**Annex 9. Item 6.5. – Chapter 4.3. Application of compartmentalisation – discussion paper**

**USA COMMENTS IN RED FONT**

Revised standards for compartmentalisation in the

WOAH *Aquatic Animal Health Code*

A discussion paper for Members’ comment developed by the

WOAH Aquatic Animal Health Standards Commission

September 2023

Summary

This discussion paper provides a means to engage WOAH members on issues relevant to the revision of *Aquatic Code* Chapter 4.3. Application of Compartmentalisation. 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. While compartmentalisation has particular relevance for aquatic animal diseases—because eradication is often not possible—it has not been adopted and recognised widely among member countries. Ultimately, revision of Chapter 4.3. aims to provide clarity on the requirements of compartments, improve acceptance and make private investment in it more attractive.

The discussion paper proposes a range of purposes for applying compartments (section 4), high-level principles to guide their application (section 6) and the concept of dependent and independent compartments (section 5). Together these proposals are intended to increase clarity on the application of compartments for effective risk management, while also broadening the range of circumstances where they might be applied.

Section 7 provides an analysis of the existing articles of Chapter 4.3.,and provides recommendations for the revision of existing articles and the development of new articles following the framework of principles proposed in section 6. A proposed article structure for the revised Chapter 4.3 is included at Attachment 2.

Questions are included throughout the document to prompt responses from members on issues of particular importance to the direction of the chapter’s revision. Member comments are invited in response to these questions and other matters relevant to the revision of Chapter 4.3. The questions are collated in Attachment 3.

Following consideration of member comments, the commission will recirculate the discussion paper to members with a summary of member responses and consensus views. Together the discussion paper and member responses will set the direction for the revision of Chapter 4.3.

1. Introduction

Compartmentalisation provides an opportunity to trade aquatic animal commodities with a specific disease-free status from zones or countries not declared free from those diseases. The application of compartmentalisation for aquatic animal diseases is considered an important mechanism to enhance safe trade—this is because eradication of aquatic animal diseases is often not possible, limiting alternative approaches to trade disease-free commodities from areas where listed diseases occur.

Chapter 4.3. of the *Aquatic Code* sets out recommendations concerning the application of compartmentalisation. Despite the passage of time since the chapter was first adopted in 2010 (and most recently updated in 2016) the concept of compartmentalisation for aquatic animal diseases has failed to be widely adopted. There are likely to be a range of reasons for this; however, it is clear that one key factor is the differing conceptual understanding of compartmentalisation among users of Chapter 4.3.

This paper aims to engage WOAH members on issues relevant to the revision of Chapter 4.3. such that the revised chapter will provide consistent and clear guidance on compartmentalisation. This discussion paper has been informed by member responses to a short questionnaire provided in the Commission’s September 2022 meeting report. A summary of member responses to the questionnaire is included at Attachment 1.

This paper also aims to explore and seek consensus on key conceptual issues relevant to compartmentalisation. For example, some member countries recognise two types of compartments: those that are dependent on the health status of the surrounding waters and those which are not. The potential for each type of compartment to engage in different types of trade (e.g. trade for human consumption versus trade for aquaculture) will be explored.

As the implementation of compartments may involve investment risk (i.e. a compartment must be established without certainty that desired market access will be granted), it is imperative that Competent Authorities, Aquatic Animal Health Services and the operators of aquaculture establishments have a common understanding of the requirements for establishing a free compartment guided by the standards of the *Aquatic Code*.

1. Objectives of the paper

The primary objective of this paper is to engage WOAH members in issues relevant to the revision of Chapter 4.3. such that the revised chapter will provide consistent and clear guidance on compartmentalisation to facilitate trade from compartments declared free from WOAH-listed diseases. Ultimately, revision of Chapter 4.3 aims to improve acceptance of compartmentalisation and make private investment in it more attractive.

