Annex 6. Item 6.2. – Draft new Chapter 4.3. 'Application of Compartmentalisation'

SECTION 4.

DISEASE PREVENTION AND CONTROL

CHAPTER 4.3.

APPLICATION OF COMPARTMENTALISATION

Norway	**Category**: general **Proposed amended text**: Not relevant **Rationale:** Norway would like to thank the Commission for addressing many of our previous concerns in this revised version of the chapter. However, we would like to reiterate our previous comment about automatically excluding semi-open production systems from eligibility to become dependent compartments. Please see our comment under Article 4.3.4. Some additional comments are also provided below. **Supporting evidence, if relevant:** not relevant

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.

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 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~~is~~ essential.

A *Competent Authority* can make 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* 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 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 ensure there are effective measures to prevent the entry or spread of *pathogenic agents* from the external environments into the *compartment* (i.e. provide functional epidemiological separation);

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.;

3) There are two categories of *compartments* (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.) and *biosecurity* and *surveillance* measures should be appropriate for the category of *compartment*;

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 4.3.3~~2~~.

Purpose~~s~~ 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 should be clearly defined.

Norway	**Category**: deletion **Proposed amended text**: ~~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 should be clearly defined.~~ **Rationale:** The text in this article is largely a repetition from Article 4.3.1. We encourage the Commission to consider whether this additional article is needed. **Supporting evidence, if relevant:** not relevant

~~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 environment: 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 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:~~

~~1)~~ Independent *compartments* have the following characteristics:

1~~a~~) are closed production system types only (as described in Chapter 4.1.);

2~~b~~) have control over all transmission pathways and complete epidemiological separation from surrounding environments;

Norway	**Category**: addition / deletion / general **Proposed amended text**: 2) have control ~~over~~ of all transmission pathways and ~~complete~~ epidemiological separation from surrounding environments; **Rationale:** A complete epidemiological separation implies perfect systems. In practice these doesn't exist, and it would mean that no system will be able to meet the definition. The definition of a closed system in Article 4.1.5. refers to "sufficient control over water entering and exiting the system". We therefore suggest that the word "complete" is removed. We additionally suggest using "control of" rather than "control over" transmission pathways. Alternatively, the Commission could review whether point 1) might be sufficient given the definition of a closed system. If so, we suggest that this point 2) is deleted. **Supporting evidence, if relevant:** not relevant

3~~c~~) 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;~~

~~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* do not have complete epidemiological separation from the surrounding environment but conditions exist which create an effective disease-specific separation between the *compartment* and 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*.

Norway	**Category**: deletion / addition **Proposed amended text**: Dependent *compartments* ~~do not~~ have ~~complete~~ limited epidemiological separation from the surrounding environment but conditions exist which create an effective disease-specific separation between the *compartment* and other *aquatic animal* populations that may be infected. The possibility of achieving such disease-specific separation must be based on risk assessment and ~~will~~ be determined by the *Competent Authority*~~, based on *risk analysis*~~. **Rationale:** See comment under Article 4.3.4 regarding complete epidemiological separation. Suggest using the word «limited» instead of “complete”, as the definition of a semi-closed system refers to, for example, “some control over the water entering and exiting the system” and semi-open systems to “not possible to have control over the water entering or exiting the system”. As it may or may not be the Competent Authority performing the actual risk assessment we suggest rewriting the last sentence. **Supporting evidence, if relevant:** not relevant

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:

a) are semi-closed production system types only (as described in Chapter 4.1.);

Norway	**Category**: addition **Proposed amended text**: a) are semi-open or semi-closed production system types only (as described in Chapter 4.1.); **Rationale:** Norway would like to reiterate its view that semi-open production systems should not be automatically excluded from the possibility of becoming a dependent compartment. This should rather be based on epidemiological risk assessments and whether or not an establishment is able to fulfil the required criteria. An example of this approach is (EU) 2020/689 Article 73 (2b and 3). **Supporting evidence, if relevant:** not relevant

b) are dependent on the health status of the surrounding waters;

c) 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~~;

d) meet the additional *biosecurity* and *surveillance* requirements to mitigate transmission *risk* from the surrounding 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.;

~~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 1.4.~~
~~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,* and in the case of international movements are certified in accordance with Chapter 5.1.

For dependent *compartments*, the *risk analysis* described in Article 4.3.4.~~4.1.8.~~ should include the assessment of *risks* within the environment surrounding the *compartment* to inform ~~and~~ the development of appropriate *risk management* and *surveillance* measures to mitigate *disease* transmission from the environment. The *risk* 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*.~~

~~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) presence~~absence~~ of *susceptible species* and pathways of exposure~~*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) presence~~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*.

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* 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 *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. off~~or~~ 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. off~~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* may be passive or targeted based on the specific 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 environment surrounding the *compartment*. The *surveillance* should be developed taking into account the factors described Article 4.3.5. 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*.

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;

Norway	**Category**: deletion **Proposed amended text**: ~~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;~~ **Rationale:** Due to the WOAH glossary definition of “aquatic animal products” and “commodity”, Norway does not consider it appropriate to refer to aquatic animal products in this context. We therefore encourage the Commission to reconsider its previous decision. The WOAH glossary contains the following definitions: “**aquatic animal products** means non-viable aquatic animals, parts of aquatic animals, or manufactured goods containing any material derived from aquatic animals that are intended for sale or trade.” “**commodity** means aquatic animals, aquatic animal products, biological products and pathological material.” Based on these definitions, it is our understanding that both “aquatic animal products” and “commodity” is referring to aquatic animal products, including products intended for end consumers. This is because “aquatic animal products” are referring both to manufactured goods and all products intended for sale or trade. The explicit division of “trade” and “sale” indicates the following understanding: “trade” is to be understood as buying and selling at business-to-business level, because “trade” involves both buying and selling, while “sale” is to be understood as selling a product to end consumers. The last part of the sentence in point 1 should therefore be deleted. **Supporting evidence, if relevant:** not relevant

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 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.

Norway	**Category**: deletion **Proposed amended text**: 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. **Rationale:** As the text appears now, in combination with Article 4.3.10, the legal obligation to facilitate a traceability system for aquatic animals, parts of aquatic animals, or manufactured goods containing any material derived from aquatic animals, all the way from the compartment to the end user, is put upon the competent authority and operators of the exporting country. Our position is that traceability systems that covers the tracking of a product back from the end user to the seller of the same product, to be understood as the business-to-consumer transaction, is to be decided and implemented by the national importing authorities, and not the competent authority and operators of the exporting country.

	The proposed amended text in this article, in combination with the proposed amended text in Article 4.3.8 point 1), transfers the legal obligation for traceability for business-to-consumer transactions to the importing country. We encourage the Commission to also ensure that this principle is clearly specified in the revised section 5 'Trade measures, importation/exportation procedures and health certification'. **Supporting evidence, if relevant:** not relevant

Article 4.3.10.

Official oversight

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

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 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.

In the event of confirmation of the *disease* for which the *compartment* was defined, the 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* 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 *Competent Authority* 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. ~~*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.~~
