**New draft chapter on Biosecurity for aquaculture establishments (Chapter 4.X) – track changes**

Chapter 4.X.
 **BIOSECURITY
FOR AQUACULTURE ESTABLISHMENTS**

Article 4.X.1.

**Purpose**

To provide recommendations on the development and implementation of *biosecurity* measures primarily to mitigate the *risk* of the introduction of specific *pathogenic agents* into *aquacultur*e *establishments*, and if *pathogenic agents* are introduced, to mitigate the *risk* of further spread within, or release from, the *aquaculture establishment*.

Article 4.X.2.

**Scope**

*Biosecurity* principles are relevant to the application of the standards in the *Aquatic Code* at the level of a country, *zone*, *compartment* or *aquaculture establishment* ~~as appropriate~~. This chapter describes recommendations on *biosecurity* to be applied to *aquaculture establishments*, including semi-open, semi-closed and closed systems. The chapter describes general principles of *biosecurity* planning, categories of *aquaculture* production systems, ~~major~~ ~~transmission pathways,~~ area management, mitigation measures for transmission pathways, ~~the use of~~ the application of *risk analysis* and approaches for *biosecurity plan* development. ~~to develop a~~ *~~biosecurity plan~~*, ~~and the key components of a plan.~~

For further guidance on *disease* prevention and control refer to other chapters of Section 4 ~~of the~~ *~~Aquatic Code~~.*

Article 4.X.3.

**Introduction**

~~The fundamental measures that underpin~~ *~~aquatic animal disease~~* ~~prevention at the level of country,~~ *~~zone~~* ~~or~~ *~~compartment~~* ~~is the application of~~ *~~biosecurity~~*~~.~~ *Biosecurity* at the level of an *aquaculture establishment* isintegral to effective *biosecurity* at the level of a country, *zone* or *compartment* and thus the optimal health status and welfare of *aquatic animal* populations. This chapter describes *biosecurity* principles designed to mitigate the *risks* associated with the introduction of *pathogenic agents* into, the spread within, or the release from *aquaculture establishments.* ~~The application of~~ *~~biosecurity~~* ~~at the level of an~~ *~~aquaculture establishment~~* ~~may be~~~~integral to effective~~ *~~biosecurity~~* ~~at the level of a country,~~ *~~zone~~* ~~or~~ *~~compartment~~* ~~to maintain the optimal health status of~~ *~~aquatic animal~~* ~~populations.~~

Given the unique challenges posed by varied *aquaculture* production systems and the vast diversity of farmed *aquatic animal* species, the development of *biosecurity plans* for *aquaculture establishments* requires the assessment of *disease risks* posed by specific *pathogenic agents* and their potential transmission pathways. A *biosecurity plan* describes management and physical ~~and management~~ measures to mitigate the identified *risks* according to the circumstances of the *aquaculture establishment*. *Aquaculture establishment* personnel ~~sStaff~~, ~~and~~ service providers and *aquatic animal health professionals* or *veterinarians* should be engaged in developing and implementing the *biosecurity plan* to ensure it is practical and effective.

The outcome achieved through the implementation of *biosecurity* at *aquaculture establishments* is improved health and welfare ~~status~~ of *aquatic animals* throughout the production cycle. The benefits may include improved market access, ~~and~~ increased productivity ~~directly~~ (through improved survival, growth rates and *feed* conversion), and ~~indirectly through~~ ~~the~~ a reduction in the use ~~in treatments~~ of veterinary medicinal products (including *antimicrobial agents*), thus leading to a reduction in ~~and associated~~ production costs and the rate of emergence of antimicrobial resistance ~~(AMR)~~.

Article 4.X.4.

**General principles**

*Biosecurity* is a set of physical and management measures which, when used together, cumulatively reduce the *risk* of *infection* in *aquatic animal* populations ~~at~~ within an *aquaculture establishment*. Planning and implementation of *biosecurity* within an *aquaculture establishment* requires ~~planning to~~ ~~identifying~~ identification of *risks* and ~~consider~~ ~~cost effective~~ cost-effective measures to achieve the identified *biosecurity* objectives of the plan. The measures required will vary among ~~between~~ *aquaculture establishments*, depending on factors such as ~~risk~~ likelihood of exposure to *pathogenic agents*, the species of farmed *aquatic animal* ~~farmed~~ ~~species~~, the category of *aquaculture* production system, husbandry practices, environmental conditions and geographical location. ~~Although~~ ~~different~~ Different approaches may be used to achieve an identified *biosecurity* objective~~,~~; however, the general principles for developing and implementing a *biosecurity plan* are consistent and are described ~~as~~ below:

~~1)~~ ~~Planning is necessary to document the objectives of the biosecurity plan, the identified risks to be managed, the measures that will be put in place to manage the disease risks, required operating procedures and monitoring, as described in Articles 4.X.6. and 4.X.7.~~

~~2~~1) Potential pathways for *pathogenic agents* to be transmitted into, spread within and released from the *aquaculture establishment* must be identified, as described in Article~~s 4.X.5. and~~ 4.X.6.,~~and~~ giving consideration to the category of *aquaculture* production system and design of the *aquaculture establishment*.

~~3~~2) *Risk analysis* should be undertaken to identify and evaluate *~~biosecurity~~* *disease* threats and ensure that the plan addresses *risks* appropriately and efficiently. The *risk analysis* may range from a simple to a complex analysis depending on the objectives of the *biosecurity plan* ~~and~~, the circumstances of the *aquaculture establishment* and the *disease risks*, as described in Article 4.X.7.

~~4~~3) *Biosecurity* measures to address identified *disease risks* should be evaluated ~~based~~ on the basis of their potential effectiveness, initial and ongoing costs (e.g. building works, maintenance), and management requirements, as described in Article 4.X.7.

~~5~~4) Management practices should be integrated into the *aquaculture establishment’s* operating procedures and ~~associated~~ relevant training ~~are is~~ provided to personnel, as described in ~~Article 4.X.7. and~~ Article 4.X.8.

~~5)~~ ~~Clear signage should be displayed to promote awareness and compliance with~~ *~~biosecurity~~**~~plan~~* ~~measures by personnel, visitors and the public.~~

~~56~~5) Appropriate records and documentation are essential to demonstrate effective implementation of the *biosecurity plan*. Examples are ~~provided~~ described in Article 4.X.8.

~~67~~6) A ~~routine review~~ schedule for routine reviews and audits of the *biosecurity plan* should be described. ~~and identified t~~Triggers for ~~ad hoc~~ *ad hoc* review must be determined (e.g. *outbreaks* of *disease*, and changes to infrastructure, production techniques, *~~disease outbreaks~~*~~,~~ or *risk* profiles). Third party audits may be required where recognition of the *biosecurity* measures is required by customers, or regulators, or for market access, as ~~described provided~~ described in Article 4.X.8.

Article 4.X.5.

**Categories of aquaculture production systems**

*~~Aquatic animals~~* ~~can be produced in f~~Four different categories of *aquaculture* production systems~~, which~~ are defined based on the capacity to treat water entering and exiting the system, and the level of control ~~of~~ over *aquatic animals* and *vectors*. These ~~measures~~ factors need to be considered in *biosecurity* planning.

Open systems

In an open ~~Open~~ *aquaculture* production system~~s,~~ it is not possible to have ~~no~~ control of the water, environmental conditions, ~~and~~ animals ~~and~~ or *vectors*. These production systems may include stock enhancement of wild populations with *aquatic animals* originating from *aquaculture establishments* or from the wild. As these systems cannot be considered ‘*aquaculture establishments’*, they are not considered further in this chapter. However, movements of *aquatic animals* between *aquaculture establishments* ~~to~~ and open systems should ~~still~~ be ~~subject to~~ assessed to determine the need for *disease* mitigation measures.

Semi-open systems

In a semi-open *aquaculture* production system, it is not possible to have control over the water entering or exiting the system, or ~~of~~ over the environmental conditions. Some *aquatic animals* and *vectors* may also enter and exit the system. Examples of semi-open *aquaculture* production systems are net pens or cages for finfish and suspended baskets or rope systems for molluscs ~~aquaculture~~ in natural water bodies ~~and mollusc~~*~~aquaculture~~*~~, either suspended in the water column or on the ocean floor~~.

Semi-closed systems

In a semi-closed *aquaculture* production system, there is some control ~~of~~ over the water entering and exiting the system and ~~of~~ over the environmental conditions. *Aquatic animals* and *vectors* ~~may~~ can be prevented from entering and exiting the system; however, there is limited control to prevent the entry or exit of *pathogenic agents*. Examples of semi-closed *aquaculture* production systems are ponds, raceways, ~~enclosed~~ floating enclosures ~~pens~~, and flow-through tanks.

Closed systems

In a closed *aquaculture* production system, ~~the~~ there is sufficient control ~~of~~ over water entering and exiting the system ~~can~~ to exclude *aquatic animals*, *vectors* and *pathogenic agents*. Environmental conditions can also be controlled. Examples of closed *aquaculture* systems include recirculating *aquaculture* production systems, production systems with a safe water supply free from *pathogenic agents* or *aquatic animals* (e.g. ground water), or those with high levels of treatment (and redundancy) of water entering ~~or~~ and exiting the system.

