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Annex 19. Item 7.1. – Draft new Chapter 4.3. ‘Application of Compartmentalisation’

SECTION 4.

DISEASE PREVENTION AND CONTROL

CHAPTER 4.3.

APPLICATION OF COMPARTMENTALISATION

Norway	<p><b>Category:</b> General</p> <p><b>Proposed amended text:</b> not relevant</p> <p><b>Rationale:</b></p> <p>Norway would like to commend the Aquatic Animal Health Standards Commission for its work on this important draft new chapter.</p> <p>In general, Norway is of the opinion that the chapter should focus solely on how to establish and maintain a compartment. Commodities are already sufficiently covered in Section 5 and the disease-specific chapters in the Aquatic code. The inclusion of examples may unintentionally narrow interpretation or create uneven applications in trade, as importing countries could selectively adopt measures based on these references rather than on risk-based principles. Therefore, Norway strongly opposes the use of examples of commodities and end-uses in this chapter as they may lead to unintended trade restrictions.</p> <p>The term “epidemiological separation” is used 7 times in the text without being clearly defined. A clear definition or description is needed to ensure a common understanding of how to interpret the exact meaning and associated prerequisites.</p> <p>Additional comments are provided below.</p> <p><b>Supporting evidence:</b> not relevant</p>
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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 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*

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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.

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.

Norway	<p><b>Category</b> (deletion):</p> <p><b>Proposed amended text</b> (or precise suggested deletion):</p> <p>Norway suggests the following deletion:</p> <p><del>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.</del></p> <p><b>Rationale:</b></p> <p>The first paragraph of this article sufficiently describes the purposes of a compartment. Commodity types are sufficiently covered in Section 5 and the disease-specific chapters.</p> <p><b>Supporting evidence:</b> Not relevant.</p>
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#### 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.;

<b>Norway</b>	<p><b>Category</b> (deletion):</p> <p><b>Proposed amended text</b> (or precise suggested deletion):</p> <p>Norway suggests the following deletion:</p> <p>2) the purpose of a <i>compartment</i> should be clearly defined (<del>e.g. disease(s) for which freedom will be claimed, species and commodities produced, intended end-uses of commodities</del>) as this will have implications for the design of <i>risk management</i> measures, as described in Article 4.3.2.;</p> <p><b>Rationale:</b></p> <p>The principles for establishing a compartment should be related to the required risk management measures, including any disease-specific risks as per the disease-specific chapters. This includes much more than species, commodities and intended end uses, and the text should be amended for clarity.</p> <p><b>Supporting evidence:</b> Not relevant.</p>
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- 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.;

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- 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;

Norway	<p><b>Category</b> (deletion):</p> <p><b>Proposed amended text</b> (or precise suggested deletion):</p> <p>Norway suggests the following deletion:</p> <p style="padding-left: 40px;">d) provide levels of <i>risk</i> mitigation suitable for all purposes, <del>commodity types and end-uses;</del></p> <p><b>Rationale:</b></p> <p>Deletion to improve clarity and focus.</p> <p><b>Supporting evidence:</b> Not relevant.</p>
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- 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).

Norway	<p><b>Category</b> (deletion, addition):</p> <p><b>Proposed amended text</b> (or precise suggested deletion):</p> <p>Norway suggests the following amendments to the text under point 2) Dependent compartments:</p> <ul style="list-style-type: none"> <li>a) <u>are semi-open or</u> semi-closed production system types <u>only</u> (as described in Chapter 4.1.);</li> <li>b) are dependent on the health status of the surrounding waters;</li> <li>c) have appropriate levels of <del>physical and management measures to maintain effective <i>biosecurity</i> for all pathways</del> <u><i>biosecurity and surveillance to mitigate the risk of introduction of specific pathogenic agents into the compartment in accordance with Article 4.3.5.</i></u></li> <li><del>d) meet the additional <i>biosecurity</i> criteria and <i>risk</i> mitigation measures for transmission via intake water which the <i>Competent Authority</i> may approve in accordance with Article 4.3.5.;</del></li> <li><del>e) d) may not provide sufficient <i>risk</i> mitigation for all purposes, <i>commodity</i> types and end-uses (e.g. supplying live <i>aquatic animals</i> for <i>aquaculture</i> or restocking, for high value <i>aquatic animals</i> such as genetically improved lines).</del></li> </ul> <p><b>Rationale:</b></p> <p>Norway encourages the Commission to reconsider whether there could be situations where a semi-open system may be able to fulfil the criteria to become a dependent compartment. If a semi-open system should be able to fulfil the requirements it would be inappropriate to exclude it. While semi-closed systems are much more likely to be able to fulfil the requirements, there may be situations where the characteristic of the pathogenic agent in question and the environmental conditions allows a semi-open system to have sufficient <i>biosecurity</i> and <i>surveillance</i> measures to be eligible for status as a dependent compartment.</p>
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	<p>Biosecurity measures, surveillance and risk mitigation are key aspects for dependent compartments and related text changes are suggested.</p> <p><b>Supporting evidence:</b> 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).

