



WORKING GROUP ACTIVITY 2: Day 2, 5 December 2018

Objective

To identify obstacles for the development of basic biosecurity measures to improve the prevention and control of aquatic animal diseases in OIE Member Countries in Africa and to review how the Focal Point can contribute to this.

Task

- What are the biggest challenges/obstacles preventing implementations of biosecurity measures?
 - discuss biosecurity at different levels: i) establishment/farm, ii) catchment / bay, iii) national iv) region (i.e. countries sharing watercourses). Worth starting at establishment level.
- What can the FPs do to help improving the situation? Examples of positive impacts of the Focal Point role?
- Where can you seek help/assistance?
- What can the **OIE** do to help the Focal points in this work?
- What can the **Delegate** do to do to help the FPs in this work?

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INSTRUCTIONS

HOW TO IMPROVE THE PREVENTION AND CONTROL OF DISEASES IN THE REGION? WHERE TO GET SUPPORT?

Context

The OIE has been addressing aquatic animal health issues and the development of international standards since 1960.

In 2008 the OIE established the National Focal Point for Aquatic Animals. Delegates were slow to nominate Focal Points but we now have nominated Focal Points for all Members except one in the region. Since 2010 two cycles of workshops for Focal Points have been held for the Africa region: first cycle in Swakopmund (2010), Namibia and second cycle in Grahamstown (EC), South Africa (2011) and Accra, Ghana (2012).

In addition, many Focal Points have also attended the two OIE Global Conferences on aquatic animal health (2011 in Panama and 2015 in Vietnam).

The Aquatic Animal Health Specialist Commission has just recently sent a new draft chapter on biosecurity in aquaculture establishments for Member Country comments. The new chapter intend to give guidance to the Member countries on basic biosecurity measure to prevent the introduction of pathogenic agents into, within and from aquaculture establishments.

See Terms of Reference are attached in [Annex 1](#)

See new draft chapter on biosecurity in aquaculture establishments in [Annex 2](#).

Objective

To identify obstacles for the development of basic biosecurity measures to improve the prevention and control of aquatic animal diseases in OIE Member Countries in Africa and to review how the Focal Point can contribute to this.

Task

Nominate someone to report back to the plenary.

Report back on:

- What is the situation in the OIE Member Countries in Africa as regard implementation of preventive and control measures for aquatic animal diseases?
- What are the biggest challenges obstacles preventing implementations of such measures?

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- What can the FPs do to help improving the situation? Examples of positive impacts of the Focal Point role?
- Where can you seek help/assistance?
- What can the **OIE** do to help the FPs in this work?
- What can the **Delegate** do to do to help the FPs in this work?
- What can the **Focal Point** do to help the FPs in this work?

Report back

Each group will report back key points from their discussions. Please don't take us through your conversation.

Terms of Reference for the OIE National Focal Point for Aquatic Animals

During the 76th General Session in May 2008 the importance of the focal point for information on animal diseases was re-iterated and Delegates were also requested to nominate additional focal points for wildlife, veterinary products, animal production food safety, animal welfare and aquatic animals.

As detailed in the final report of the 76th OIE General Session in May 2008, the responsibilities of the focal points are under the authority of the OIE Delegate. Any information transmitted to the OIE from the different focal points needs to be transmitted under the designated authority of the OIE Delegate. This practice would equally apply, if focal points are located in other Departments or Ministries not under jurisdiction of the Veterinary Authority, as from a legal perspective, the OIE considers the official OIE Delegate to be the unique representative of the country.

Details on proposed tasks of the national focal point for aquatic animals:

1. to establish a network of aquatic animal health experts within her/his country or to communicate with the existing network;
2. to establish and maintain a dialogue with the Competent Authority for aquatic animal health in her/his country, and to facilitate cooperation and communication among several authorities where responsibility is shared;
3. under the authority of the OIE Delegate of her/his country, to support the optimal collection and submission of aquatic animal disease information to the OIE through WAHIS (immediate notifications and follow-up reports, six-monthly reports, and annual questionnaires) to enable the OIE Delegate to more efficiently manage his OIE Member obligations;
4. to act as a contact point with the OIE Animal Health Information Department on matters related to information on aquatic animals including aquatic animal diseases;
5. to receive from the OIE Central Bureau copies of the reports of the Aquatic Animal Health Standards Commission and other relevant reports, and conduct the in-country consultation process with recognised aquatic animal health experts on draft texts of standards proposed in those reports; and
6. to prepare comments for the Delegate on relevant meeting reports reflecting the scientific view and position of the individual OIE Member Country or Territory and/or the region, including comments on the proposals for new or revised OIE standards related to aquatic animals.