In exploring issues relevant to revision of Chapter 4.3. this discussion paper aims to:

* Explore the conceptual understanding of what a compartment is and what its purpose is
* Draw on member’s experiences with compartmentalisation to inform revision of the standards to provide maximum common benefit while supporting safe trade
* Develop consensus on key conceptual issues prior to the commencement of drafting of the revised chapter.

In addressing the objectives described above, several principles are proposed to achieve these objectives, including that the provisions of the revised chapter should:

1. provide confidence among Members in the strength of self-declarations of compartment freedom in accordance with any proposed approaches in the *Aquatic Code*;
2. articulate the variety of purposes for which compartmentalisation might be applied;
3. provide risk management that is appropriate for different production system/product/pathway combinations;
4. provide standards that are as clear as possible to develop common understanding of requirements;
5. integrate with existing standards in other chapters of the *Aquatic Code*.

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| **Q1. Are the above principles (points A-E) to guide revision of Chapter 4.3. Compartmentalisation appropriate? If not, please suggest alternatives.** |
| Response:  The United States does not have any comments or concerns regarding the principles in points A or E.  Regarding point B: We view compartmentalization as a tool for the safe trade of animals/products, as defined in the Aquatic Code glossary. According to the Aquatic Code, compartment “means one or more aquaculture establishments under a common biosecurity management system containing an aquatic animal population with a distinct health status with respect to a specific disease or diseases for which required surveillance and control measures are applied and basic biosecurity conditions are met for the purpose of international trade. Such must be clearly documented by the Competent Authority(ies).” This definition is different from the Terrestrial Code equivalent, which specifies a compartment is for the “purposes of international trade or disease prevention and control in a country or zone.” As written, it is unclear in point B what additional “purposes for which compartmentalisation might be applied” is referring to beyond safe trade.  Regarding points C and D: We caution that guidance for compartmentalization can easily become too prescriptive or otherwise insufficient when applied across all system/product/pathway combinations. We therefore highly encourage a flexible approach. For example, instead of defining what risk management strategies are acceptable, WOAH could provide guidance on how to design a program or approach to oversee/verify acceptable risk strategies. The Competent Authority could then construct a mechanism or program around which *site-specific* risk management and surveillance strategies, commensurate with country level risks, could be evaluated and verified. Ideally, WOAH Standards would be output rather than input based, focused on the goal (e.g., pathway risk management) rather than a particular approach (e.g., well or treated water). This is something the surveillance chapter now does very well (e.g., focusing on the output confidence derived rather than the input fish sampled), and we recommend this approach for the compartmentalization chapter as well. |

1. Member responses to 2022 questionnaire

This discussion paper has been informed by member responses to a short questionnaire provided in the Commission’s September 2022 meeting report. The questionnaire invited responses from Members on their experiences in the application of compartments, including the purpose of compartments, positive experiences, acceptance by trading partners and constraints. A summary of member responses to the questionnaire is included at Attachment 1.

1. Purposes of compartmentalisation

The current definition of a compartment in the glossary of the *Aquatic Code* limits the purpose of a compartment to international trade (see section 8 of this discussion paper, definitions). However, free compartments are established to provide an assurance of disease freedom for a range of commodity types, trade pathways and intended end uses. These factors have implications for management of disease risk.

The commodities traded from a free compartment may include live aquatic animals (gametes, fertilised eggs, juveniles or adults) or aquatic animal products (ranging from whole slaughtered animals to any number of processed products consisting of parts of animals).

There are numerous potential end-uses for commodities traded from a compartment. Some of the principal end-uses that might be anticipated include:

* Human consumption – directly as live aquatic animals or products; or indirectly following grow out of juveniles in another aquaculture establishment.
* Breeding – use as brood stock in hatcheries or breeding centres to produce animals for grow-out; or for establishment of a new aquaculture species, or genetically selected lines of species, in a territory.
* Stock enhancement – release into open systems to enhance or recover wild populations.
* Ornamental purposes – for sale within the pet trade; or for display at zoos or aquariums.
* Research – provision of aquatic animals for scientific purposes.