<b>Norway</b>	<p><b>Category</b> (deletion):</p> <p><b>Proposed amended text</b> (or precise suggested deletion):</p> <p>Norway suggests the following deletion:</p> <p>The suitability of a dependent <i>compartment</i> to achieve the required level of <i>risk</i> mitigation should be determined following consideration of the purpose of the <i>compartment</i> (refer to Article 4.3.2.), <del>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).</del></p> <p><b>Rationale:</b></p> <p>The suitability of a dependent compartment to achieve the required level of risk mitigation is the key aspect, based on risk analysis. As previously mentioned, commodities are sufficiently covered in Section 5 and the disease specific chapters.</p> <p><b>Supporting evidence, if relevant</b></p> <p>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*.

Table 1. A summary of the characteristics of independent and dependent compartments

<b>Independent</b>	<b>Dependent</b>
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

<b>Norway</b>	<p><b>Category</b> (deletion, addition):</p> <p><b>Proposed amended text</b> (or precise suggested deletion):</p> <p>Norway suggests amendment of the following text in the table under the “Independent” heading:</p> <p>Suitable for all <del>commodities and</del> pathways</p> <p>Norway suggests the amendment of the following text in the table under the “Dependent” heading:</p> <p><del>Only Semi-open and</del> semi-closed systems <del>are a may be</del> suitable production system <del>type types</del></p> <p>May not meet the required level of <i>risk</i> mitigation for all <del>commodities and</del> pathways</p> <p><b>Rationale:</b></p> <p>See comment earlier about potential eligibility of semi-open systems and commodities being sufficiently covered in Section 5 and the relevant disease-specific chapters.</p> <p>The Commission is also encouraged to reconsider whether this table is needed given the easy-to-read list of characteristics earlier in this article.</p> <p><b>Supporting evidence:</b> Not relevant.</p>
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#### 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*).

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*.

<b>Norway</b>	<p><b>Category</b> (addition):</p> <p><b>Proposed amended text</b> (or precise suggested deletion):</p> <p>Norway suggests the addition of the following text:</p> <p>For some <a href="#">semi-open and</a> semi-closed aquaculture establishments, it may not be possible to mitigate identified <i>risks</i> from the surrounding 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 dependent <i>compartment</i></p> <p><b>Rationale:</b></p>
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	<p>Text needs to be amended if semi-open aquaculture establishments are included for dependent compartments.</p> <p><b>Supporting evidence:</b> Not relevant.</p>
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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*.

*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*.

Norway	<p><b>Category</b> (general):</p> <p><b>Proposed amended text</b> (or precise suggested deletion):</p> <p>The description of “external surveillance” in the Aquatic code is limited compared to that for “internal surveillance”. Norway requests the Commission to consider whether additional details should be given to improve clarity on how external surveillance should be conducted.</p> <p><b>Rationale:</b></p>
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	<p>Further description should ensure a uniform understanding of the requirements related to “external surveillance”.</p> <p><b>Supporting evidence:</b> Not relevant.</p>
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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 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;

<b>Norway</b>	<p><b>Category</b> (deletion, addition):</p> <p><b>Proposed amended text</b> (or precise suggested deletion):</p> <p>Norway suggests the following amendments:</p> <ol style="list-style-type: none"> <li>1) be appropriate for the <i>aquatic animal</i> species and for application to individual or groups of <i>aquatic animals</i> <del>or aquatic animal products</del>, as necessary;</li> </ol> <p><b>Rationale:</b></p> <p>Compartments are relevant for trade with live aquatic animals, for which traceability systems are important to ensure safe trade. The example of “aquatic animal products” is inappropriate as it could indicate traceability requirements for the compartment operator all the way to the final consumer, including for Ready-to-Eat products based on aquatic animal species. This would cause an unreasonable burden on the operator and is in contradiction to the provisions for</p>
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	trade with aquatic animal products for human consumption in the disease specific chapters in the Aquatic code.  <b>Supporting evidence:</b> Not relevant.
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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.

Norway	<p><b>Category</b> (editorial):</p> <p><b>Proposed amended text</b> (or precise suggested deletion):</p> <p>Norway suggests the following editorial change:</p> <p>A <i>Competent Authority</i> must have the authority to approve the operation of the <i>aquaculture establishment(s)</i> that <del>compromise</del> <u>comprise</u> the <i>compartment</i>.</p> <p><b>Rationale:</b></p> <p>Editorial change.</p> <p><b>Supporting evidence:</b> Not relevant.</p>
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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.