**Annex 50. Item 8.1. – Chapter 4.3. Application of compartmentalisation – discussion paper**

Revised standards for compartmentalisation in the

WOAH *Aquatic Animal Health Code*

A discussion paper developed by the

WOAH Aquatic Animal Health Standards Commission

Version 2, February 2024

(including member responses)

Summary

This discussion paper has been used as a means to engage WOAH Members on issues relevant to the revision of the *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, as eradication is often not possible, it has not been adopted and recognised widely among Members. 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 proposed 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 were 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 provided an analysis of the existing articles of Chapter 4.3., and provided 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 as Attachment 2.

Questions were included throughout the document to prompt responses from Members on issues of particular importance to the direction of the chapter’s revision. Member comments were received on the first version of the discussion paper (September 2023) from Australia, Canada, Chile, China, Japan, New Caledonia, Norway, Peru, Singapore, Thailand, United Kingdom, United States of America (USA), African Union-Interafrican Bureau for Animal Resources, and the European Union (EU).

The responses from Members were considered by the Aquatic Animals Commission at its February 2024 meeting. Member comments are summarised within this revision of the document with the majority views presented together with significant comments or minority views. Based on this consideration of Member comments, the Commission has proposed preferred approaches to the drafting of the revised Chapter 4.3.

This is the final version of the discussion paper which will be used as a reference for drafting a revision of Chapter 4.3. Further consultation with Members will be through the revised draft of Chapter 4.3. which will be provided to Members for comment in the report of a subsequent meeting of the Commission.

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 discussion paper aimed 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. The discussion paper was 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 aimed to explore and seek consensus on key conceptual issues relevant to compartmentalisation. For example, some Members 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) was 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 was 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 aimed 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 were 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.  |
| Member responses: Members supported these principles to guide the revision of Chapter 4.3., most without any comment. Some Members emphasised the importance of some principles or provided comment on particular principles. Some points raised by individual Members include:* A Member emphasised the importance of principle A (confidence in the strength of self-declarations of compartment freedom), noting that variation in application of approved compartment standards has been a long-standing issue for them and that without a common standard the potential for conflict between trading partners is raised, as is the possibility of disease introduction.
* Some Members recommended that an outcome-based approach (i.e. confidence in disease freedom) be followed to ensure that there is flexibility within Chapter 4.3. for Members in how freedom is achieved and to avoid an overly prescriptive, input-based approach (i.e. specific measures). One Member commented that appropriate risk minimisation is based on the assessment of risk and the determination of an importing country’s appropriate level of protection.
* Some Members noted that the system for self-declaration of freedom is not being fully utilised and recommended that WOAH explore how the scheme can be developed to ensure a greater value as documentation for trade.

Discussion and Commission’s proposed approach:The principles for the revision of Chapter 4.3 are sound but will require some balance between competing principles (e.g. clear guidance to support Member confidence in self-declaration of freedom while also supporting flexibility and outcome-based approaches). |

1. Member responses to 2022 questionnaire

This discussion paper was 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 principle 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.  |
| Member responses: Members in general agreed with the proposed end-uses of products but noted that, as worded these are end-uses rather than objectives for establishing a compartment. Some Members provided alternative wording or queried the relevance of the question, noting that for whatever reason it was established, a compartment must meet the surveillance and biosecurity requirements which are necessary to ensure there is disease-specific separation between it and the surrounding environment.Some Members noted that, broadly, the reasons for establishing a compartment are to facilitate trade or for disease prevention and control. One Member commented that the concept of compartmentalisation with respect to the *Aquatic Code* should be limited to international trade, noting that animals and animal products from a disease-free compartment for international trade purpose could also be traded domestically. Another member emphasised the importance of free compartments for re-establishing freedom following a disease outbreak, for protecting trade in the event of a disease outbreak, and for protecting valuable stock with genetic or environmental importance.One Member commented that the current definition of a compartment enables multiple production units that can be geographically separated to be included in a single compartment, however, there is no clear guidance as to how to connect multiple production units while maintaining disease free status within one compartment.A Member commented that it should not be necessary to require a disease-free compartment for aquatic animal products for human consumption (i.e. seafood), that this could create unnecessary barriers to trade, and proposed that other existing standards are sufficient to ensure safe trade in seafood.Some Members questioned how certain examples of production system/product scenarios could meet the requirements of a compartment. One Member noted that while a compartment may be able to supply disease free product, there may be difficulty in maintaining freedom along the supply chain (e.g. ornamental fish traded through distribution centres).Discussion and Commission’s proposed approach:The Commission agreed to reword the end-uses of product derived from a compartment to define these more clearly as purposes, with broad categories of facilitating trade and for disease prevention and control. The revised wording, adapted from a Member’s suggestion, will be utilised in the drafting of chapter 4.3. and would appear in article 4.3.2.The Commission noted that the *Aquatic Code* provides recommendations for international trade between Members but agreed that it also provides guidance for disease prevention and control. The Commission agreed that, while some standards of the *Aquatic Code* are intended for international trade among Members, it was unnecessary to define compartments as being exclusively for international trade.The Commission did not agree with the Member comment that compartments should not be used for trade of products. The Commission considered that this is contrary to the current approach of the *Aquatic Code* and would drastically reduce the application of compartments for disease-free trade.The Commission noted that to achieve free status, the proponent would need to demonstrate epidemiological separation of the compartment from other populations. This would not always be feasible or cost-beneficial and alternative risk mitigation measures may be more appropriate in some circumstances. |