Trade pathways from a compartment may include domestic or international trade (note that the current *Aquatic Code* definition is limited to international trade). Trade from a free compartment could, in most circumstances, be expected to occur from a zone or country not declared free to a country, zone or compartment declared free. Compartmentalisation might also be applied to provide epidemiological separation from populations of susceptible aquatic animals within a free country or zone to protect valuable aquatic animals (e.g. selected lines) in the event of a disease outbreak within the previously free zone/country.

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| **Q2. Do these purposes encompass the principal reasons for establishing a compartment, defined by product type, pathway and end use? If not, please provide alternative suggestions.** |
| Response: The purpose for establishing a compartment should be independent of the end use(s). Once the compartment is established with a given health status, then movement into or out of the compartment should take the health status of the compartment into consideration while also meeting the potential risks of disease transmission specific to given end use(s). In aquaculture, a single compartment could potentially provide commodities for all the end uses listed above (animals and products).  If we take the approach proposed above, then we support updating the definition of compartment in the Aquatic Code to better reflect the intent of the definition in the Terrestrial Code which includes the purpose of disease prevention and control, in addition to trade. |

1. Independent versus dependent compartments

Members have noted that there are two major types of compartments that have been recognised for international trade and which are categorised by the degree of epidemiological separation from the surrounding environment: independent and dependent compartments (see Attachment 1). Chapter 4.3. of the *Aquatic Code* does not currently differentiate types of compartments based on the degree of epidemiological separation.

Independent compartments have complete epidemiological separation from surrounding environments. These compartments have high levels of physical and management measures to maintain effective biosecurity. Independent compartments are closed-systems that have control over all transmission pathways into the compartment. An independent compartment may use disease free water sources (e.g. bore water) or have disinfection procedures in place to prevent the entry of pathogens of concern. Independent compartments may be used for high value aquatic animals (e.g., genetically improved lines, brood stock) and may be suited to end uses such as aquaculture and restocking programmes.

Dependent compartments do not have complete epidemiological separation from the surrounding environment and maintenance of their health status is dependent on freedom from diseases of concern in the surrounding natural waters. Dependent compartments are semi-closed systems which may have control over all transmission pathways but may not utilise sterile water sources (e.g., pump ashore tank or pond aquaculture). A dependent compartment would need to be established considering epidemiological factors to maintain epidemiological independence of the compartment (e.g., geographical location; environmental conditions; proximity to populations of susceptible species; presence, abundance, and behaviour of populations of susceptible species; disease status of any nearby populations of susceptible species; hydrological conditions in the adjacent water bodies). Dependent compartments can be considered to provide a lower degree of assurance of disease freedom relative to independent compartments; however, additional assurance may be provided through increased targeted surveillance and other epidemiological circumstances. Dependent compartments may be best suited for certain product types and end uses, e.g. processed product intended for human consumption.