Article 4.X.5. bis

**Area management**

It may not be possible to control the transmission of *pathogenic agents* among semi-open or semi-closed *aquaculture establishments* that are in close proximity within shared water bodies. In these circumstances, a consistent set of *biosecurity* measures should be applied by all of the *aquaculture establishments* considered to be epidemiologically linked. Area management agreements can formalise the coordination of common *biosecurity* measures among all of the epidemiologically linked *aquaculture establishments*.

Article 4.X.6.

**Transmission pathways~~,~~ ~~and~~ ~~associated risks~~ and mitigation measures**

*Pathogenic agents* can move into, spread within, and be released from *aquaculture establishments* via various transmission pathways. The identification of all potential transmission pathways is essential for the development of an effective *biosecurity plan*. ~~Mitigation of p~~Pathways that are likely to result in transmission of specific ~~may expose susceptible~~ *~~aquatic animals~~* ~~to high loads of~~ *pathogenic agents* should be prioritised for mitigation.

The *risks* associated with the introduction into, spread within, and release of *pathogenic agents* from the *aquaculture establishment* need to be considered for each of the following transmission pathways.

1.Aquatic animals

Movement of *aquatic animals* into, within and from *aquaculture establishments*, either intentionally or unintentionally, ~~may~~ ~~usually~~ may pose ~~pose~~ ~~has~~ a high likelihood *~~risk~~* of transmitting *pathogenic agents* ~~transmission~~. This is particularly the case when clinically and sub-clinically infected *aquatic animals*, or *aquatic animals* with unknown health status are moved into a susceptible population.

*Aquatic animal*s intentionally ~~brought~~ introduced into, or moved within, an *aquaculture establishment*~~, or moved within it,~~ may include broodstock, larvae, juvenile stock for on-growing, and genetic material such as *eggs* and milt. Both horizontal and vertical transmission mechanisms of *pathogenic agents* should be considered for *aquatic animals*. The *risk* of transmitting *pathogenic agents* via *aquatic animals* should be managed~~; possible mitigation measures~~ ~~include the~~ giving consideration to the following mitigation measures ~~can be managed by~~:

a) Only ~~introducing~~ introduce into the *aquaculture establishment* *aquatic animals* with a known health status ~~into the~~ *~~aquaculture establishment~~* ~~with known health status~~, which is of equal or higher status than the existing animals in the establishment.

b) ~~Quarantining~~ ~~Placing introduced~~ If *aquatic animals* of unknown *disease* status are introduced, they should be placed into *quarantine* ~~from other farm populations in separate production units or dedicated~~ *~~quarantine~~* ~~facilities~~.

c) Where appropriate, ~~treating~~ treat ~~treatment of~~ *quarantined* *aquatic animals* to mitigate *disease risks* (for example, treatment for external parasites).

d) ~~Ensuring~~ Ensure biosecure transport of *aquatic animals* that avoids exposure to and release of *pathogenic agents.*

e) Only ~~moving~~ move *aquatic animals* between different populations within the establishment following consideration of the *disease risks* and with a view to maintaining the highest possible health status of the *aquatic animal* population.

f) ~~Isolating Isolate~~ Where possible, isolate *aquatic animal* populations that display clinical signs of *disease* from other populations until the cause is known and the situation is resolved.

g) ~~Removing~~ Remove ~~sick~~ moribund or dead *aquatic animals* from production units as soon as possible and ~~disposing~~ dispose of them in a biosecure manner in accordance with Chapter 4.7.

h) ~~Reporting of~~ Report unexplained or unusual mortalities, or suspicion of a notifiable *disease* or an *emerging* *disease* in *aquatic animals* to the *Competent Authority* in accordance with local requirements. Investigation and *diagnosis* of the cause of mortality should be undertaken by *aquatic animal health professionals* or *veterinarians*.

i) If possible, completely remove *aquatic animals* from all or parts of ~~totally~~ ~~depopulating~~ ~~depopulate~~ the *aquaculture establishment* at intervals, for instance between *aquatic animal* generations or production cycles, followed by cleaning, ~~and~~ *disinfection* and drying of production installations. Sites should be fallowed for a period sufficient to interrupt *infection* cycles and reduce or eliminate pathogen challenge to restocked *aquatic animals*. *Fallowing* should be coordinated for *aquaculture establishments* that are epidemiologically linked through shared water bodies.

j) ~~Where possible, preventing unintended movement of~~ *~~aquatic animals~~* ~~into, within or from the establishment.~~ ~~Considering~~ Consider physical measures to minimise the likelihood of escape of farmed *aquatic animals* or the entry of wild *aquatic animals* into the *aquaculture establishment*. The likelihood of entry or escape of *aquatic animals* will be higher for semi-open than for closed or semi-closed systems.

~~The~~ *~~risk~~* ~~of~~ ~~unintentional movements of~~ *~~aquatic animals~~* ~~will be influenced by the category of~~ *~~aquaculture~~* ~~production system, with the likelihood being higher for semi-open than closed systems.~~ ~~If~~ *~~risks~~* ~~are found to be high, physical mitigation measures may be necessary~~.

2. Aquatic animal products and aquatic animal waste

*Aquatic animal products* may also be brought into, moved within ~~and~~ or moved out of ~~an~~ *aquaculture establishments*~~or moved within it~~; for example, *aquatic animal products* derived from *aquatic animals* harvested at other sites. *Aquatic animal* ~~waste~~ *waste* may ~~include the~~ be generated ~~entire body or parts of~~ when *aquatic animals* ~~that~~ have died or been killed for *disease* control purposes, ~~as~~ or when they ~~through killing and processing of~~ *~~aquatic animals~~* have been killed and processed ~~and their parts, that are not intended~~ for human consumption or other purposes.

Movement of *aquatic animal products* and *aquatic animal* ~~waste~~ *waste* into, within ~~and out of~~ or from *aquaculture establishments* may pose a *risk* of *pathogenic agent* transmission. This is particularly the case when a susceptible population is exposed to *aquatic animal products* and *aquatic animal* ~~waste~~ *waste* derived from clinically or sub-clinically infected *aquatic animals*. ~~High~~ *~~risk~~* ~~waste includes~~ *~~aquatic animal~~* ~~waste~~ *~~waste~~* ~~that constitutes, or is suspected of constituting, a high significant health~~ *~~risk~~*~~to~~ *~~aquatic animals~~*~~.~~ Movement of *aquatic animal* *waste* into *aquaculture establishments* should be avoided ~~where possible~~. *Aquatic animal waste* should be stored, transported, disposed of and treated as ~~following the guidance~~ described in Chapter 4.7. ~~Handling, disposal and treatment of~~ *~~aquatic animal waste~~*.

For intentional movements of *aquatic animal products* and *aquatic animal* ~~waste~~ *waste*, the likelihood of presence of *pathogenic agents* in the *aquatic animals* from which ~~products~~ *aquatic animal products* and *aquatic animal waste* are derived should be evaluated giving consideration to the species, source, and health status.

The *risk* of transmitting *pathogenic agents* via *aquatic animal products* and *aquatic animal* ~~waste~~ *waste* should be assessed and managed~~; possible mitigation measures~~ ~~include the~~ giving consideration to the following mitigation measures ~~can be managed by~~:

a) ~~determining~~ Determine the potential *disease risk* of *aquatic animal products* and *aquatic animal waste* to *aquatic animals* in the establishment and the environment;

b) ~~Manage~~ Manage *aquatic animal products* and *aquatic animal waste* in areas within the *aquaculture establishment* that are isolated ~~isolating areas within the~~ *~~aquaculture establishment~~* ~~where~~ *~~aquatic animal products~~* ~~and~~ *~~aquatic animal~~* ~~waste~~ *~~waste~~* ~~are managed~~ from *aquatic animal* populations to minimise identified *disease* transmission *risks*;

c) ~~ensuring~~ Ensure procedures ~~systems~~ are implemented for appropriate collection, treatment (inactivating *pathogenic agents*), transport, storage or disposal of *aquatic animal products* and *aquatic animal waste* ~~waste~~ to minimise identified *disease* transmission *risks* ~~the~~ *~~risks~~* ~~of transmitting~~ *~~pathogenic agents~~*.

3.  Water

Water ~~is an important asset that supports productivity and~~ *~~aquatic animal~~* ~~health but~~ may present a *risk* of the introduction of *pathogenic agents* into, spread within, and release from *aquaculture establishments.* The source of the water, and how it may provide~~s~~ an epidemiological link between the *aquaculture establishment* and other farmed or wild populations or processing plants, should be identified and considered. Exposure to transport water and ballast water should be considered.

The *risk* of the *aquaculture establishment* being exposed to water containing *pathogenic agents* may be influenced by the category of *aquaculture* production system, the likelihood being higher for semi-open than for semi-closed and closed systems. Any water that is flowing from *aquatic animals* with lower or unknown health status presents a potential *risk* of transmitting *pathogenic agents* to *aquatic animals* of a higher health status.

