transmission pathways identified through risk analysis and complete epidemiological separation from the surrounding water body environments;” 23e) have appropriate levels of biosecurity and surveillance to mitigate the risk of introduction of specific the pathogenic agent(s) (for which the compartment has been established) into the compartment in accordance with Article 4.3.5. and identified through risk analysis. physical and management measures to maintain effective biosecurity for all pathways;” Rationale: We propose removing paragraph 2 because physical control of a given disease transmission pathway does not by itself infer mitigation of risk. Instead, the objective should be to mitigate pathogen introduction via appropriate biosecurity and surveillance measures proportionate to the risk profile of the given compartment. Additionally, since one of the characteristics of an independent compartment must be that it is a closed production system, Article 4.1.5. already defines a closed system as having “sufficient control over water entering and exiting the system to exclude aquatic animals, vectors and pathogenic agents. Environmental conditions can also be controlled...” which makes paragraph 2 redundant. Edits proposed to the pathogenic agent(s) for which the compartment has been established are to align with paragraph 3 of the dependent compartment characteristics since the same principles should apply.
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d) ~~provide levels of risk management 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

Dependent compartments have a hydrological connection to do not have complete epidemiological separation from the surrounding water body environment but conditions exist which create a functional an effective disease-specific separation between the compartment and infected other aquatic animal populations that may be infected. The possibility of achieving such disease-specific separation will be determined by the Competent Authority, based on risk analysis.

United States	Category: change Proposed amended texts (or precise suggested deletion): Please see the proposed changes in blue – “Dependent compartments do not meet the definition of closed production system types (as described in Chapter 4.1.), have a hydrological connection to do not have complete epidemiological separation from the surrounding water body environment but yet conditions or mitigations exist which create a functional an effective disease-specific separation between the compartment and its surroundings infected other aquatic animal populations that may be infected. The possibility of achieving such disease-specific separation will be determined by the Competent Authority, based on risk analysis.”
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	Rationale: Categorization as a dependent compartment should be available to any facility that is not a closed production system type (as described in Chapter 4.1.), but can still demonstrate epidemiologic separation via all disease transmission pathways based on risk analysis. Dependent compartment status should not be limited to semi-closed aquaculture establishments as long as the compartment can demonstrate and uphold a health status distinct from its surroundings per the WOAHA definition. Semi-open and semi-closed designations are based on the degree of physical control over the influent water (as described in Chapter 4.1.); however, physical control of the influent water (in cases such as semi-closed production types) alone, does not infer adequate risk mitigation of disease introduction. Conversely, the lack of physical control over the influent water (in cases of semi-open production system types) alone does not infer unavoidable risk mitigation of disease introduction. For example, an aquaculture establishment that routes water through a raceway (i.e., semi-closed per Chapter 4.1.) would be eligible for dependent compartment status per the standards as written; however, a risk analysis would be necessary to determine whether the re-routed water has been exposed to pathogens upstream. If the influent water was not treated (and adequately maintained), this facility is no safer than a net pen (i.e., semi-open production system per Chapter 4.1.) that is also reliant on the health status of the surrounding waterbody. Alternatively, the semi-open net pen could be protected geographically from waters exposed to diseases of concern (e.g., a net pen in a remote inland lake with no susceptible species and located far from any other aquaculture establishments sourced by a mountain spring), and therefore not epidemiologically linked. In both the semi-closed and semi-open examples, dependent compartment status cannot be inferred based on the production system type alone, and both require risk assessment to ascertain whether the health status is distinct from waters of concern. Consequently, the results of a risk evaluation, not the production system type, should determine eligibility for compartmentalization.
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The concept of dependent *compartments* broadens the application of compartmentalisation to a wider range of production systems and *aquaculture establishments*, creating additional opportunities for trade in disease-free commodities where such *compartments* ensure an appropriate level of *risk management*.