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| **Q3. Do you support including the concepts of independent and dependent compartments in the revised Chapter 4.3? What are your reasons?** |
| **Response:** In general, we do not support the inclusion of independent and dependent compartments in this chapter. We do, however,support the broadening of the compartmentalization concept to include/address facilities beyond those that are fully enclosed (i.e., independent), as it is important for facilities to have the opportunity to address risk in context-specific and, sometimes novel, ways. If dependent compartments are defined in a manner that we (members) trust and hence facilitate trade, we question why there would be a need for an alternative, more stringent definition for an “independent” compartment? Instead of creating a second “compartment” type, we recommend defining compartments with respect to their dependencies, such as the zone or country status, and establish guidance for how to address the concerns about the inter-dependencies. We feel there should only be one kind of compartment. We also recognize that compartments which currently meet the parameters of an “independent” compartment will most likely have an easier time meeting the parameters of a single WOAH-defined compartment but should not otherwise receive special status through the designation of an “independent” compartment. We are concerned that assigning special “independent” status to those that have an easier time meeting the compartment parameters, would only serve to provide an excuse for denying compartmental status to situations where more effort is required.  In summary, we do not support the use of independent vs. dependent compartments, and instead recommend that this chapter focuses on providing parameters and guidance for evaluating and establishing a compartment, emphasizing an output-based approach focusing on the goal (e.g., pathway risk management) rather than a particular approach (e.g., well or treated water). This is something the surveillance chapter now does very well (e.g., focusing on the output confidence derived rather than the input fish sampled), and we recommend this approach for the compartmentalization chapter as well. Programs using output-based standards/approach aim to demonstrate the degree of confidence in current (and future) pathogen absence, rather than simply whether the participant used a WOAH-described approach. |
| **Q4. Should a dependent compartment be able to supply live aquatic animals for aquaculture or restocking? If yes, under what conditions should this trade be allowed (e.g. epidemiological separation, targeted surveillance)?** |
| **Response:** Please see the response to Question 3 above regarding the use of independent vs. dependent compartments. In general, the end goal of trade between compartments should be to inform like-to-like movements or low-to-high risk movements. We therefore recommend (as described above), an output-based approach which is ideally overseen by a program that is auditable by trading partners. These benchmarks and parameters then provide the information and confidence necessary to make informed movement decisions. |

1. General principles of compartmentalisation

The following principles are proposed as high-level guidance for the development of compartments and to frame the article structure of a revised Chapter 4.3.

1. A disease-free compartment represents a functional epidemiological separation of a population of aquatic animals within it from other sources of infection.
2. The purpose of the compartment must be clearly defined (e.g., species and commodities produced, disease(s) for which freedom will be claimed, end uses of commodities) as this will have implications for the design of risk management measures.
3. Compartments may include two principal categories: those that are dependent on the disease status of the surrounding environment and those which are independent from it.
4. A compartment must have an effective biosecurity plan in accordance with Chapter 4.1. that is applied consistently across all elements of the compartment.
5. Surveillance measures to establish the compartment as free, and the measures to maintain compartment freedom, must be clearly described in accordance with Chapter 1.4., including elements of internal and external surveillance as appropriate.
6. Reliable laboratory testing services are required to underpin surveillance testing. The laboratory services must have independence from the compartment operator and have quality management accreditation.
7. Traceability systems must provide assurance of provenance of commodities from the free compartment.
8. Record keeping must support the transparent and ongoing application of all measures on which the compartment has been granted disease free status.
9. Official oversight responsibilities must be clearly documented, including registration or approval by the Competent Authority, an auditing schedule and underpinning regulatory instruments.
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.

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| **Q5. Do the general principles of compartmentalisation described above provide an appropriate high-level framework for the establishment and recognition of a compartment? Please suggest any amendments or additional principles that should be considered?** |
| **Response:** In general, these principles cover the overall framework needed for establishing and recognizing a compartment, except for Principle 3 – “Compartments may include two principal categories: those that are dependent on the disease status of the surrounding environment and those which are independent from it.” We do not support the use or delineation of “dependent” vs. “independent” compartments (see additional responses above to Questions 3 and 4). We feel total independence is a very difficult threshold to meet, and instead recommend focusing on the goal of a defined output (e.g., confidence in health status) and how that output is verified, rather than oversimplified input (dependent versus independent) categories. |

1. Analysis of the current adopted text of Chapter 4.3.
   1. Article 4.3.1. Introduction and objectives

Current situation and analysis

Article 4.3.1. provides a broad description of compartments and comparison to declaration of freedom at a country or zone level. The current text describes compartments through comparison, for example to zones, rather than describing what a compartment is more directly. The current text lacks clarity on some basic concepts related to compartments; for example, their purposes, benefits, and roles for establishment and maintenance. The article is titled introduction and objectives; however, the article does not clearly state any objectives for the chapter.

Recommended approach

It is important that article 4.3.1. clearly define what a compartment is. This is important to convey a common understanding and to avoid varying conceptual interpretations, which has been indicated as a constraint (see Attachment 1).