The *risk* of transmitting *pathogenic agents* via water should be assessed, and managed~~; possible mitigation measures~~ ~~include the~~ giving consideration to the following mitigation measures ~~can be managed by~~:

a) Where possible, ~~choosing~~ choose a water source that ~~are~~ isentirely free of susceptible *aquatic animal* populations and *pathogenic agents* of concern. Such water sources may include saline or fresh groundwater, de-chlorinated municipal water, and artificial seawater. These water sources may be particularly suitable for ~~high health status~~ *aquatic animals* with high health status, such as broodstock.

b) ~~Providing~~ Provide an appropriate level of screening, filtration or *disinfection* (in accordance with Chapter 4.3.) of water from sources that are likely to contain *susceptible species* and which may present a *risk* of *pathogenic agent* transmission (e.g. oceans, streams or lakes). The type and level of treatment required will depend on the identified *risks*.

c) Provide an appropriate level of filtration and *disinfection* ~~or holding~~ (in accordance with Chapter 4.3.) of effluent water (and associated filtered waste) from *aquaculture establishments* (or associated slaughterhouses or processing facilities) where it may present a *risk* of *pathogenic agent* transmission to wild *aquatic animals* or other *aquaculture establishments* with *susceptible species*. The type and level of treatment required will depend on the identified *risks*.

~~c~~d) ~~Ensuring~~ Ensure the position of water intakes and outlets for semi-closed and closed *aquaculture establishments*, and the location of semi-open *aquaculture establishments*, minimises contamination from other farmed or wild populations or processing plants, taking into account factors such as distance and water currents.

e)The likelihood of ingress of contaminated water either through flooding from external sources or from defective infrastructure (e.g. leaking pipes, blocked drains, bund wall failure) should be assessed and appropriate management or infrastructure measures applied.

f) Assess the *risk* and establish procedures to treat and dispose of *waste* water resulting from the transport of *aquatic animals*.

4. Feed

*Feed* can be an important pathway for transmission of *pathogenic agents* to *aquatic animals*. *Feed* manufactured from infected *aquatic animals* may contain *pathogenic agents*, or become contaminated during harvest, transport, storage or processing. *~~Feed~~* ~~may be initially infected with contain~~ *~~pathogenic agents~~* ~~or~~~~become contaminated during harvest, transport, storage and processing of~~ *~~commodities~~* ~~used as~~ *~~feed~~**~~ingredients~~*~~.~~ Poor hygiene may contribute to contamination during manufacture, transport, storage and use of *feed*.

In closed or semi-closed production systems there can be a high level ~~on~~ of control of *aquatic animal feed~~s~~*. However, in semi-open production systems, *aquatic animals* may obtain food from their environment (e.g. filter-feeding molluscs or predation of wild fish ~~which may be preyed on predated~~ by farmed fish in net pens or cages). The *risk* of *disease* transmission from *feed* to the environment also needs to be managed.

The *risk* of transmitting *pathogenic agents* via *aquatic animal feed* ~~can~~ should be assessed, and managed by mitigation measures as ~~described~~ ~~provided~~ described in Chapter 4.8., for example using *feed* and *feed* *ingredients* that:

a) have undergone sufficient processing to inactivate *pathogenic agents* of concern;

b) are from sources that are declared free from the *pathogenic agents* of concern or have been confirmed (e.g. by testing) that [*pathogenic agents*](http://www.oie.int/index.php?id=171&L=0&htmfile=glossaire.htm#terme_agent_pathogene)are not present in the *feed* or *feed ingredients* [*~~commodity~~*](http://www.oie.int/index.php?id=171&L=0&htmfile=glossaire.htm#terme_marchandise);

c) have been processed, manufactured, stored, ~~and~~ transported and delivered during feeding to *aquatic animals* in a manner to prevent contamination by [*pathogenic agents*](http://www.oie.int/index.php?id=171&L=0&htmfile=glossaire.htm#terme_agent_pathogene).

5. Fomites

Equipment, *vehicles*, packaging material, clothing, footwear, sediments, infrastructure and other fomites can mechanically transfer *pathogenic agents* into, within and from an *aquaculture establishment*.

The ~~level of~~ *~~risk~~* likelihood of transferring *pathogenic agents* will depend on the stability of the *pathogenic agent* in the environment, the presence and nature of organic matter on the fomite surface, as well as the type of surface and its ~~ability~~ capacity to hold water. The *~~risk~~* likelihood of transferring *pathogenic agents* may be higher for fomites which are difficult to clean and disinfect. Sharing equipment~~Equipment~~ ~~that is shared~~ between *aquaculture establishments,* ~~between~~ *~~aquaculture establishments~~* ~~and processing facilities~~, or between different production units ~~with~~ within an *aquaculture establishment,* orbetween *aquaculture establishments* and processing facilities, ~~with unequal health status,~~ may result in the spread of *pathogenic agents* ~~present a higher~~ *~~risk~~* ~~than compared to new or dedicated equipment.~~ The ~~risk~~ *risk* ~~likelihood~~ of transmitting *pathogenic agents* via fomitesshould be assessed and managed~~; possible mitigation measures~~ ~~include the~~ giving consideration to the following mitigation measures ~~can be managed by~~:

a) ~~Assessing~~ Assess the *disease risk* associated with any fomites ~~brought~~ moved into, within or from the *aquaculture establishment* ~~for their~~ *~~disease risk~~*.

b) ~~Ensuring~~ Ensure procedures and infrastructure are in place to clean and disinfect fomites, including at designated delivery and loading areas, prior to entry into the *aquaculture establishment*. Recommendations for the cleaning and ~~disinfection~~ *disinfection* of fomites are described in Chapter 4.3.

~~c)~~ ~~Assigning dedicated equipment for use in production units of different health status. Where equipment must be used in multiple production units it should be cleaned and disinfected prior to movement between units.~~

c) ~~Wherever possible, dedicating~~ Dedicate~~,~~ ~~where possible~~, items that are difficult to disinfect, or those with a high likelihood of contamination, to a specific *aquaculture establishment* or to areas within an establishment ~~rather than~~ instead of moving them ~~between~~ *~~aquaculture establishments~~* after *disinfection*.

d) ~~Applying~~ Apply the mitigation measures described at points a) to c)above to the movement of fomites between production units within an *aquaculture establishment* with the measures determined based on an evaluation of the *risk* of *disease* transmission *~~disease risks~~*.

6.  Vectors

*Vectors* can ~~transport~~ ~~transfer~~ transmit *pathogenic agents* to susceptible *aquatic animals* in *aquaculture establishments*. ~~These~~ They may include ~~wild~~ *aquatic animals* entering via the water supply, predators, wild birds, ~~and~~ scavengers, and pest animals such as rodents~~, and people~~. *Vectors* can also ~~transfer~~ transmit *pathogenic agents* ~~into,~~ within and from an *aquaculture establishment*~~, either by mechanical transfer or as a developmental stage of the~~ *~~pathogenic agent~~* ~~within the~~ *~~vector~~*. ~~The~~ *~~risk~~* ~~of unintentional exposure to~~ *~~vectors~~* ~~will be influenced by the category of~~ *~~aquaculture~~* ~~production system.~~

The *~~risk~~* likelihood of ~~transferring~~ transmitting *pathogenic agents* via *vectors* varies with the type of *vector* ~~species~~, the nature of the *pathogenic agent*, the category of *aquaculture* production system, and the level of *biosecurity*. ~~Measures identified to mitigate~~ *~~risks~~* ~~associated with~~ *~~aquatic animals,~~* ~~as described in point 1, can also be applied to mitigate~~ *~~risks~~* ~~associated with~~ *~~vectors~~*~~. Mitigation measures for other~~ *~~vectors~~* ~~include:~~

The *risk* of transmitting *pathogenic agents* via *vectors* should be assessed~~,~~ and managed giving consideration to the following mitigation measures:

a) ~~netting (to prevent access by birds);~~ Physical mitigation measures ~~should be used~~ to prevent the access of *vectors* to *aquaculture establishments* ~~including~~ may include:

i) filtering or screening of water entering and exiting semi-closed and closed *aquaculture* production systems to prevent entry of wild *aquatic animals*;

ii) surrounding land-based *aquaculture* production systems by a fence or a wall to prevent entry of animals and people, with a gate for controlled access for authorized personnel and visitors;

iii) surrounding floating *aquaculture* production systems by barriers on the establishment perimeter to prevent contact with or entry of wild *aquatic animals* and other animals;

iv) covering ~~outdoor~~ outdoor or unenclosed *aquaculture* production systems with nets to prevent access by birds.