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 for intake water 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 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?  |
| Member responses: A majority of Members supported the concept of independent and dependent compartments, however, several Members opposed the concept. Members supporting the concept of dependent compartments noted that it would enable compartmentalisation to be applied to more types of production systems and more establishments, increasing opportunities to trade in disease-free commodities. Some of these Members noted that the requirements for dependent compartments, to ensure confidence in their disease-free status (e.g. biosecurity and surveillance), would need to be clear. A Member noted that the concepts of both independent and dependent compartments are currently recognised for international trade among some countries.Some Members opposing the concept of dependent compartments commented that it would not be possible to define a compartment as free without complete epidemiological separation from surrounding environments. One Member commented that for dependent compartments, maintenance of free status may not be fully within the control of the operator and that this could create risk. One Member, while not supporting distinction into two types of compartments, supported the broadening of the compartmentalisation concept to include facilities beyond those that are fully enclosed (i.e., independent), and explained that it is important for facilities to have the opportunity to address risk in context-specific and sometimes novel ways.Discussion and Commission’s proposed approach:Consistent with the majority view of Members, the Commission agreed to develop the revised draft chapter to include the concepts of dependent and independent compartments. The Commission considered the comments of all Members (those supportive and those not supportive of dependent compartments) in the context of the principles in Section 2 of this discussion paper, in particular:* That some Members indicated a lack of confidence in the strength of declarations of freedom associated with dependent compartments. The Commission considered that appropriate risk management measures for dependent compartments may address these concerns.
* Many Members wish to broaden the application of compartmentalisation beyond independent compartments. The Commission noted that some Members currently recognise dependent compartments in bilateral trade, and may also recognise other arrangements that may be comparable (e.g. facility freedom). These arrangements are currently outside the scope of the standards of the *Aquatic Code*, and harmonised standards for dependent compartments may provide guidance for some of these circumstances.
* The standards of the disease-specific chapters of the *Aquatic Code* currently provide risk management guidance for specific product types and end-uses. This approach can be applied to dependent compartments as necessary; however to maintain flexibility, it should be in the form of risk mitigation options rather than be prescriptive.
* The inclusion of two types of compartments would create some complexity for Chapter 4.3., however, the Commission agreed the benefits of the approach to meet other principles of Section 2 are compelling.
* The Commission considered that the concepts of both dependent and independent compartments could be integrated within the framework of the disease specific chapters of the *Aquatic Code*.

Additionally, the Commission noted that due to the wide distribution of some diseases, country freedom was not a feasible avenue for many Members to trade in disease-free aquatic animals or their products. In this context, the concept of dependent compartments may increase the opportunities for disease-free trade. It may also make private investment in compartmentalisation more attractive.The Commission agreed that, based on Member responses, only closed systems are suitable to be defined as independent compartments (see production type definitions in Chapter 4.1. ‘Biosecurity for aquaculture establishments’). The Commission considered that dependent compartments should be restricted to semi-closed systems. Semi-open systems would not provide adequate enterprise-level control, and freedom for these system types would be best demonstrated through zoning. A summary of the proposed characteristics of dependent and independent compartments are provided below. Characteristics of independent and dependent compartments: |
| Independent | **Dependent** |
| High level of biosecurity management across all pathways | High level of biosecurity management across most pathways.  |
| Status not dependent on disease free status of the surrounding waters | Status dependent on the disease free status of the surrounding waters  |
| Only closed systems are a suitable production system type | Only semi-closed systems are a suitable production system type |
| 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 |
| Suitable for all product types and pathways | May not meet the required level of risk mitigation for all product types and pathways |