Dependent compartments have the following characteristics:

- 1a)** are semi-closed production system types only (as described in Chapter 4.1.);
- 2b)** are dependent on the health status of the surrounding **water body**;
- 3e)** have appropriate levels of *biosecurity* and *surveillance* to mitigate the *risk* of introduction of ~~specific~~ the *pathogenic agent(s)* (for which the *compartment* has been established) in accordance with Article 4.3.5. ~~physical and management measures to maintain effective *biosecurity* for all pathways;~~
- 4d)** meet the additional *biosecurity* and *surveillance* requirements to mitigate transmission *risk* from the surrounding **water body environment** as informed by a *risk analysis* ~~via intake water criteria and risk mitigation measures for transmission via intake water which the *Competent Authority* may approve in accordance with Article 4.3.5.;~~

United States	Category: change Proposed amended texts (or precise suggested deletion): Please see the proposed changes in blue –
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	“1a) do not meet the definition of are semi-closed production system types only (as described in Chapter 4.1.); 2b) are dependent on the health status of the surrounding waters body; 3e) have appropriate levels of <i>biosecurity</i> and <i>surveillance</i> to mitigate the <i>risk</i> of introduction of specific the <i>pathogenic agent(s)</i> (for which the <i>compartment</i> has been established) in accordance with Article 4.3.5 and identified through risk analysis; physical and management measures to maintain effective biosecurity for all pathways; 4d) meet the additional biosecurity and surveillance requirements to mitigate transmission risk from the surrounding water body environment as informed by a risk analysis via intake water criteria and risk mitigation measures for transmission via intake water which the Competent Authority may approve in accordance with Article 4.3.5.; Rationale: We recommend revising paragraph 1 and removing paragraph 2 because categorization as a dependent compartment should be available to any facility that is not a closed production system type (as described in Chapter 4.1.), but can still demonstrate epidemiologic separation via all disease transmission pathways based on risk analysis. Dependent compartment status should not be limited to semi-closed aquaculture establishments as long as the compartment can demonstrate and uphold a health status distinct from its surroundings per the WOA definition. Semi-open and semi-closed designations are based on the degree of physical control over the influent water (as described in Chapter 4.1.); however, physical control of the influent water (in cases such as semi-closed production types) alone, does not infer adequate risk mitigation of disease introduction. Conversely, the lack of physical control over the influent water (in cases of semi-open production system types) alone does not infer unavoidable risk mitigation of disease introduction. For example, an aquaculture establishment that routes water through a raceway (i.e., semi-closed per Chapter 4.1.) would be eligible for dependent compartment status per the standards as written; however, a risk analysis would be necessary to determine whether the re-routed water has been exposed to pathogens upstream. If the influent water was not treated (and adequately maintained), this facility is no safer than a net pen (i.e., semi-open production system per Chapter 4.1.) that is also reliant on the health status of the surrounding waterbody. Alternatively, the semi-open net pen could be protected geographically from waters exposed to diseases of concern (e.g., a net pen in a remote inland lake with no susceptible species and located far from any other aquaculture establishments sourced by a mountain spring), and therefore not epidemiologically linked. In both the semi-closed and semi-open examples, dependent compartment status cannot be inferred based on the production system type alone, and both require risk assessment to ascertain whether the health status is distinct from waters of concern. Consequently, the results of a risk evaluation, not the production system type, should determine eligibility for compartmentalization. We recommend revising paragraph 3 and removing paragraph 4 because the objective should be to mitigate pathogen introduction via appropriate biosecurity and surveillance measures proportionate to the risk profile of the given compartment. These changes also mirror those proposed in the corresponding section for independent compartments.
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- 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).~~

The suitability of a dependent compartment should be assessed against the minimum risk factors outlined in Article 4.3.5. If these measures cannot be effectively implemented, the Competent Authority cannot grant approval. Where effective disease-specific separation is possible, approval may be granted provided that specific risk management measures are applied. Both the risk analysis and the specified measures must be documented in the dossier of evidence referred to in Article 1.4.16.

~~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).~~

~~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.~~

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
Biosecurity across all pathways in accordance with Chapter 4.1.	Biosecurity 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 surveillance generally not required to maintain freedom (but may be useful to inform biosecurity measures)	Ongoing external surveillance may be required to maintain freedom in accordance with Chapter 4.4.
Suitable for all commodities and pathways	May not meet the required level of risk mitigation for all commodities and pathways

Article 4.3.5.

Biosecurity and ~~other~~ risk management~~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 management~~mitigation~~ across all elements of the compartment.

The Competent Authority should require Ensure that all movements of disease-free aquatic animals into a free compartment originate from a free country, free zone or free compartment, declared free from diseases for which the compartment has been established, and any of international origin should be and in the case of international movements are certified in accordance with Chapter 5.1.