Text could be added to this article to articulate a clear objective of the chapter, for example, to describe the requirements for establishing a free compartment and for meeting the requirements for a self-declaration of compartment freedom to be made.

It is proposed that article 4.3.1. be revised to more directly describe the concept of a compartment, rather than by comparison to zones. The text should also introduce the purposes of establishing compartments, the benefits for facilitating trade and disease management, and the roles of the private sector and competent authorities broadly.

It is also proposed that a new article 4.3.X. be included in the revised chapter to clearly describe the varying purposes of establishing compartments, as indicated by member responses to the survey (see Attachment 1). These would include facilitating trade of disease-free animals and animal products (not limited to international trade), to contribute to disease management, and to protect and preserve valuable aquatic animals (e.g. selected lines) in the event of a disease outbreak in an otherwise free country or zone.

* 1. Article 4.3.2. Principles for defining a compartment

Current situation and analysis

Article 4.3.2. indicates that a compartment should have its components and interrelationships described and that epidemiological factors should be defined. This text does not adequately articulate a set of principles for defining a compartment.

Recommended approach

It is proposed that this article be revised to clearly state the high-level principles that must be met for a compartment to be established and for a self-declaration of compartment freedom made. These principles would then align with the article structure for the chapter which would provide further details on how to meet the requirements of each principle. This approach has been used in Chapter 4.1. Biosecurity for aquaculture establishments (see article 4.1.2.) and Chapter 4.4. Disinfection of aquaculture establishments and equipment (see article 4.4.2.).

Possible principles for inclusion in this article could reflect those of section 6 above.

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| **Q6. Do you support the revision of article 4.3.2. to include the principles in section 6 above (as modified based on member comments)? Are there any additional key issues or requirements that should be addressed within a set of principles?** |
| **Response:** In general, we support these revisions as long as they are not too prescriptive. We recommend this article instead focus on guidelines for building a program that measures/verifies confidence in health status, rather than setting specific biosecurity/surveillance requirements that may or may not apply in different contexts. |

* 1. Article 4.3.3. Separation of a compartment from potential sources of infection

Current situation and analysis

Article 4.3.3. is a large article that covers four main topics as subpoints:

1. Physical or spatial factors that affect the status of biosecurity in a compartment
2. Infrastructural factors
3. Biosecurity plan
4. Traceability system

A significant portion of this article covers biosecurity planning and measures that are addressed more comprehensively in Chapter 4.1. Biosecurity in aquaculture establishments.

Recommended approach

It is proposed that article 4.3.3. be revised to focus on the description of a compartment and the nature of its epidemiological independence. This would include describing the concepts of dependent and independent compartments (see section 5 above).

It is proposed that biosecurity plan and traceability requirements be addressed in separate articles as appropriate to align with the principles proposed for article 4.3.2.

* 1. Article 4.3.4. Documentation

Current situation and analysis

Article 4.3.4. provides guidance on the records that should be kept to provide evidence that the requirements of a compartment are being met. Much of this article focuses on record keeping relevant to matters addressed in a biosecurity plan or for surveillance requirements. The article indicates that the time periods for maintaining records may vary.

Recommended approach

For the elements of this article relevant to documentation of a biosecurity plan, it is proposed that a cross reference to the relevant articles in Chapter 4.1. be included.

For the elements of this article relevant to surveillance, it is proposed that this text be revised and replaced with more specific requirements of the evidence to meet surveillance requirements to claim self-declaration of compartment freedom, and to maintain freedom. This would include reference to Article 4.3.5. (as revised, see below) and any relevant articles in Chapter 1.4.

It is proposed that guidance be provided on factors for determining the time periods for keeping records. These should be linked to production cycles, surveillance, biosecurity plan requirements, auditing, and traceability requirements.

It is proposed that this article be moved lower such that it would follow all relevant articles for which there is a record keeping requirement.