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 *aquaculture 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 application of the standards in the *Aquatic Code* at the level of 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, the use of *risk analysis* to develop a *biosecurity plan*, and the key components of a plan.

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*. This chapter describes *biosecurity* principles 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 physical and management measures to mitigate the identified *risks* according to the circumstances of the *aquaculture establishment*. Staff and service providers 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 status of *aquatic animals* throughout the production cycle. The benefits include market access and increased productivity, directly through improved survival, growth rates and *feed* conversion and indirectly through the reduction in treatments and associated production costs.

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 an *aquaculture establishment*. Implementation of *biosecurity* within an *aquaculture establishment* requires planning to identify *risks* and consider cost effective measures to achieve the identified *biosecurity* objectives of the plan. The measures required will vary between *aquaculture establishments*, depending on factors such as *risk* of exposure to *pathogenic agents*, *aquatic animal* species, category of *aquaculture* production system, husbandry practices and geographic location. Although different approaches may be used to achieve an identified objective, the general principles for developing and implementing a *biosecurity plan* are described as below:

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- 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) Potential pathways for *pathogenic agents* to be transmitted into, spread within and released from the *aquaculture establishment* must be identified, as described in Articles 4.X.5. and 4.X.6., and giving consideration to the category of *aquaculture* production system and design of the *aquaculture establishment*.
- 3) *Risk analysis* should be undertaken to evaluate *biosecurity* threats and ensure 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 *disease risks*, as described in Article 4.X.7.
- 4) *Biosecurity* measures to address identified *disease risks* should be evaluated based on their potential effectiveness, initial and ongoing costs (e.g. building works, maintenance), and management requirements, as described in Article 4.X.7.
- 5) Management practices should be integrated into the *aquaculture establishment's* operating procedures and associated training are provided to personnel, as described in Articles 4.X.7. and 4.X.8.
- 6) A routine review schedule of the *biosecurity plan* and identified triggers for *ad hoc* review must be determined (e.g. changes to infrastructure, production techniques or *risk* profiles). Third party audit may be required where recognition of the *biosecurity* measures is required by customers, regulators or for market access, as described in Article 4.X.8.

Article 4.X.5.

Categories of aquaculture production systems

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

Open systems

Open *aquaculture* production systems have no control of water, environmental conditions and animals. These production systems may include stock enhancement of wild populations. As these systems cannot be considered 'establishments', they are not considered further in this chapter.

Semi-open

In a semi-open *aquaculture* production system, it is not possible to have control of water entering or exiting the system, or 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 in natural water bodies and mollusc *aquaculture*, either suspended in the water column or on the ocean floor.

Semi-closed

In a semi-closed *aquaculture* production system, there is some control of water entering and exiting the system and of environmental conditions. *Aquatic animals* and *vectors* may 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 pens and flow through tanks.

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Closed

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

Article 4.X.6.

Transmission pathways and associated risks

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 pathways that may expose susceptible *aquatic animals* to high loads of *pathogenic agents* should be prioritised.

The *risks* associated with introduction, spread, 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 *risk* of *pathogenic agent* 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 animals intentionally brought into an *aquaculture establishment*, or moved within it, may include broodstock, juvenile stock for on-growing, and genetic material such as eggs. Both horizontal and vertical transmission mechanisms should be considered for *aquatic animals*. The *risk* of transmitting *pathogenic agents* via *aquatic animals* can be managed by:

- a) Only introducing *aquatic animals* into the *aquaculture establishment* with known health status, which is of equal or higher status than the animals in the establishment.
- b) Quarantining introduced *aquatic animals* of unknown *disease* status from other farm populations in separate production units or dedicated *quarantine* facilities.
- c) Where appropriate, treatment of quarantined *aquatic animals* to mitigate *disease risks* (for example, for external parasites).
- d) Ensuring biosecure transport of *aquatic animals* that avoids exposure to *pathogenic agents*.
- e) Only moving *aquatic animals* between different populations within the establishment following consideration of the *disease risks* and with a view to maintaining high health status of *aquatic animal* population.
- f) Isolating *aquatic animal* populations that display clinical signs of *disease* from other populations until the cause is known and the situation is resolved.
- g) Removing sick or dead *aquatic animals* from production units as soon as possible and disposing of them in a biosecure manner in accordance with Chapter 4.7.
- h) Where possible, preventing unintended movement of *aquatic animals* into, within or from the establishment.

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.

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2. Aquatic animal products and waste

Aquatic animal products may also be brought into an *aquaculture establishment* or moved within it; for example, *aquatic animal products* derived from *aquatic animals* harvested at other sites. *Aquatic animal waste* may include the entire body or parts of *aquatic animals* that have died or been killed for *disease control* purposes, as well as slaughtered *aquatic animals*, and their parts, that are not intended for human consumption.

Movement of *aquatic animal products* and *aquatic animal waste* into, within and out of *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*. High *risk waste* includes *aquatic animal waste* that constitutes, or is suspected of constituting, a high health *risk* to *aquatic animals*.

For intentional movements of *aquatic animal products* and *aquatic animal waste*, the likelihood of presence of *pathogenic agents* in the *aquatic animals* from which products and 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* can be managed by:

- a) determining the potential *disease risk* of *aquatic animal products* and *waste* to the establishment and the environment;
- b) isolating areas within the *aquaculture establishment* where *aquatic animal products* and *waste* are managed from *aquatic animal* populations to minimise identified *disease transmission risks*;
- c) ensuring systems are implemented for appropriate collection, treatment (inactivating *pathogenic agents*), transport, storage or disposal of *aquatic animal products* and *waste* to minimise 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 introduction of *pathogenic agents* into, spread within, and release from *aquaculture establishments*. The source of the water and how it provides 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 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 can be managed by:

- a) Where possible, choosing water sources that are entirely 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* such as broodstock.
- b) Providing 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 may present a *risk* of *pathogenic agent* transmission (e.g. oceans, streams or lakes). The level of treatment required will depend on the identified *risks*.

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- c) Ensuring 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.

4. Feed

Feed can be an important pathway for transmission of *pathogenic agents* to *aquatic animals*. *Feed* may be initially infected with *pathogenic agents* or 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 of control on *aquatic animal feeds*. However, in semi-open production systems, *aquatic animals* may obtain food from their environment (e.g. filter feeding molluscs or wild fish which may be predated in net pens).

The *risk* of transmitting *pathogenic agents* via *aquatic animal feed* can be managed 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* are not present in the commodity;
- c) have been processed, manufactured, stored and transported in a manner to prevent contamination by *pathogenic agents*.

5. Fomites

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

The level of *risk* of transferring *pathogenic agents* will depend on the presence and nature of organic matter on the fomite surface, as well as the type of surface and its ability to hold water. The *risk* of transferring *pathogenic agents* may be higher for fomites which are difficult to clean and disinfect. Equipment that is shared between *aquaculture establishments*, between *aquaculture establishments* and processing facilities or between different production units within an *aquaculture establishment* with unequal health status, may present a higher *risk* compared to new or dedicated equipment. The *risk* of transmitting *pathogenic agents* via fomites can be managed by:

- a) Assessing any fomites brought into the *aquaculture establishment* for their *disease risk*.
- b) Ensuring procedures and infrastructure are in place to clean and disinfect fomites, including at designated delivery and loading areas. Recommendations for the cleaning and 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.

6. Vectors

Vectors can transport *pathogenic agents* to susceptible *aquatic animals* in *aquaculture establishments*. These include wild *aquatic animals* entering via the water supply, predators, wild birds, and pest animals such as rodents. *Vectors* can transfer *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*.

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The risk of transferring *pathogenic agents* via *vectors* varies with *vector* species, the nature of the *pathogenic agent*, the category of *aquaculture* production system, and the level of *biosecurity*.

Article 4.X.7.

Risk analysis

Risk analysis is an accepted approach for evaluating *biosecurity* threats and 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.).