~~b)~~ ~~barriers on the establishment perimeter to prevent entry by of other animals (e.g. electric fencing);~~

~~b)~~~~Controlling~~~~Access of personnel to~~ *~~aquaculture establishments~~* ~~should be controlled by creating a defined border between the outer risk area and the inner biosecure area comprising facilities for:~~

~~i)~~ ~~changing of clothes and shoes, or use of disposal coverings (hoods, coats, shoe coverings);~~

~~ii)~~ *~~disinfection~~* ~~of hands, and the use of foot baths for shoe disinfection.~~

~~c~~b) P~~p~~est control. ~~and secure storage of feed and mortalities~~

7. Personnel and visitors

a)Access of personnel and visitors to *aquaculture establishments* should be controlled by creating a defined border between the outer *risk* area and the inner biosecure area comprising facilities for:

i)completion of a register, which should include visitors’ names, contact information, and details of exposure to *aquatic animals* or *pathogenic agents* over a preceding period, including visits to other *aquaculture establishments* or other facilities;

ii) changing of clothes and shoes, or use of disposable coverings (e.g. hoods, coats, gloves, shoe coverings);

iii) *disinfection* of hands, and the use of foot baths ~~for shoe disinfection~~.

b) All visitors should be briefed and supervised to ensure compliance with the *biosecurity* *plan*.

c) *C*lear signage should be displayed to promote awareness and compliance with *biosecurity* *plan* measures by personnel, visitors and the public.

Article 4.X.7.

**Risk analysis**

*Risk analysis* is an accepted approach for evaluating *biosecurity* threats and is used to support the development of mitigation measures. A formal *risk analysis* has four components: *hazard* identification, *risk assessment*, *risk management* and *risk communication* ~~(see Chapter 2.1.)~~. This article elaborates the principles described in Chapter 2.1. and applies them ~~for~~ to guide the development of *biosecurity* *plans* for *aquaculture establishments*.

A *biosecurity plan* may not necessarily require a comprehensive *risk analysis* to evaluate *disease risks* linked to transmission pathways. The chosen approach may depend on the objectives of the *biosecurity plan*, the level of *biosecurity* that is appropriate for the specific production requirements of the *aquaculture establishment*, the complexity of the threats to be addressed, and the availability of information and resources. Depending on these circumstances, a partial analysis may be appropriate, and can build on previous experiences to identify the *hazards* associated with relevant transmission pathways.

The three formal steps of the *risk analysis* process to underpin a ~~the~~ *biosecurity plan* are:

**Step 1 ‒ Hazard ~~I~~identification**

*Hazard* identification determines which *pathogenic agents* should be the subject of the *risk assessment*. A *hazard* may include a specific *pathogenic agent* or be defined in more general terms as a group of *pathogenic agents.* This step includes identifying and collecting relevant information on the *pathogenic agents* that have ~~a~~ potential to cause *diseases* in *aquatic animal* populations within an *aquaculture establishment*. This process must consider the *aquatic animal health status* of the establishment and, for semi-open and semi-closed *aquaculture* production systems, the *aquatic animal health status* of the epidemiologically linked environments. ~~The following step is to identify both known and~~ *~~emerging diseases~~*~~, not present in the~~ *~~aquaculture establishment~~*~~, which may negatively impact the farmed population.~~ Known and *emerging* *diseases* which could negatively impact the farmed population should be identified, regardless of whether they are present in the *aquaculture establishment*.

To complete the next steps of the *risk assessment*, ~~required~~ information on the identified *hazards* is required ~~needed~~ and includes: i) the frequency of occurrence, ii) the biophysical characteristics, iii) the likelihood of detection if present and iv) the possible transmission pathways (described in Article 4.X.6.). Many of the *hazards* will share the same pathways. ~~A~~ *~~hazard~~* ~~may include a specific~~ *~~pathogenic agent~~* ~~or be defined in more general terms as a group of~~ *~~pathogenic agents.~~*

**Step 2 – Risk ~~A~~assessment**

A *risk assessment* can be initiated once it has been identified that a ~~biological~~ *hazard* exists, and the required information listed under step 1 has been gathered. The aim of the *risk assessment* is to establish a *risk* estimate, which is the product of the likelihood and consequences of entry of a *pathogenic agent* ~~entry~~ into, spread within or release from the *aquaculture establishment*.

A *risk assessment* can be quantitative or qualitative. Both methods require the same conceptual pathway which identifies the necessary steps for *hazard* introduction, establishment and spread to be constructed. In a qualitative assessment, introduction and establishment are estimated using descriptors of likelihood. A quantitative assessment requires data on which to estimate likelihood. In most circumstances, the likelihood of *disease* transmission and associated consequences ~~pathways~~ will be assessed qualitatively but within a formal *risk assessment* framework. Examples of descriptors for qualitative estimates of likelihood and consequence are given in Tables 1 and 2. Table 3 illustrates how estimates of likelihood and consequence can be combined in a matrix to give an estimate of *risk*. Table 4 provides an interpretation of *risk* estimates.

**Table 1. Qualitative descriptors of likelihood**

|  |  |
| --- | --- |
| **Estimate** | **Descriptor** |
| Remote | ~~Never heard of~~ Very unlikely, but not impossible. |
| Unlikely | May occur ~~here~~, but only in rare circumstances. |
| Possible | Clear evidence to suggest this is possible in this situation. |
| Likely | It is likely, but not certain, to occur ~~here~~. |
| Certain | It is certain to occur. |

**Table 2. Qualitative descriptors of consequences**

|  |  |
| --- | --- |
| **Estimate** | **Descriptor of consequences at level of the aquaculture establishment** |
| Insignificant | Impact not detectable or minimal. No trade impacts. |
| Minor | ~~Impact~~ Limited decreased production ~~on~~ *~~aquaculture establishment~~* ~~productivity limited to some~~ affecting only a small number of ~~production~~ units or short-term, and/or very limited and transitory disruption to trade. ~~only.~~ |
| Moderate | ~~Widespread impact on~~ *~~aquaculture establishment~~* ~~productivity due to increased mortality or decreased performance.~~ Decreased production (e.g. sustained increased mortality or decreased growth rate) and/or some short-term to medium-term disruption to trade, resulting in financial loss.  |
| Major | Considerable, decreased ~~impact on~~ *~~aquaculture establishment~~* production, and/or some medium-term to long-term disruption to trade, resulting in significant financial loss ~~resulting in serious supply constraints and financial impact~~. |
| Catastrophic | Complete ~~depopulation~~ production loss, ~~in of the~~ *~~aquaculture establishment~~* ~~and~~ possibly barriers to resumption of production, and/or complete loss of trade, resulting in extreme financial loss. |

**Table 3. Matrix for ~~assessing~~ estimating risk**

|  |  |
| --- | --- |
| **Likelihood estimate** | Consequence rating |
|  | insignificant | minor | moderate | major | catastrophic |
| remote | negligible | low | low | low | medium |
| unlikely | low | low | medium | medium | high |
| possible | low | medium | medium | high | high |
| likely | low | medium | high | high | extreme |
| certain | ~~medium~~ low | high | high | extreme | extreme |

~~Results of~~ *~~r~~Risk assessments* inform~~s~~ which ~~biological~~ *hazards* need to be addressed, which critical control points on the transmission pathway should be targeted for management, and the measures ~~which~~ that are most likely to be effective in reducing *risk*.

**Table 4. Interpretation of risk estimates**

|  |  |
| --- | --- |
| ***Risk* ~~level~~ estimate\*** | **Explanation and management response** |
| Negligible | Acceptable level of *risk*. No action required. |
| Low | Acceptable level of *risk*. On-going monitoring may be required. |
| Medium | Unacceptable level of *risk*. ~~Active management~~ Review and strengthen the *risk* mitigation measures ~~is required~~ ~~to reduce the level of~~ *~~risk~~.* |
| High | Unacceptable level of *risk*. ~~Intervention~~ Identify and implement additional *risk* mitigation measures ~~is required to mitigate the~~ *~~risk~~.* |
| Extreme | Unacceptable level of *risk*. Take immediate action to mitigate the *risk*. ~~Urgent intervention is required to mitigate the level of~~ *~~risk.~~* |

\*~~The~~ *~~Rrisk~~* ~~level estimate is determined by from a combination of the likelihood and consequence estimates score obtained using the~~ *~~risk~~* ~~matrix (Table 3)~~. Likelihood and consequence estimates are combined using the *risk* matrix (Table 3) to produce the *risk* estimate.

**Step 3 ‒ Risk ~~M~~management**

*Risk management* is used to determine the appropriate management response for the assessed level of *risk* as described in Table 4. The *risk assessment* process identifies the steps within transmission pathways necessary for a *risk* to be realised and thus allows the most effective mitigation measures to be determined. Many of the *hazards* will share the same pathways and ~~thus~~ therefore mitigation measures may be effective against more than one *hazard*. Information on *hazards* and their pathways of introduction (step 1) should be combined with an assessment of *risk* associated with each ~~the assessment of the~~ pathway~~s~~ (step 2) to identify the most appropriate and cost-effective *risk* mitigation measures.

Article X.X.6. describes some possible mitigation measures relevant ~~for~~ to different transmission pathways. The most appropriate mitigation measures for a specific *aquaculture establishment* will depend on ~~the~~ *~~risks~~**~~hazards~~* ~~identified,~~ the effectiveness and reliability of the mitigation measure, the category of *aquaculture* production system and cost.

After the implementation of the *biosecurity plan*, *hazards* should be regularly reassessed, and measures adjusted according to any changed *risk* estimates.