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| 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)? |
| Member responses: A small majority of Members were supportive of a dependent compartment supplying live aquatic animals for aquaculture or restocking, contingent on surveillance and biosecurity requirements being met that provided sufficient assurance of disease freedom. Several possible measures to provide additional assurance were suggested such as post-harvest testing, auditing within the production cycle, targeted surveillance to meet WOAH standards within the compartment and in the zone surrounding the compartment, and a higher level of surveillance to maintain the compartment than would be required for an independent compartment.Many Members were opposed to a dependent compartment supplying live aquatic animals for aquaculture or restocking. Some of these countries cited the risk of disease transmission as a reason that such trade should only occur from a dependent compartment. Some Members opposing this trade proposed additional risk mitigation activities that may provide appropriate assurance. Several Members commented that the standards should not be too prescriptive, so that they can be adapted to the circumstances of trade among different countries.Discussion and Commission’s proposed approach:The Commission agreed that it is preferable that the standards provide a degree of risk management that is broadly suitable to Member circumstances. The Commission noted that an importing country is free to apply measures that are less stringent than the standards as relevant to their circumstances. Conversely, if the standards do not meet a Member’s appropriate level of protection (ALOP), more stringent measures can be applied if justified by a risk analysis. The Commission noted that revisions to Chapter 4.3. can provide a flexible outcome-based approach (i.e. assurance of freedom sufficient to meet an importing country’s ALOP), whilst also providing clear expectations on the procedures for declaration and recognition of a free compartment. In this regard, the Commission agreed that Chapter 4.3. should avoid being too prescriptive about the conditions for dependent compartments, however, guidance on appropriate risk mitigation measures which can be applied may be of assistance to Members.  |

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?  |
| Member responses: Members were generally supportive of the proposed principles. Specific comments were provided as described below. Discussion and Commission’s proposed approach:Principle 1. Epidemiological separation. Some Members questioned whether functional epidemiological separation could be achieved for dependent compartments. The Commission noted that epidemiological separation for dependent compartments (i.e. between disease-free populations within the compartment and external diseased populations) is achieved through some additional measures and epidemiological circumstances (e.g. absence of susceptible species in surrounding environment, absence of infection in surrounding environment). The requirements for epidemiological separation would preclude some enterprises from being able to demonstrate dependent compartment freedom. Principle 2. Purpose. Two Members questioned having defined end-uses of compartments, one questioned the merit of production of seafood from compartments. The Commission noted that product for human consumption from free countries, zones or compartments is consistent with the standards of the *Aquatic Code*. The Commission agreed that the purposes of a dependent compartment may have a bearing on the development of risk management measures (refer to Member responses and discussion for questions 2 and 4 above) to meet Competent Authority requirements of an importing country. The Commission also noted that international standards for quality management systems (e.g., ISO 9001) may be used to implement and audit biosecurity plans and quality management systems require the purpose/goods of the enterprise to be defined.Principle 3. Independent/dependent. Some Members which are not supportive of the concept of dependent compartments did not agree with this principle. The Commission agreed that this principle would be retained in accordance with the Member comments and discussion for question 3 (see above).One Member noted that when such a compartment is used for breeding, it is common to operate with a closed population but it must be supplied with new genetics at regular intervals and this possibility must be accommodated. The Commission considered that the management of risks associated with this scenario would be determined through the development of a compartment’s biosecurity plan and could also be guided by the other existing standards of the *Aquatic Code*.Principle 4. Biosecurity plan. One Member commented that the word “effective’ should be removed as an “effective biosecurity” plan was subjective. The Commission agreed.Principle 5. Surveillance. One Member queried how surveillance requirements would apply for dependent compartments. The Commission agreed that guidance for surveillance to establish and maintain a dependent compartment should be elaborated in the revision of chapter 4.3. The Commission noted that some complementary revisions to Chapter 1.4. may need to be considered as Chapter 4.3. is revised. This had been anticipated at the time the revised Chapter 1.4. was developed.Principle 6. Laboratory testing. One Member raised concerns about the consequences of introducing a requirement for laboratories to have quality management accreditation. The Commission noted that accreditation for laboratory testing services to support a declaration of freedom is not currently a requirement within Chapter 1.4. of the *Aquatic Code*. However, the Commission noted that Article 1.4.5. requires that for any self-declaration of freedom, the quality of Aquatic Animal Health Services (AAHS) must be substantiated to meet the requirements of Chapter 3.1. This issue is addressed further at question 7.Another Member emphasised the importance of laboratory testing services and surveillance protocols discussed being open to scrutiny by the competent authorities. The Commission noted that transparency is fundamental to the self-declaration process in accordance with Article 1.4.4. of the *Aquatic Code*.Principle 7. Traceability. Members supported this principle.Principle 8. Record keeping. Some Members commented that they would like to see specific reference to record keeping, as this is a key factor in maintaining an approved compartment, particularly with reference to full traceability of animals and products entering the site, and maintenance of accurate and contemporary mortality records. Principle 9. Official oversight. Some Members emphasised the important role played by the Competent Authority in the establishment, recognition, and ongoing maintenance of disease-freedom for compartments. They commented that the operator of a compartment must implement any measures which are required by the Competent Authority. Some Members emphasised the importance of auditing and noted that audits can be done by the AAHS, not necessarily by the Competent Authority, but that Competent Authorities should have a system of oversight for the AAHS providing audit services. Other Members sought explicit guidance on the roles of CAs versus AAHS. The Commission agreed that the CA is responsible for oversight, may authorise third parties within the aquatic animal health services for important roles (e.g. auditing), but must ensure the quality of the aquatic animal health services providing those services. Principle 10. Notification. Members agreed with the need for notification and response requirements. One Member commented that notification must include any other listed disease, or any other diseases relevant to trade from the compartment because a disease outbreak in an approved compartment may indicate a breakdown in biosecurity. One Member noted that in the event of disease detection, thorough investigation into the occurrence should be undertaken to try to learn any lessons associated with biosecurity breaches. The Commission noted that this is accommodated in the provisions for returning to freedom after an outbreak which require a review of basic biosecurity conditions.  |