For dependent compartments, the risk analysis described below in Article 4.3.4 4.1.8. should assess include the assessment of risks within the water body environment surrounding the compartment. The geographic scope of the risk analysis and development of appropriate risk management and surveillance should be informed by the factors below. to inform and the development of appropriate risk management and surveillance measures to mitigate disease transmission from the environment. The riskRisk management mitigation measures should be developed in accordance with Article 4.1.8. and may include the application of specific biosecurity measures, a higher level of internal targeted surveillance and external surveillance to monitor for changes in disease risk. the identified risks.

United States	Category: change Proposed amended texts (or precise suggested deletion): Please see the proposed changes in blue – “For dependent all compartments, the risk analysis described below in Article 4.3.4 4.1.8. should assess include the assessment of risks withinposed by the water bodyenvironment surrounding the compartment, as well as all other disease transmission pathways (i.e. animals, feed, vectors, and fomites) into the compartment. The geographic scope...” Rationale: We feel strongly that a risk analysis should be conducted for all categories of compartment; this is further supported by Article 4.3.2. which highlights that all compartments “must have effective measures (established through risk analysis) to prevent the entry or spread of pathogenic agents into the compartment (i.e. to provide functional epidemiological separation between the compartment and infected populations)”. While we recognize that it may be easier to demonstrate epidemiological separation for closed production system types (i.e., independent compartments), this is not a guarantee. For example, a land-based, closed, groundwater-fed facility may be at risk of pathogen exposure if the well depth is inadequate, or if storm waters flood the facility. Similarly, a land-based, closed, RAS system may be at risk if the filtration and/or UV are not adequately configured or maintained. Additionally, it is important to clarify and emphasize that regardless of the production system type, all disease transmission pathways should be assessed as part of the risk analysis – water, animals, feed, vectors, and fomites. Both closed (independent) and non-closed (dependent) production systems may be at risk for disease introduction through animals, feed, vectors, or fomites, irrespective of its hydrobiological connection to the surrounding water body.
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~~The Competent Authority should consider in~~ At a minimum, the following factors should be addressed within the risk analysis:

- 1) characteristics of the pathogenic agent(s);
- 2) ~~presenceabsence~~ of susceptible species and pathways of exposureinfection in the surrounding environment water body and the probability of exposure to the pathogenic agent(s), due to geographical location, environmental conditions or the application of biosecurity measures. Specific consideration should be given to:
 - a) the hydrological conditions inof the surrounding water body;
 - b) the geographical location of each aquaculture establishment comprising the dependent compartment and the nature of their the water supply;

- c) the health status of other *aquaculture establishments* containing *susceptible species* within the surrounding shared water body system and their source of *aquatic animals*, location and method of production;
- d) proximity of 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);
- ef) the presence and abundance of wild *susceptible species* in the surrounding water body and their health status;
- fg) the details of whether the susceptible species referred to in point (ef) are sedentary or migratory and their natural distribution and migratory movement patterns;

United States	Category: general If the intent of paragraph f is to highlight the difference between susceptible species that are migratory versus those that can move, but don't do so frequently, then we agree with the term "sedentary"; however, the term "sessile" may be more appropriate if the intent is to highlight those species that don't move.
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- gh) the ability to exclude the exclusion of the wild *aquatic animals* referred to in point (ef) from entering the *compartment*;
- hi) the general *biosecurity* measures applied in *aquaculture establishments* and processing facilities in the surrounding shared water body;

United States	Category: addition Proposed amended texts (or precise suggested deletion): Please see the proposed addition in blue – i) the conditions and biosecurity measures applied in aquaculture establishments to control the risks of introduction via other disease transmission pathways (i.e., feed, vectors, and fomites);" Rationale: We feel it is important to clarify and emphasize that all disease transmission pathways should be assessed as part of the risk analysis – water, animals, feed, vectors, and fomites. Both closed (independent) and non-closed (dependent) production systems may be at risk for disease introduction through animals, feed, vectors, or fomites, irrespective of its hydrobiological connection to the surrounding water body. Since other paragraphs in Article 4.3.5. address animals and water, we propose an additional paragraph to address the remaining disease transmission pathways into a compartment.
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- 3) presenceabsence of *infection* in any nearby populations of *susceptible species* demonstrated by appropriate external *surveillance*;
- 4) additional internal targeted *surveillance* (i.e. in the *aquaculture establishment(s)* that comprise the *compartment*).

Where ~~For some semi-closed aquaculture establishments, it is~~ may not be possible to mitigate identified risks from the water body surrounding a semi-closed aquaculture establishment 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*.