Article 4.X.8.

**Biosecurity plan development**

The purpose of a *biosecurity plan* is primarily to reduce the *risk* of introducing *pathogenic agents* intoan *aquacultur*e *establishment*, and if *pathogenic agents* are introduced, to reduce the *risk* of further spread within or release from the *aquaculture establishment*. The plan will document identified transmission pathways and the outputs of any *risk analysis* performed (*hazards, risk* estimate and mitigation measures), and information relevant to ongoing implementation, monitoring and review of the plan.

1. Development of a biosecurity plan

The process ~~to~~ of developing a *biosecurity plan* will vary depending on its objectives ~~of the~~ *~~biosecurity plan~~*, the level of *biosecurity* appropriate to the specific production system requirements, the complexity of the *disease risks* to be addressed, and availability of information and resources. Consideration and documentation of the following issues are recommended:

a) objectives, scope and regulatory requirements for the *biosecurity plan*;

b) information about the *aquaculture establishment* including an up-to-date plan of the layout of buildings and production units (including *epidemiological units*, if any, and structures and ~~the~~ processes to maintain separation~~methods~~), loading/unloading, unpacking, processing, *feed* storage, ~~waste~~ *aquatic animal waste* storage, reception areas, access points and maps showing major movements of *aquatic animals*, *aquatic animal products* and *aquatic animal* ~~waste~~ *waste*, water, *feed* and fomites ~~(including staff, equipment and~~ *~~vehicles~~*~~)~~;

c) the potential pathways for entry of *pathogenic agents* into, spread within or release from the *aquaculture establishment* (refer to Article X.X.6. above);

d) a *risk analysis*, including identification of the major *disease hazards* to the *aquaculture establishment* (refer to Article X.X.7. above);

e) the mitigation measures that have been determined to address ~~identified~~ *risks*;

f) emergency procedures in the event of a *biosecurity* failure. These ~~They~~ may include reporting requirements, and emergency measures to eradicate *pathogenic agents* such as *aquatic animal* depopulation and disposal, and site *disinfection*, in accordance with Chapters 4.3. and 7.4.;

~~g)~~ ~~standard operating procedures required to support implementation of the mitigation measures, emergency procedures and the training requirements of personnel;~~

~~h~~g) internal and external communication procedures, ~~and~~ roles and responsibilities of ~~personnel~~ *aquaculture establishment* personnel~~staff~~ and essential contact information, e.g. for ~~personnel,staff~~ personnel, *aquatic animal health professionals* or *veterinarians* ~~farm~~ *~~veterinarian~~* and the *Competent Authority*;

~~i~~h) monitoring and audit schedule;

i~~j~~) performance evaluation;

j) standard operating procedures required to support ~~all~~ implementation of the mitigation measures described by the *biosecurity* *plan*, emergency procedures and the training requirements of establishment personnel.

2. Key components of a biosecurity plan

a) Standard operating procedures (SOPs)

SOPs describe routine management processes that must be performed to support the effectiveness of the *biosecurity plan*. Each SOP should clearly describe its objectives, ~~staff~~ personnel responsibilities, the procedure (including record keeping), precautions and a review date.

~~Staff Personnel should be trained in the application of the SOPs including completion of forms, checklists and other records associated with each procedure, as well as routine communication requirements.~~

b) Training of personnel

Personnel should be trained in the application of the SOPs including completion of forms, checklists and other records associated with each procedure, as well as routine communication requirements.

The *biosecurity plan* should include a training programme to ensure that all personnel are capable of playing their role in the implementation of *biosecurity* at the *aquaculture establishment*.

~~b~~c) Documentation and record keeping

The *biosecurity plan* describes the documentation necessary to provide evidence of compliance with the ~~mitigation measures~~ plan. The level of detail required in the documentation depends on the outcomes of the transmission pathway assessment.

Examples of documentation required ~~may~~ include: *aquaculture establishment* layout, movements of *aquatic animals*, ~~escapees,~~ origin and destination and health status of the *aquatic animals* introduced to the *aquaculture establishment*, *quarantine* measures, records of visitors to the establishment, escapees, stocking densities, feeding and growth rates, records of ~~staff~~ personnel training, treatments/vaccination, water quality, cleaning and *disinfection* events, morbidity and mortality (including removal and disposal of mortalities), *surveillance* and laboratory records.

~~c~~d) Emergency procedures

Procedures should be developed and, when necessary, implemented to minimise the impact of emergencies, *disease* events, or unexplained mortality in *aquatic animals*. These procedures should include clearly defined thresholds that help to identify an emergency incident and activate response protocols, including reporting requirements.

~~d~~e)Health monitoring

Health monitoring as part of the *biosecurity plan* involves monitoring of the health status of *aquatic animals* in *aquaculture establishments*. Monitoring should be performed at a production unit and establishment level. Activities may include *disease surveillance*, routine monitoring of stock for important health and production parameters (e.g. by personnel ~~staff~~, an *aquatic animal health professional* or a *veterinarian*), recording of clinical signs of *disease*, morbidity and mortality, laboratory test results and analysis of these data (e.g. calculation of rates of morbidity and mortality ~~and diseases~~).

~~e~~f) Routine review and auditing

The *biosecurity plan* should describe a systematic auditing schedule to verify implementation and compliance with the requirements of the *biosecurity plan*. Routine revision of the *biosecurity plan* is necessary to ensure that it continues to effectively address *biosecurity risks*.

The *biosecurity plan* should also be reviewed at least annually or in response to changes to the *aquaculture establishment* operations, changes in facility design, changes ~~to~~ in husbandry approaches, identification of a new *disease risk*, or the occurrence of a *biosecurity* incident. *Biosecurity* incidents, and actions taken to remedy them, should be documented to enable ~~SOP~~ re-assessments of SOPs.

~~f)~~ ~~Training of personnel~~

~~The~~ *~~biosecurity plan~~* ~~should include a training programme to ensure that all personnel are capable of playing their role in the implementation of~~ *~~biosecurity~~* ~~at the~~ *~~aquaculture establishment~~*~~.~~

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**New draft chapter on Biosecurity for aquaculture establishments (Chapter 4.X) – clean version**

Chapter 4.X.
 **BIOSECURITY
FOR AQUACULTURE ESTABLISHMENTS**

Article 4.X.1.

**Purpose**

To provide recommendations on the development and implementation of *biosecurity* measures primarily to mitigate the *risk* of the introduction of specific *pathogenic agents* into *aquacultur*e *establishments*, and if *pathogenic agents* are introduced, to mitigate the *risk* of further spread within, or release from, the *aquaculture establishment*.

Article 4.X.2.

**Scope**

*Biosecurity* principles are relevant to the application of the standards in the *Aquatic Code* at the level of a country, *zone*, *compartment* or *aquaculture establishment*. This chapter describes recommendations on *biosecurity* to be applied to *aquaculture establishments*, including semi-open, semi-closed and closed systems. The chapter describes general principles of *biosecurity* planning, categories of *aquaculture* production systems, area management, mitigation measures for transmission pathways, the application of *risk analysis* and approaches for *biosecurity plan* development.

For further guidance on *disease* prevention and control refer to other chapters of Section 4*.*

Article 4.X.3.

**Introduction**

*Biosecurity* at the level of an *aquaculture establishment* isintegral to effective *biosecurity* at the level of a country, *zone* or *compartment* and thus the optimal health status and welfare of *aquatic animal* populations. This chapter describes *biosecurity* principles designed to mitigate the *risks* associated with the introduction of *pathogenic agents* into, the spread within, or the release from *aquaculture establishments.*

Given the unique challenges posed by varied *aquaculture* production systems and the vast diversity of farmed *aquatic animal* species, the development of *biosecurity plans* for *aquaculture establishments* requires the assessment of *disease risks* posed by specific *pathogenic agents* and their potential transmission pathways. A *biosecurity plan* describes management and physical measures to mitigate the identified *risks* according to the circumstances of the *aquaculture establishment*. *Aquaculture establishment* personnel, service providers and *aquatic animal health professionals* or *veterinarians* should be engaged in developing and implementing the *biosecurity plan* to ensure it is practical and effective.

The outcome achieved through the implementation of *biosecurity* at *aquaculture establishments* is improved health and welfare of *aquatic animals* throughout the production cycle. The benefits may include improved market access,increased productivity (through improved survival, growth rates and *feed* conversion), and a reduction in the use of veterinary medicinal products (including *antimicrobial agents*), thus leading to a reduction in production costs and the rate of emergence of antimicrobial resistance.

Article 4.X.4.

**General principles**

*Biosecurity* is a set of physical and management measures which, when used together, cumulatively reduce the *risk* of *infection* in *aquatic animal* populations within an *aquaculture establishment*. Planning and implementation of *biosecurity* within an *aquaculture establishment* requires identification of *risks* and cost-effective measures to achieve the identified *biosecurity* objectives of the plan. The measures required will vary among *aquaculture establishments*, depending on factors such as likelihood of exposure to *pathogenic agents*, the species of farmed *aquatic animal*, the category of *aquaculture* production system, husbandry practices, environmental conditions and
geographical location. Different approaches may be used to achieve an identified *biosecurity* objective; however, the general principles for developing and implementing a *biosecurity plan* are consistent and are described below:

1) Potential pathways for *pathogenic agents* to be transmitted into, spread within and released from the *aquaculture establishment* must be identified, as described in Article 4.X.6., giving consideration to the category of *aquaculture* production system and design of the *aquaculture establishment*.