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 a compartment. 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 to be 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 4.3. ‘Disinfection of aquaculture establishments’ (see article 4.3.2.).

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?  |
| Member responses: All Members supported the inclusion of these principles in Article 4.3.2 (as discussed in question 5); however, some Members noted that they should not be too prescriptive.Discussion and Commission’s proposed approach:The Commission noted the agreement of Members. |

* 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 factors 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.  |
| Member responses: Members broadly supported the suggested requirements for independence and mandatory reporting. However, Members had divergent views on the requirement for laboratory accreditation.Several Members emphasised the need for quality of the testing services and agreed that ISO 17025 accreditation was appropriate. One Member advised that accreditation is a mandatory requirement for testing laboratories under their national legislation. However, some Members were concerned that a requirement for ISO 17025 accreditation or an equivalent standard was not the only means to establish the quality of testing services and that a more flexible approach may be appropriate. Discussion and recommended approach:The Commission agreed that laboratory accreditation in accordance with ISO17025 or an equivalent standard was preferable but should not be prescribed. The Commission noted that the provisions of the *Aquatic Code* do not currently require accreditation of laboratory testing services associated with a self-declaration of freedom (for a country, zone or compartment). However, Article 1.4.5. requires that for any self-declaration of freedom, the quality of Aquatic Animal Health Services must be substantiated in accordance with the requirements of Chapter 3.1., and quality management systems are relevant substantiation for testing laboratories. This issue is also addressed at question 5.The Commission emphasised the fundamental importance of independence of the laboratory testing services from the compartment operator. |

* 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 principle 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: Members broadly supported the approach to revise Article 4.3.8. Some Members commented that the roles of the Competent Authorities and the Aquatic Animal Health Services be clearly articulated, including the central role of the Competent Authority. A Member commented that once the Competent Authority has established the guidance and authorisation of a compartment, the AAHS should be able to administer ongoing maintenance. One Member requested that the revised articles acknowledge that a trading partner may recognise a Competent Authority’s oversight and the quality of their Aquatic Animal Health Services through a system audit. They also requested recognition that direct establishment-based audits may be requested by trading partners before initiation of trade under certain circumstances.A Member noted that revision of Chapter 3.1. ‘Quality of Aquatic Animal Health Service’s is on the forward workplan of the Commission and that this may need to be taken into account when revising Article 4.3.8. |

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 in 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. 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.

The first version of the discussion paper was provided to members in the September 2023 report of the Aquatic Animals Commission. This second version of the discussion paper incorporates Member responses to eight questions included in version 1. Members responses to these questions are summarised, together with the Commission’s considerations and proposed approaches to revision of Chapter 4.3.

The proposed article structure for the revised Chapter 4.3. remains unchanged from that provided in version 1 of the discussion paper and is provided at Attachment 2. The content and emphasis of these articles will be informed by the outcomes of this discussion paper process.