United States	Category: change Proposed amended texts (or precise suggested deletion): Please see the proposed changes in blue – “4) additional internal <u>passive or targeted surveillance</u> (i.e. in the <i>aquaculture establishment(s)</i> that comprise the <i>compartment</i>).” “...surrounding <u>an semi-closed aquaculture establishment</u> aquaculture establishment environment (e.g. presence of <i>disease</i> in adjacent wild populations of <i>susceptible species</i>), and the <i>aquaculture establishment</i> would not be eligible to be recognised as a <u>dependent compartment</u>.” Rationale: We recommend the insertion of “passive” surveillance into point 4 because the types of surveillance utilized can be broader than just targeted surveillance. This change is also consistent with Chapter 1.4. which allows for passive surveillance as part of the early detection system. In the last paragraph of this article, we feel it is important to clarify and emphasize that all disease transmission pathways should be assessed as part of the risk analysis – water, animals, feed, vectors, and fomites. Both closed (independent) and non-closed (dependent) production systems may be at risk for disease introduction through animals, feed, vectors, or fomites, irrespective of its hydrobiological connection to the surrounding water body. We therefore recommend removing the reference to a “semi-closed” aquaculture establishment and a “dependent” compartment in this paragraph based on the proposed edits above to Article 4.3.4. and Article 4.3.5. The focus of this paragraph should be that if any category of compartment cannot mitigate the risk of disease introduction, and therefore achieve a distinct health status which is a requisite component of the glossary term <i>compartment</i>, then it is not eligible for compartment status.
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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*, and as well as the requirements to maintain that freedom in accordance with Article 1.4.15.

~~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 pathogenic agent of 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. ~~offer~~ populations of *susceptible species* within a *compartment*) is required to make a *self-declaration of freedom from disease* for both independent and dependent *compartments* as described in the relevant disease-specific chapters and Article 1.4.4. 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. ~~offer~~ populations of *susceptible species* in the environment outside a *compartment*) is used to evaluate risk presented to the compartment by the surrounding water body. It 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 may be passive and/or targeted based on the specific requirements to evaluate risk situation in accordance with the relevant disease-specific chapters and Chapter 1.4.

For dependent *compartments*, ~~external~~External *surveillance* is required for ~~dependent compartments~~if populations of *susceptible species* are present in the water bodyenvironment surrounding the *compartment*. The *surveillance* should be developed taking into account the factors described in Article 4.3.5., and be at a level sufficient to inform the risk analysis described in Article 4.3.4. The area for which external *surveillance* is required must be defined and should take into account any *surveillance* which is carried out on adjacent *aquaculture establishments* keeping *susceptible species*. For a dependent *compartment* occurring within a *free zone* or *free country*, the *surveillance* to establish and maintain a *free zone* or *free country* constitutes the external *surveillance* for the *compartment*.

If the pathogenic agent is detected in the surrounding water body of the dependent compartment the Competent Authority should notify the operator of the compartment and assess the risk of disease exposure to the compartment and the surrounding water body. If risk management cannot be implemented in accordance with this chapter, the Competent Authority should revoke the disease-free status of the compartment.

Where the disease-free status of a dependent compartment is conditional on its location within a free zone or free country, and the disease-free status of the free zone or free country is lost, the Competent Authority should assess the risk of disease exposure to the compartment and the surrounding water body. If risk management cannot be implemented in accordance with this chapter, the Competent Authority should revoke the disease-free status of the compartment.