2) *Risk analysis* should be undertaken to identify and evaluate *disease* threats and ensure that the plan addresses *risks* appropriately and efficiently. The *risk analysis* may range from a simple to a complex analysis depending on the objectives of the *biosecurity plan*, the circumstances of the *aquaculture establishment* and the *disease risks*, as described in Article 4.X.7.

3) *Biosecurity* measures to address identified *disease risks* should be evaluated on the basis of their potential effectiveness, initial and ongoing costs (e.g. building works, maintenance), and management requirements, as described in Article 4.X.7.

4) Management practices should be integrated into the *aquaculture establishment’s* operating procedures and relevant training provided to personnel, as described in Article 4.X.8.

5) Appropriate records and documentation are essential to demonstrate effective implementation of the *biosecurity plan*. Examples are described in Article 4.X.8.

6) A schedule for routine reviews and audits of the *biosecurity plan* should be described. Triggers for *ad hoc* review must be determined (e.g. *outbreaks* of *disease*, and changes to infrastructure, production techniques, or *risk* profiles). Third party audits may be required where recognition of the *biosecurity* measures is required by customers, or regulators, or for market access, as described in Article 4.X.8.

Article 4.X.5.

**Categories of aquaculture production systems**

Four different categories of *aquaculture* production systems are defined based on the capacity to treat water entering and exiting the system, and the level of control over *aquatic animals* and *vectors*. These factors need to be considered in *biosecurity* planning.

Open systems

In an open *aquaculture* production system it is not possible to have control of the water, environmental conditions, animals or *vectors*. These production systems may include stock enhancement of wild populations with *aquatic animals* originating from *aquaculture establishments* or from the wild. As these systems cannot be considered ‘*aquaculture establishments’*, they are not considered further in this chapter. However, movements of *aquatic animals* between *aquaculture establishments* and open systems should be assessed to determine the need for *disease* mitigation measures.

Semi-open systems

In a semi-open *aquaculture* production system, it is not possible to have control over the water entering or exiting the system, or over the environmental conditions. Some *aquatic animals* and *vectors* may also enter and exit the system. Examples of semi-open *aquaculture* production systems are net pens or cages for finfish and suspended baskets or rope systems for molluscs in natural water bodies.

Semi-closed systems

In a semi-closed *aquaculture* production system, there is some control over the water entering and exiting the system and over the environmental conditions. *Aquatic animals* and *vectors* can be prevented from entering and exiting the system; however, there is limited control to prevent the entry or exit of *pathogenic agents*. Examples of semi-closed *aquaculture* production systems are ponds, raceways, floating enclosures, and flowthrough tanks.

Closed systems

In a closed *aquaculture* production system, there is sufficient control over water entering and exiting the system to exclude *aquatic animals*, *vectors* and *pathogenic agents*. Environmental conditions can also be controlled. Examples of closed *aquaculture* systems include recirculating *aquaculture* production systems, production systems with a safe water supply free from *pathogenic agents* or *aquatic animals* (e.g. ground water), or those with high levels of treatment (and redundancy) of water entering and exiting the system.

Article 4.X.5.bis

**Area management**

It may not be possible to control the transmission of *pathogenic agents* among semi-open or semi-closed *aquaculture establishments* that are in close proximity within shared water bodies. In these circumstances, a consistent set of *biosecurity* measures should be applied by all of the *aquaculture establishments* considered to be epidemiologically linked. Area management agreements can formalise the coordination of common *biosecurity* measures among all of the epidemiologically linked *aquaculture establishments*.

Article 4.X.6.

**Transmission pathways and mitigation measures**

*Pathogenic agents* can move into, spread within, and be released from *aquaculture establishments* via various transmission pathways. The identification of all potential transmission pathways is essential for the development of an effective *biosecurity plan*. Pathways that are likely to result in transmission of specific *pathogenic agents* should be prioritised for mitigation.

The *risks* associated with the introduction into, spread within, and release of *pathogenic agents* from the *aquaculture establishment* need to be considered for each of the following transmission pathways.

1.Aquatic animals

Movement of *aquatic animals* into, within and from *aquaculture establishments*, either intentionally or unintentionally, may pose a high likelihood of transmitting *pathogenic agents*. This is particularly the case when clinically and sub-clinically infected *aquatic animals*, or *aquatic animals* with unknown health status are moved into a susceptible population.

*Aquatic animal*s intentionally introduced into, or moved within, an *aquaculture establishment* may include broodstock, larvae, juvenile stock for on-growing, and genetic material such as *eggs* and milt. Both horizontal and vertical transmission mechanisms of *pathogenic agents* should be considered for *aquatic animals*. The *risk* of transmitting *pathogenic agents* via *aquatic animals* should be managed giving consideration to the following mitigation measures:

a) Only introduce into the *aquaculture establishment* *aquatic animals* with a known health status, which is of equal or higher status than the existing animals in the establishment.

b) If *aquatic animals* of unknown *disease* status are introduced, they should be placed into *quarantine*.

c) Where appropriate, *quarantined* *aquatic animals* to mitigate *disease risks* (for example, treatment for external parasites).

d) Ensure biosecure transport of *aquatic animals* that avoids exposure to and release of *pathogenic agents.*

e) Only move *aquatic animals* between different populations within the establishment following consideration of the *disease risks* and with a view to maintaining the highest possible health status of the *aquatic animal* population.

f) Where possible, isolate *aquatic animal* populations that display clinical signs of *disease* from other populations until the cause is known and the situation is resolved.

g) Remove moribund or dead *aquatic animals* from production units as soon as possible and dispose of them in a biosecure manner in accordance with Chapter 4.7.

h) Report unexplained or unusual mortalities, or suspicion of a notifiable *disease* or an *emerging* *disease* in *aquatic animals* to the *Competent Authority* in accordance with local requirements. Investigation and *diagnosis* of the cause of mortality should be undertaken by *aquatic animal health professionals* or *veterinarians*.

i) If possible, completely remove *aquatic animals* from all or parts of the *aquaculture establishment* at intervals, for instance between *aquatic animal* generations or production cycles, followed by cleaning, *disinfection* and drying of production installations. Sites should be fallowed for a period sufficient to interrupt *infection* cycles and reduce or eliminate pathogen challenge to restocked *aquatic animals*. *Fallowing* should be coordinated for *aquaculture establishments* that are epidemiologically linked through shared water bodies.

j) Consider physical measures to minimise the likelihood of escape of farmed *aquatic animals* or the entry of wild *aquatic animals* into the *aquaculture establishment*. The likelihood of entry or escape of *aquatic animals* will be higher for semi-open than for closed or semi-closed systems.

2. Aquatic animal products and aquatic animal waste

*Aquatic animal products* may also be brought into, moved within or moved out of *aquaculture establishments*; for example, *aquatic animal products* derived from *aquatic animals* harvested at other sites. *Aquatic animal* *waste* may be generated when *aquatic animals* have died or been killed for *disease* control purposes, or when they have been killed and processed for human consumption or other purposes.

Movement of *aquatic animal products* and *aquatic animal waste* into, within or from *aquaculture establishments* may pose a *risk* of *pathogenic agent* transmission. This is particularly the case when a susceptible population is exposed to *aquatic animal products* and *aquatic animal waste* derived from clinically or sub-clinically infected *aquatic animals*. Movement of *aquatic animal* *waste* into *aquaculture establishments* should be avoided. *Aquatic animal waste* should be stored, transported, disposed of and treated as described in Chapter 4.7.

For intentional movements of *aquatic animal products* and *aquatic animal* *waste*, the likelihood of presence of *pathogenic agents* in the *aquatic animals* from which *aquatic animal products* and *aquatic animal waste* are derived should be evaluated giving consideration to the species, source, and health status.

The *risk* of transmitting *pathogenic agents* via *aquatic animal products* and *aquatic animal* *waste* should be assessed and managed giving consideration to the following mitigation measures:

a) Determine the potential *disease risk* of *aquatic animal products* and *aquatic animal waste* to *aquatic animals* in the establishment and the environment;

b) Manage *aquatic animal products* and *aquatic animal waste* in areas within the *aquaculture establishment* that are isolated from *aquatic animal* populations to minimise identified *disease* transmission *risks*;

c) Ensure procedures are implemented for appropriate collection, treatment (inactivating *pathogenic agents*), transport, storage or disposal of *aquatic animal products* and *aquatic animal waste* to minimise identified *disease* transmission *risks*.

3.  Water

Water may present a *risk* of the introduction of *pathogenic agents* into, spread within, and release from *aquaculture establishments.* The source of the water, and how it may provide an epidemiological link between the *aquaculture establishment* and other farmed or wild populations or processing plants, should be identified and considered. Exposure to transport water and ballast water should be considered.