This version 2 of the discussion paper is the final step in the discussion paper process. This document will now be used as a reference to guide the drafting of the revised Chapter 4.3. and further consultation with Members will be based on the revised draft of Chapter 4.3 that will be provided to members following a subsequent meeting of the Commission.

Attachment 1. Summary of member responses to 2022 questionnaire

Comments were received from Australia, Brazil, Canada, China, Germany, Ireland, Japan, New Zealand, Slovenia, Spain, Sweden, Switzerland, UK, USA and the EU.

At its September 2022 meeting the Commission agreed to circulate a questionnaire for Members to inform the revision of Chapter 4.3. Application of compartmentalisation. For those Members who responded that they have established or are in the process of establishing compartments, the purpose of the compartments was primarily for:

* domestic or international trade (aquaculture species and ornamental aquatic animals)
* support and protect hatcheries from introduction of disease or disease response activities in the event of incursion of disease within the zone;
* enhancement of wild aquatic animal populations;
* human consumption.

Members indicated positive experiences related to establishment of compartments mainly related to benefits for trade and disease control such as:

* increased market access and ease or facilitation of trade;
* overall increased health status of the defined aquatic animal populations;
* protection of health status in the event of disease incursion within the surrounding zone;
* shorter time duration for return to disease -free status.

For those Members with established compartments, the acceptance of these compartments by trade partners varied. When compartments were not accepted or had delayed acceptance by trade partners, it was related to constraints/impediments that must be overcome such as:

* Members may have a different understanding or application of compartmentalisation which can impact acceptance of recognised compartments by their trade partners;
* the use of dependent compartments may limit potential market access;
* audit of the established compartments by trade partners were required prior to acceptance and initiation of trade.

In addition to trade related constraints and impediments there were other constraints or threats that either had to be overcome or prevented the establishment of compartments. These threats were mainly relating to the industry and competent authority:

Industry

* may be constrained or prevented from establishing compartments by the type of aquaculture production system used (open/ semi-open/semi-closed systems). The requirements for establishing a compartment may not be achievable.
* the aquaculture establishment must make the business decision to invest the money and effort to establish a compartment based on the potential market access. The real return on investment won’t be known until the compartment has been established.
* once a free status has been established, the introduction of new genetics/live animals may be limited due to a potential resulting change in health status.

Competent Authority

* development of parameters to ensure separation of the compartment from the surrounding zone and implementation of compartments based on the zone health status requires Competent Authority oversight and corresponding resources (human and financial).
* potential lack of understanding by the Competent Authority.

Specifically in regard to the revision of the Chapter 4.3. Application of Compartmentalisation, Members were supportive and identified several gaps in the current chapter where additional detail could be incorporated:

* introducing when compartmentalisation is appropriate for use;
* incorporate cross references to Chapter 4.1. Biosecurity in aquaculture establishments and the different types of aquaculture production systems where compartmentalisation is possible (e.g. dependent and independent compartments);
* indicate the difference between standards for the establishment of a compartment health status, standards for maintenance of the health status and recovery after a disease incursion to regain freedom.

Attachment 2. Proposed article structure for the revised Chapter 4.3.

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| **Article number** | **Content** |
| 4.3.1. | Objective and introduction |
| 4.3.2. | Purposes of compartments |
| 4.3.3. | Principles for establishing a compartment |
| 4.3.4. | Dependent and independent compartments  |
| 4.3.5. | Biosecurity |
| 4.3.6. | Surveillance requirements to claim and maintain freedom |
| 4.3.7. | Laboratory testing |
| 4.3.8. | Traceability |
| 4.3.9. | Record keeping |
| 4.3.10. | Official oversight |
| 4.3.11. | Quality of aquatic animal health services |
| 4.3.12. | Notification and response measures |

Attachment 3. Questions for response by Members

The questions below are included in the body of the discussion paper text and are collated here for ease of reference.

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| **Question** | **Section reference** |
| Q1. Are the above principles (points A-E) to guide revision of Chapter 4.3. Compartmentalisation appropriate? If not, please suggest alternatives. | 2. Objectives of the paper |
| 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.  | 4. Purposes of compartmentalisation |
| Q3. Do you support including the concepts of independent and dependent compartments in the revised chapter 4.3.? What are your reasons? | 5. Independent versus dependent compartments |
| 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)? | 5. Independent versus dependent compartments |
| 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? | 6. General principles of compartmentalisation |
| 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? | 7.2. Article 4.3.2. Principles for defining a compartment |
| 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. | 7.6. Article 4.3.6. Diagnostic capabilities and procedures |
| 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. | 7.8. Article 4.3.8. Supervision and control of a compartment |