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 the *biosecurity plan* are:

Step 1 – Hazard Identification

Hazard identification determines which *pathogenic agents* should be the subject of the *risk assessment*. 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.

To complete the next steps of the *risk assessment*, required information on the identified *hazards* is 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. A *hazard* may include a specific *pathogenic agent* or be defined in more general terms as a group of *pathogenic agents*.

Step 2 – Risk Assessment

A *risk assessment* can be initiated once it has been identified that a biological *hazard* exists. The aim of the *risk assessment* is to establish a *risk* estimate, which is the product of the likelihood and consequences of *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, transmission pathways will be assessed qualitatively but within a formal *risk assessment* framework. Examples of descriptors for 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 1. Qualitative descriptors of likelihood

Estimate	Descriptor
Remote	Never heard of, 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.

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Annex 12 (contd)

Table 2. Qualitative descriptors of consequences

Estimate	Descriptor
Insignificant	Impact not detectable or minimal.
Minor	Impact on <i>aquaculture establishment</i> productivity limited to some production units or short term only.
Moderate	Widespread impact on <i>aquaculture establishment</i> productivity due to increased mortality or decreased performance.
Major	Considerable impact on <i>aquaculture establishment</i> production resulting in serious supply constraints and financial impact.
Catastrophic	Complete depopulation of the <i>aquaculture establishment</i> and possibly barriers to resumption of production.

Table 3. Matrix for assessing risk

	Consequence rating					
		insignificant	minor	moderate	major	catastrophic
Likelihood estimate	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	high	high	extreme	extreme

Results of *risk assessment* informs which biological *hazards* need to be addressed, which critical control points on the transmission pathway should be targeted, and the measures which are most likely to be effective in reducing *risk*.

Table 4. Interpretation of risk estimates

Risk level*	Explanation and management response
Negligible	Acceptable level of <i>risk</i> . No action required.
Low	Acceptable level of <i>risk</i> . On-going monitoring may be required.
Medium	Unacceptable level of <i>risk</i> . Active management is required to reduce the level of <i>risk</i> .
High	Unacceptable level of <i>risk</i> . Intervention is required to mitigate the <i>risk</i> .
Extreme	Unacceptable level of <i>risk</i> . Urgent intervention is required to mitigate the level of <i>risk</i> .

*Risk level determined by combination of likelihood and consequence score using the *risk* matrix (Table 3).

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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 thus mitigation measures may be effective against more than one *hazard*.

Article X.X.6. describes some possible mitigation measures relevant for different transmission pathways. The most appropriate mitigation measures for a specific *aquaculture establishment* will depend on the *risks* 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* into an *aquaculture 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 develop a *biosecurity plan* will vary depending on 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 is recommended:

- a) objectives and regulatory requirements for the *biosecurity plan*;
- b) information about the *aquaculture establishment* including the layout of buildings and production units, and maps showing major movements of *aquatic animals*, *aquatic animal products* and 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;
- g) standard operating procedures required to support implementation of the mitigation measures, emergency procedures and the training requirements of personnel;
- h) internal and external communication procedures, and roles and responsibilities of personnel;
- i) monitoring and audit schedule;

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- j) performance evaluation.

2. Key components of a biosecurity plan

- a) Standard operating procedures (SOPs)

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

Staff 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) Documentation and record keeping

The *biosecurity plan* describes documentation necessary to provide evidence of compliance with the mitigation measures. 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 health status of the *aquatic animals* introduced to the *aquaculture establishment*, stocking densities, feeding and growth rates, records of staff training, treatments/vaccination, water quality, morbidity and mortality, *surveillance* and laboratory records.

- c) 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) Health monitoring

Health monitoring as part of the *biosecurity plan* involves monitoring of the health status of *aquatic animals* in *aquaculture establishments*. Activities may include *disease surveillance*, routine monitoring of stock for important health and production parameters, recording of clinical signs of *disease*, morbidity and mortality, and analysis of these data (e.g. calculation of mortality and diseases).

- e) 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 it continues to effectively address *biosecurity risks*.

The *biosecurity plan* should also be reviewed in response to changes to the *aquaculture establishment* operations, changes to 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-assessment.