The *risk* of the *aquaculture establishment* being exposed to water containing *pathogenic agents* may be influenced by the category of *aquaculture* production system, the likelihood being higher for semi-open than for semi-closed and closed systems. Any water that is flowing from *aquatic animals* with lower or unknown health status presents a potential *risk* of transmitting *pathogenic agents* to *aquatic animals* of a higher health status.

The *risk* of transmitting *pathogenic agents* via water should be assessed, and managed giving consideration to the following mitigation measures:

a) Where possible, choose a water source that isentirely free of susceptible *aquatic animal* populations and *pathogenic agents* of concern. Such water sources may include saline or fresh groundwater, de-chlorinated municipal water, and artificial seawater. These water sources may be particularly suitable for *aquatic animals* with high health status, such as broodstock.

b) Provide an appropriate level of screening, filtration or *disinfection* (in accordance with Chapter 4.3.) of water from sources that are likely to contain *susceptible species* and which may present a *risk* of *pathogenic agent* transmission (e.g. oceans, streams or lakes). The type and level of treatment required will depend on the identified *risks*.

c) Provide an appropriate level of filtration and *disinfection* (in accordance with Chapter 4.3.) of effluent water (and associated filtered waste) from *aquaculture establishments* (or associated slaughterhouses or processing facilities) where it may present a *risk* of *pathogenic agent* transmission to wild *aquatic animals* or other *aquaculture establishments* with *susceptible species*. The type and level of treatment required will depend on the identified *risks*.

d) Ensure the position of water intakes and outlets for semi-closed and closed *aquaculture establishments*, and the location of semi-open *aquaculture establishments*, minimises contamination from other farmed or wild populations or processing plants, taking into account factors such as distance and water currents.

e)The likelihood of ingress of contaminated water either through flooding from external sources or from defective infrastructure (e.g. leaking pipes, blocked drains, bund wall failure) should be assessed and appropriate management or infrastructure measures applied.

f) Assess the *risk* and establish procedures to treat and dispose of *waste* water resulting from the transport of *aquatic animals*.

4. Feed

*Feed* can be an important pathway for transmission of *pathogenic agents* to *aquatic animals*. *Feed* manufactured from infected *aquatic animals* may contain *pathogenic agents*, or become contaminated during harvest, transport, storage or processing. Poor hygiene may contribute to contamination during manufacture, transport, storage and use of *feed*.

In closed or semi-closed production systems there can be a high level of control of *aquatic animal feed*. However, in semi-open production systems, *aquatic animals* may obtain food from their environment (e.g. filter-feeding molluscs or predation of wild fish by farmed fish in net pens or cages). The *risk* of *disease* transmission from *feed* to the environment also needs to be managed.

The *risk* of transmitting *pathogenic agents* via *aquatic animal feed* should be assessed, and managed by mitigation measures as described in Chapter 4.8., for example using *feed* and *feed* *ingredients* that:

a) have undergone sufficient processing to inactivate *pathogenic agents* of concern;

b) are from sources that are declared free from the *pathogenic agents* of concern or have been confirmed (e.g. by testing) that [*pathogenic agents*](http://www.oie.int/index.php?id=171&L=0&htmfile=glossaire.htm#terme_agent_pathogene)are not present in the *feed* or *feed ingredients*;

c) have been processed, manufactured, stored, transported and delivered during feeding to *aquatic animals* in a manner to prevent contamination by [*pathogenic agents*](http://www.oie.int/index.php?id=171&L=0&htmfile=glossaire.htm#terme_agent_pathogene).

5. Fomites

Equipment, *vehicles*, packaging material, clothing, footwear, sediments, infrastructure and other fomites can mechanically transfer *pathogenic agents* into, within and from an *aquaculture establishment*.

The likelihood of transferring *pathogenic agents* will depend on the stability of the *pathogenic agent* in the environment, the presence and nature of organic matter on the fomite surface, as well as the type of surface and its capacity to hold water. The likelihood of transferring *pathogenic agents* may be higher for fomites which are difficult to clean and disinfect. Sharing equipment between *aquaculture establishments,* or between different production units within an *aquaculture establishment,* orbetween *aquaculture establishments* and processing facilities, may result in the spread of *pathogenic agents*. The *risk* of transmitting *pathogenic agents* via fomitesshould be assessed and managed giving consideration to the following mitigation measures:

a) Assess the *disease risk* associated with any fomites moved into, within or from the *aquaculture establishment*.

b) Ensure procedures and infrastructure are in place to clean and disinfect fomites, including at designated delivery and loading areas, prior to entry into the *aquaculture establishment*. Recommendations for the cleaning and *disinfection* of fomites are described in Chapter 4.3.

c) Dedicate items that are difficult to disinfect, or those with a high likelihood of contamination, to a specific *aquaculture establishment* or to areas within an establishment instead of moving them after *disinfection*.

d) Apply the mitigation measures described at points a) to c)above to the movement of fomites between production units within an *aquaculture establishment* with the measures determined based on an evaluation of the *risk* of *disease* transmission.

6.  Vectors

*Vectors* can transmit *pathogenic agents* to susceptible *aquatic animals* in *aquaculture establishments*. They may include *aquatic animals* entering via the water supply, predators, wild birds, scavengers, and pest animals such as rodents. *Vectors* can also transmit *pathogenic agents* within and from an *aquaculture establishment*.

The likelihood of transmitting *pathogenic agents* via *vectors* varies with the type of *vector*, the nature of the *pathogenic agent*, the category of *aquaculture* production system, and the level of *biosecurity*.

The *risk* of transmitting *pathogenic agents* via *vectors* should be assessed and managed giving consideration to the following mitigation measures:

a) Physical mitigation measures to prevent the access of *vectors* to *aquaculture establishments* may include:

i) filtering or screening of water entering and exiting semi-closed and closed *aquaculture* production systems to prevent entry of wild *aquatic animals*;

ii) surrounding land-based *aquaculture* production systems by a fence or a wall to prevent entry of animals and people, with a gate for controlled access for authorized personnel and visitors;

iii) surrounding floating *aquaculture* production systems by barriers on the establishment perimeter to prevent contact with or entry of wild *aquatic animals* and other animals;

iv) covering outdoor or unenclosed *aquaculture* production systems with nets to prevent access by birds.

b) Pest control.

7. Personnel and visitors

a)Access of personnel and visitors to *aquaculture establishments* should be controlled by creating a defined border between the outer *risk* area and the inner biosecure area comprising facilities for:

i)completion of a register, which should include visitors’ names, contact information, and details of exposure to *aquatic animals* or *pathogenic agents* over a preceding period, including visits to other *aquaculture establishments* or other facilities;

ii) changing of clothes and shoes, or use of disposable coverings (e.g. hoods, coats, gloves, shoe coverings);

iii) *disinfection* of hands, and the use of foot baths.

b) All visitors should be briefed and supervised to ensure compliance with the *biosecurity* *plan*.

c) *C*lear signage should be displayed to promote awareness and compliance with *biosecurity* *plan* measures by personnel, visitors and the public.

Article 4.X.7.

**Risk analysis**

*Risk analysis* is an accepted approach for evaluating *biosecurity* threats and is used to support the development of mitigation measures. A formal *risk analysis* has four components: *hazard* identification, *risk assessment*, *risk management* and *risk communication*. This article elaborates the principles described in Chapter 2.1. and applies them to guide the development of *biosecurity* *plans* for *aquaculture establishments*.

A *biosecurity plan* may not necessarily require a comprehensive *risk analysis* to evaluate *disease risks* linked to transmission pathways. The chosen approach may depend on the objectives of the *biosecurity plan*, the level of *biosecurity* that is appropriate for the specific production requirements of the *aquaculture establishment*, the complexity of the threats to be addressed, and the availability of information and resources. Depending on these circumstances, a partial analysis may be appropriate, and can build on previous experiences to identify the *hazards* associated with relevant transmission pathways.

The three formal steps of the *risk analysis* process to underpin a *biosecurity plan* are:

**Step 1 ‒ Hazard identification**

*Hazard* identification determines which *pathogenic agents* should be the subject of the *risk assessment*. A *hazard* may include a specific *pathogenic agent* or be defined in more general terms as a group of *pathogenic agents.* This step includes identifying and collecting relevant information on the *pathogenic agents* that have potential to cause *diseases* in *aquatic animal* populations within an *aquaculture establishment*. This process must consider the *aquatic animal health status* of the establishment and, for semi-open and semi-closed *aquaculture* production systems, the *aquatic animal health status* of the epidemiologically linked environments. Known and *emerging* *diseases* which could negatively impact the farmed population should be identified, regardless of whether they are present in the *aquaculture establishment*.

To complete the next steps of the *risk assessment*, information on the identified *hazards* is required and includes: i) the frequency of occurrence, ii) the biophysical characteristics, iii) the likelihood of detection if present and iv) the possible transmission pathways (described in Article 4.X.6.). Many of the *hazards* will share the same pathways.