United States	Category: change Proposed amended texts (or precise suggested deletion): Please see the proposed changes in blue – <u>“If the pathogenic agent is detected in the surrounding water body of the dependent compartment the Competent Authority should notify the operator of the compartment and assess the risk of disease exposure to the compartment and the surrounding water body. If risk management cannot be implemented in accordance with this chapter, the Competent Authority should revoke the disease-free status of the compartment.</u> <u>Where the disease-free status of a dependent compartment is conditional on its location within a free zone or free country, and the disease-free status of the free zone or free country is lost, the Competent Authority should assess the risk of disease exposure to the compartment and the surrounding water body. If risk</u>
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	<u>management cannot be implemented in accordance with this chapter, the Competent Authority should revoke the disease free status of the compartment.</u> Rationale: We feel strongly that if a pathogenic agent is detected in the surrounding water body of either category of compartment, the operator should notify the Competent Authority and an assessment of the risk of disease exposure should be conducted. While we recognize that it may be easier to demonstrate epidemiological separation for closed production system types (i.e., independent compartments), this is not a guarantee. For example, a land-based, closed, groundwater-fed facility may be at risk of pathogen exposure if the well depth is inadequate, or if storm waters flood the facility. Similarly, a land-based, closed, RAS system may be at risk if the filtration and/or UV are not adequately configured or maintained. Also, disease introduction into an independent compartment is not limited to transmission via water. Both closed (independent) and non-closed (dependent) production systems may be at risk for disease introduction through animals, feed, vectors, or fomites, irrespective of its hydrobiological connection to the surrounding water body, therefore necessitating an assessment of all disease transmission pathways regardless of the production system type. For example, a fomite could transmit the pathogenic agent from the affected surrounding water body into the independent compartment. Additionally, since the glossary definition of a compartment (regardless of the category) specifies it must have a distinct health status with respect to a specific disease(s), the recommended changes help to clarify that all compartments must have a distinct health status irrespective from the health status of their environment, and all compartments should assess the risk of disease introduction should a detection occur in the surrounding water body.
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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~~ conducts testing in accordance with the recommendations of the *Aquatic Manual*;
- 3) can confirm or exclude cases of *infection*~~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 nature of the supply chains of the aquatic animal species and for application to individual or groups of *aquatic animals* or *aquatic animal products*, as necessary;
- 2) record all aquatic animal movements into and out of the compartment including origin and destination. 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, vaccination records, veterinary treatments 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 for which records should be maintained should be meet the 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.

Competent Authority responsibilities Official oversight

A *Competent Authority* must have the authority to approve the operation of the *aquaculture establishment(s)* that ~~comprise~~ comprise 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*.

A Competent Authority⁴ 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 which are independent from the management and ownership structures of the compartment and approved by Competent Authorities.

The *Competent Authority* must report any significant modification of the *biosecurity and risk management measures* identified in the *compartment* that supported its initial approval. The *Competent Veterinary Authority* should ensure that any changes to the health status including suspension or revocation of the *compartment* should be notified to the *Competent 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 by the Competent Authority, 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 operator of the *compartment* should immediately notify the *Competent Authority*. The *Competent Authority* should then determine whether the disease-free status of the *compartment* should be immediately suspended and importing countries should be notified following the provisions of Chapter 1.1. while the occurrence of the disease is confirmed or ruled-out.

If the *disease* for which the *compartment* was defined is confirmed within the *compartment*, the *Competent Authority* should immediately revoke its disease-free status, notify *importing countries* and make an immediate *notification* following the provisions of Chapter 1.1. In the event of confirmation of the disease for which the compartment was defined, the disease free status should immediately be suspended.

The operator of a *compartment* should report any event which could lead to a breach of *biosecurity measures* to the *Competent Authority*. 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 by the Competent Authority to determine whether a breach of *biosecurity measures* has occurred which could impact the health status of the compartment.

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* *disease-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 by the The *Competent Authority* may only re-approve the compartment and make a self-declaration of freedom from disease after the depopulation, decontamination and *fallowing* have been completed, previously existing *basic biosecurity conditions* have been reviewed and modified as necessary, and *surveillance* in accordance with Chapter 1.4. and the relevant disease-specific chapter(s) has been completed. Disease freedom must be maintained in accordance with Article 1.4.15. and the relevant disease-specific chapter. *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.

United States	Category: change Proposed amended texts (or precise suggested deletion): Please see the proposed changes in blue – <u>“The <i>Competent Authority</i> may only re-approve the compartment and make a <i>self-declaration of freedom from disease</i> after the depopulation, decontamination and <i>fallowing</i> have been completed if warranted, previously existing <i>basic biosecurity conditions</i> have been reviewed and modified as necessary, and <i>surveillance</i> in accordance with Chapter 1.4. and the relevant disease-specific chapter(s) has been completed.”</u> Rationale: We disagree with the assertion that depopulation is required in all events of the loss of a compartment’s freedom status. There may be breaches to biosecurity which, once adequately investigated, do not result in pathogen introduction. We therefore propose amendments that better align with the standards described in Article 4.3.6. (“If risk management cannot be implemented in accordance with this chapter, the Competent Authority should revoke the disease-free status of the compartment.”). We agree with the cross-reference to Chapter 1.4. in this paragraph.
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