* 1. Article 4.3.5 Surveillance for the pathogenic agent or disease

Current situation and analysis

This article advises that the surveillance system should comply with Chapter 1.4. on surveillance and the specific recommendations for surveillance for the disease(s) for which the compartment was defined. The article notes that the sensitivity of the surveillance system should be reviewed if there is an increased risk of exposure to the agent for which the compartment has been defined.

The article also describes internal and external surveillance requirements. Internal surveillance is described as allowing the Competent Authority to certify that animals within the compartment comply with its defined status and to enable early detection of disease. External surveillance is intended to identify a significant change in the level of exposure for the identified pathways of disease introduction into the compartment.

Recommended approach

It is proposed that this article be revised to align more closely with the requirements for making a self-declaration of compartment freedom and the requirements for maintaining freedom. These requirements are included in Chapter 1.4. and the relevant disease specific chapters of the *Aquatic Code*.

The concepts of internal and external surveillance are likely to be useful however they are not terms that are used in Chapter 1.4. or in disease specific chapters. It is proposed that these concepts be considered and perhaps applied in the context of dependent and independent compartments. See section 5 above.

* 1. Article 4.3.6. Diagnostic capabilities and procedures

Current situation and analysis

This Article advises that testing laboratories should be officially designated and that testing procedures should comply with recommendations of the *Aquatic Manual*. It also advises that testing laboratories should have procedures in place for reporting results to the Competent Authority.

Article 4.3.6. provides guidance on diagnostic procedures that underpin surveillance within a compartment and confidence in the compartment’s disease-free status. Several factors that influence the quality of diagnostic testing are not referenced in the article.

Recommended approach

It is suggested that article 4.3.6. be revised to address additional factors that contribute to reliable diagnostic testing. These include independence of the testing laboratory from management and ownership structures of the compartment and a requirement for officially approved testing laboratories to be accredited to ISO Standard 17025 or equivalent.

There should be a mandatory requirement for testing laboratories to report positive test results to the competent authority for compartments declared disease free for the purposes of international trade. This is necessary to meet the requirements of basic biosecurity conditions of a compartment as specified in Article 1.4.6. of Chapter 1.4 of the *Aquatic Code*.

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| **Q7. Do you support the recommended approach to revision of article 4.3.6., including requirements for independence, accreditation and mandatory laboratory reporting? Please provide rationale or further comments.** |
| **Response:** In general, we support the inclusion of these principles; however, reporting of WOAH listed pathogens by laboratories should not be dependent or qualified by compartment status, and all  detections of listed pathogens should be reported. WOAH pathogen chapters (for aquatics) are often out-dated and do not include newer test methods and many of the test methods listed for aquatic animal pathogens are not validated. Therefore, laboratories receiving samples may not be aware of said status. Furthermore, laboratory quality management should be balanced with diagnostic methodology and proficiency. In our experience, just because a laboratory has paid for ISO status, this status alone does NOT indicate quality, accuracy, or reliability of diagnostic work. Lastly, the current WOAH basic biosecurity conditions seem to apply best to zones and countries, rather than compartments. We therefore recommend the terminology for compartments should focus on biosecurity or risk management. |

* 1. Article 4.3.7. Emergency response and notification

Current situation and analysis

This article provides guidance on the actions to be taken if there is suspicion of occurrence of the disease from which the compartment has been declared free. Paragraph 1 advises that if there is suspicion of occurrence of the disease, free status should be suspended, and importing countries notified in accordance with Chapter 1.1. The language in this paragraph differs from Chapter 1.1 which requires notification of occurrence or recurrence, not suspicion.

Paragraph 2 advises that a review of biosecurity measures should be initiated to determine if there has been a breach of biosecurity measures and free status should only be reinstated after the compartment has adopted the necessary measures to re-establish the original biosecurity level and the Competent Authority has re-approved the status of the compartment. The requirements of this paragraph differ subtly from those of Chapter 1.4. and disease specific chapters which require that basic biosecurity measures be reviewed and amended as appropriate. Further, for the purposes of international trade, free status can only be reclaimed once the requirements of Chapter 1.4 and the relevant disease specific chapters have been met.