**Step 2 – Risk assessment**

A *risk assessment* can be initiated once it has been identified that a *hazard* exists, and the required information listed under step 1 has been gathered. The aim of the *risk assessment* is to establish a *risk* estimate, which is the product of the likelihood and consequences of entry of a *pathogenic agent* into, spread within or release from the *aquaculture establishment*.

A *risk assessment* can be quantitative or qualitative. Both methods require the same conceptual pathway which identifies the necessary steps for *hazard* introduction, establishment and spread to be constructed. In a qualitative assessment, introduction and establishment are estimated using descriptors of likelihood. A quantitative assessment requires data on which to estimate likelihood. In most circumstances, the likelihood of *disease* transmission and associated consequences will be assessed qualitatively but within a formal *risk assessment* framework. Examples of descriptors for qualitative estimates of likelihood and consequence are given in Tables 1 and 2. Table 3 illustrates how estimates of likelihood and consequence can be combined in a matrix to give an estimate of *risk*. Table 4 provides an interpretation of *risk* estimates.

**Table 1. Qualitative descriptors of likelihood**

|  |  |
| --- | --- |
| **Estimate** | **Descriptor** |
| Remote | Very unlikely, but not impossible. |
| Unlikely | May occur, but only in rare circumstances. |
| Possible | Clear evidence to suggest this is possible in this situation. |
| Likely | It is likely, but not certain, to occur. |
| Certain | It is certain to occur. |

**Table 2. Qualitative descriptors of consequences**

|  |  |
| --- | --- |
| **Estimate** | **Descriptor of consequences at level of the aquaculture establishment** |
| Insignificant | Impact not detectable or minimal. No trade impacts. |
| Minor | Limited decreased production affecting only a small number of units or short-term, and/or very limited and transitory disruption to trade.  |
| Moderate | Decreased production (e.g. sustained increased mortality or decreased growth rate) and/or some short-term to medium-term disruption to trade, resulting in financial loss.  |

|  |  |
| --- | --- |
| Major | Considerable, decreased production, and/or some medium-term to long-term disruption to trade, resulting in significant financial loss. |
| Catastrophic | Complete production loss, possibly barriers to resumption of production, and/or complete loss of trade, resulting in extreme financial loss. |

**Table 3. Matrix for estimating risk**

|  |  |
| --- | --- |
| **Likelihood estimate** | Consequence rating |
|  | insignificant | minor | moderate | major | catastrophic |
| remote | negligible | low | low | low | medium |
| unlikely | low | low | medium | medium | high |
| possible | low | medium | medium | high | high |
| likely | low | medium | high | high | extreme |
| certain | low | high | high | extreme | extreme |

*Risk assessments* inform which *hazards* need to be addressed, which critical control points on the transmission pathway should be targeted for management, and the measures that are most likely to be effective in reducing *risk*.

**Table 4. Interpretation of risk estimates**

|  |  |
| --- | --- |
| ***Risk* estimate\*** | **Explanation and management response** |
| Negligible | Acceptable level of *risk*. No action required. |
| Low | Acceptable level of *risk*. On-going monitoring may be required. |
| Medium | Unacceptable level of *risk*. Review and strengthen the *risk* mitigation measures*.* |
| High | Unacceptable level of *risk*. Identify and implement additional *risk* mitigation measures*.* |
| Extreme | Unacceptable level of *risk*. Take immediate action to mitigate the *risk*. |

\* Likelihood and consequence estimates are combined using the *risk* matrix (Table 3) to produce the *risk* estimate.

**Step 3 ‒ Risk management**

*Risk management* is used to determine the appropriate management response for the assessed level of *risk* as described in Table 4. The *risk assessment* process identifies the steps within transmission pathways necessary for a *risk* to be realised and thus allows the most effective mitigation measures to be determined. Many of the *hazards* will share the same pathways and therefore mitigation measures may be effective against more than one *hazard*. Information on *hazards* and their pathways of introduction (step 1) should be combined with an assessment of *risk* associated with each pathway (step 2) to identify the most appropriate and cost-effective *risk* mitigation measures.

Article X.X.6. describes some possible mitigation measures relevant to different transmission pathways. The most appropriate mitigation measures for a specific *aquaculture establishment* will depend on the effectiveness and reliability of the mitigation measure, the category of *aquaculture* production system and cost.

After the implementation of the *biosecurity plan*, *hazards* should be regularly reassessed, and measures adjusted according to any changed *risk* estimates.

Article 4.X.8.

**Biosecurity plan development**

The purpose of a *biosecurity plan* is primarily to reduce the *risk* of introducing *pathogenic agents* intoan *aquacultur*e *establishment*, and if *pathogenic agents* are introduced, to reduce the *risk* of further spread within or release from the *aquaculture establishment*. The plan will document identified transmission pathways and the outputs of any *risk analysis* performed (*hazards, risk* estimate and mitigation measures), and information relevant to ongoing implementation, monitoring and review of the plan.

1. Development of a biosecurity plan

The process of developing a *biosecurity plan* will vary depending on its objectives, the level of *biosecurity* appropriate to the specific production system requirements, the complexity of the *disease risks* to be addressed, and availability of information and resources. Consideration and documentation of the following issues are recommended:

a) objectives, scope and regulatory requirements for the *biosecurity plan*;

b) information about the *aquaculture establishment* including an up-to-date plan of the layout of buildings and production units (including *epidemiological units*, if any, and structures and processes to maintain separation), loading/unloading, unpacking, processing, *feed* storage, *aquatic animal waste* storage, reception areas, access points and maps showing major movements of *aquatic animals*, *aquatic animal products* and *aquatic animal waste*, water, *feed* and fomites;

c) the potential pathways for entry of *pathogenic agents* into, spread within or release from the *aquaculture establishment* (refer to Article X.X.6. above);

d) a *risk analysis*, including identification of the major *disease hazards* to the *aquaculture establishment* (refer to Article X.X.7. above);

e) the mitigation measures that have been determined to address *risks*;

f) emergency procedures in the event of a *biosecurity* failure. These may include reporting requirements, and emergency measures to eradicate *pathogenic agents* such as *aquatic animal* depopulation and disposal, and site *disinfection*, in accordance with Chapters 4.3. and 7.4.;

g) internal and external communication procedures, roles and responsibilities of *aquaculture establishment* personneland essential contact information, e.g. for personnel, *aquatic animal health professionals* or *veterinarians* and the *Competent Authority*;

h) monitoring and audit schedule;

i) performance evaluation;

j) standard operating procedures required to support implementation of the mitigation measures described by the *biosecurity* *plan*, emergency procedures and the training requirements of establishment personnel.

2. Key components of a biosecurity plan

a) Standard operating procedures (SOPs)

SOPs describe routine management processes that must be performed to support the effectiveness of the *biosecurity plan*. Each SOP should clearly describe its objectives, personnel responsibilities, the procedure (including record keeping), precautions and a review date.

b) Training of personnel

Personnel should be trained in the application of the SOPs including completion of forms, checklists and other records associated with each procedure, as well as routine communication requirements.

The *biosecurity plan* should include a training programme to ensure that all personnel are capable of playing their role in the implementation of *biosecurity* at the *aquaculture establishment*.

c) Documentation and record keeping

The *biosecurity plan* describes the documentation necessary to provide evidence of compliance with the plan. The level of detail required in the documentation depends on the outcomes of the transmission pathway assessment.

Examples of documentation required include: *aquaculture establishment* layout, movements of *aquatic animals*, origin and destination and health status of the *aquatic animals* introduced to the *aquaculture establishment*, *quarantine* measures, records of visitors to the establishment, escapees, stocking densities, feeding and growth rates, records of personnel training, treatments/vaccination, water quality, cleaning and *disinfection* events, morbidity and mortality (including removal and disposal of mortalities), *surveillance* and laboratory records.

d) Emergency procedures

Procedures should be developed and, when necessary, implemented to minimise the impact of emergencies, *disease* events, or unexplained mortality in *aquatic animals*. These procedures should include clearly defined thresholds that help to identify an emergency incident and activate response protocols, including reporting requirements.

e)Health monitoring

Health monitoring as part of the *biosecurity plan* involves monitoring of the health status of *aquatic animals* in *aquaculture establishments*. Monitoring should be performed at a production unit and establishment level. Activities may include *disease surveillance*, routine monitoring of stock for important health and production parameters (e.g. by personnel, an *aquatic animal health professional* or a *veterinarian*), recording of clinical signs of *disease*, morbidity and mortality, laboratory test results and analysis of these data (e.g. calculation of rates of morbidity and mortality).

f) Routine review and auditing

The *biosecurity plan* should describe a systematic auditing schedule to verify implementation and compliance with the requirements of the *biosecurity plan*. Routine revision of the *biosecurity plan* is necessary to ensure that it continues to effectively address *biosecurity risks*.

The *biosecurity plan* should also be reviewed at least annually or in response to changes to the *aquaculture establishment* operations, changes in facility design, changes in husbandry approaches, identification of a new *disease risk*, or the occurrence of a *biosecurity* incident. *Biosecurity* incidents, and actions taken to remedy them, should be documented to enable re-assessments of SOPs.

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