Paragraph 3 advises that any changes in disease risk in the surrounding area should be considered, the status of the compartment re-evaluated and the need for additional biosecurity measures implemented. This paragraph appears to be most relevant for dependent compartments; however, could be considered as part of the review of basic biosecurity conditions. Specific mention of factors to be reviewed for either dependent or independent compartments may be warranted.

Recommended approach

Article 4.3.7. requires revision to ensure guidance is consistent with other provisions of the *Aquatic Code*, for example, notification requirements of Chapter 1.1. and the requirements for returning to compartment freedom specified in Chapter 1.4. and the relevant disease-specific chapter(s). The article may also require cross-referencing to new chapters under development for Section 4 of the *Aquatic Code* on emergency preparedness and outbreak management.

* 1. Article 4.3.8. Supervision and control of a compartment

Current situation and analysis

Article 4.3.8. requires that the authority, organisation, and infrastructure of the Aquatic Animal Health Services be clearly documented to provide confidence in the integrity of the compartment. The article cross references to Chapter 3.1. Quality of Aquatic Animal Health Services but does not limit documentation of the Aquatic Animal Health Services to those aspects relevant to the self-declaration of compartment freedom. The article specifies that authority, organisation, and infrastructure of the Aquatic Animal Health Services should be documented; however, Chapter 3.1. includes 14 fundamental principles of quality. The article might be improved by clarifying that the Aquatic Animal Health Services relevant to the self-declaration of freedom should be documented, including how these relevant Aquatic Animal Health Services meet the requirements of Chapter 3.1.

The article also advises that “the” Competent Authority has final authority on approving or suspending status and that the Competent Authority should continuously supervise compliance with all requirements critical to maintaining compartment status. This is a principal concept of Competent Authority oversight of a disease-free compartment. It may be beneficial to more clearly articulate the role of competent authorities and the Veterinary Authority in establishing and approving a disease-free compartment, providing ongoing oversight (including of relevant Aquatic Animal Health Services) and for communication with WOAH and trading partners as specified in relevant chapters of the *Aquatic Code*.

Recommended approach

It is suggested that Article 4.3.8. be separated into two articles: one on quality of Aquatic Animal Health Services and one on supervision and authority. The article on quality of Aquatic Animal Health Services should clarify that the Aquatic Animal Health Services relevant to the self-declaration of freedom should be documented, including how they meet the requirements of Chapter 3.1. The second article should clearly articulate the role of competent authorities and the veterinary authority in establishing and approving a disease-free compartment, and providing ongoing oversight.

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| **Q8. Do you support the proposed revision of article 4.3.8., including division into two articles: one on quality of Aquatic Animal Health Services and one on Competent Authority oversight? Please provide rationale or further comments.** |
| **Response:** It is our understanding that the current definition of “Aquatic Animal Health Services” broadly includes laboratories, veterinarians, and other stakeholders; as such, the proposed approach may be too prescriptive for members which have different government authorities involved in aquatic animal health that may also have differing mechanisms of regulations and authority. In general, we support a broader approach to this guidance which identifies principal thresholds that must be met, while also allowing a given country/member the flexibility to meet those thresholds within their current systems of oversight. |

1. Definitions

Current status

Two terms specific to compartments are included within the glossary of the *Aquatic Code* and will require consideration during the revision of Chapter 4.3. Compartmentalisation. These include the definitions for “compartment” and “free compartment”. The current definitions for these terms as included in the 2023 edition of the *Aquatic Code* are:

*COMPARTMENT* means one or more *aquaculture establishments* under a common *biosecurity* management system containing an *aquatic animal* population with a distinct health status with respect to a specific *disease* or *diseases* for which required *surveillance* and control measures are applied and *basic biosecurity conditions* are met for the purpose of *international trade*. Such must be clearly documented by the *Competent Authority(ies)*.

*FREE COMPARTMENT*means a *compartment* that fulfils the requirements for *self-declaration of freedom from disease* with respect to the *disease(s)* under consideration in accordance with the relevant chapter(s) in the *Aquatic Code*.

Many additional defined terms are relevant to the revision of Chapter 4.3., for example those related to surveillance and biosecurity. Many of these terms, have been recently revised during the development and adoption of the new Chapter 4.1. Biosecurity for Aquaculture Establishments (adopted 2021) and revision of Chapter 1.4. Aquatic Animal Health Surveillance (adopted 2022).

Analysis

The specific terms related to compartments are likely to require revision to ensure they are fit for purpose for the agreed scope, purposes and concepts included in the revised chapter. For example, some issues that may need to be addressed are:

* the current definition limits the purpose of a compartment to international trade. This may be too narrow based on Member comments (see Attachment 1) and consideration of the concepts in sections 5 and 6 above.
* there may be a need to define “types” of compartments that offer different levels of risk management based on their purpose (e.g. dependent and independent compartments). Members raised different types and purposes of compartments in their survey responses (see Attachment 1) that may need to be reflected in revised definitions, or be the subject of new definitions.

1. Other interacting standards

There are several chapters within the WOAH *Aquatic Code* that are relevant to a revision of Chapter 4.3. It is important that these standards are considered so that appropriate cross references are provided, and that duplication or conflicting guidance avoided. This section of the discussion paper identifies key standards of the *Aquatic Code* that should be considered in the revision of Chapter 4.3.

**Disease specific chapters.**

Each disease specific chapter of the *Aquatic Code* provides guidance on the requirements for declaring a free compartment for that disease. The requirements in these articles are consistent with and cross reference Chapter 1.4. Surveillance.

In addition, the disease-specific chapters provide recommendations on risk management for aquatic animal commodities (of susceptible species for that disease) for different end uses; in particular, where the source of the commodities is a country, zone or compartment not declared free.

**Chapter 1.4 Surveillance.**

Chapter 1.4. provides guidance on the surveillance required to demonstrate freedom at the level of a compartment. The provisions in Chapter 1.4. for surveillance to declare a compartment free complement the provisions of disease-specific chapters.

**Chapter 3.1. Quality of Aquatic Animal Health Services**

Chapter 3.1. sets out the fundamental principles of an ethical, organisational, legislative, regulatory and technical nature which define the quality of aquatic animal health services. The provisions of Chapter 3.1 are important to characterise the transparent and independent oversight and services that underpin confidence in the ongoing disease free status of a compartment.

**Chapter 4.1. Biosecurity of aquaculture establishments.**

Chapter 4.1. provides detailed guidance on the requirements for developing and implementing a biosecurity plan. The provisions in Chapter 4.1. are fundamental to establishing and maintaining compartment freedom.

**Chapter 5.3. WOAH procedures relevant to the Agreement on the Application of Sanitary and Phytosanitary Measures of the World Trade Organization.**

Article 5.3.7 describes the sequence of steps to be taken to establish a zone or compartment and have it recognised for international trade purposes.

1. Discussion

This paper has aimed to engage WOAH members on issues relevant to the revision of Chapter 4.3. so that the revised chapter will provide consistent and clear guidance on compartmentalisation. Principles are presented in section 3 to guide the intended outcome of the revision. The discussion paper has explored conceptual issues relevant to the revision of the paper, analysed the current structure of the existing Chapter 4.3 and sought responses from members on key issues of importance to its revision.

A proposed article structure for the revised Chapter 4.3. has been proposed at Attachment 2, based on the analysis and discussion presented in this paper.

Following consideration of member comments, the commission will recirculate the discussion paper to members with a summary of member responses and consensus views. Together the discussion paper and member responses will set the direction for the revision of Chapter 4.3.

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