UNITED STATES’ COMMENTS IN RED BELOW

Annex 40. Item 7.1. – Draft new Chapter 4.X. ‘Emergency disease preparedness’

SECTION 4

DISEASE PREVENTION AND CONTROL

CHAPTER 4.X.

EMERGENCY DISEASE PREPAREDNESS

**GENERAL COMMENTS**

Now that there are definitions for “Competent Authority” vs. “Veterinary Authority”, we feel there may be areas of this chapter where the authority currently referenced is not in alignment with the glossary definitions as we understand them.

Additionally, we do not see reference to the importance of developing case definitions for pathogens of concern prior to a disease outbreak. It is unclear if this information should be added to this section of Chapter 4.X. or if it will be addressed elsewhere in the chapter. If case definitions are not mentioned elsewhere, then we recommend adding them under Article 4.X.4. of this chapter.

Article 4.X.1.

Purpose

To describe the essential elements of an emergency disease preparedness framework which a *Competent Authority and/or Veterinary Authority* should develop in accordance with country priorities and resources to ensure that *outbreaks* of important and *emerging* *aquatic animal* *diseases* can be rapidly identified and efficiently managed, and which will guide a country, *zone* or *compartment*, towards a suitable path to recovery.

**RATIONAL**

It is unclear if the responsible authority should be the *Competent Authority*, the *Veterinary Authority,* or both*.* We recommend including either both or just the “Veterinary Authority” for this activity.

An important *aquatic animal disease* is one which has been identified by the *~~Competent Authority~~*  *Veterinary Authority* in accordance with Article 4.X.6. Such *diseases* may be listed in Chapter 1.3., or they may be *emerging diseases* or other *aquatic animal diseases*.

**RATIONAL**

It is unclear if the responsible authority should be the *Competent Authority*, the *Veterinary Authority*, or both.We recommend “Veterinary Authority” for this activity.

Article 4.X.2.

Scope

This chapter describes recommendations for the development of an emergency disease preparedness framework. This framework encompasses all the elements that will enable the *~~Competent Authority~~*  *Veterinary Authority* to activate an efficient response to a *disease* *outbreak*, thereby minimising the impact on *aquatic animal* populations, trade, the economy, and the financial resources that are required to manage *disease outbreaks*. The specific actions which are necessary to operationalise the framework in the event of a *disease* *outbreak* are described in Chapter 4.Y.

Article 4.X.3.

Introduction

*Aquatic animal* *disease*s have the potential to spread quickly, often with serious consequences. In many parts of the world, these *disease* events appear to be increasing in frequency and severity, due to increased *aquaculture* production and *international trade*. This chapter provides recommendations for a *Competent Authorities* to identify and coordinate the elements of a framework, which will achieve a suitable level of preparedness for those emergencies.

When developing the framework, it is of fundamental importance to ensure that the *aquatic animal* *disease*s which are important to a country, *zone* or *compartment*, are identified in advance (i.e. in peacetime) by the *Competent Authorities*, and that their future control is supported by adequate legislative and funding measures. The statutory list of important *disease*s that is developed after conducting a *risk analysis* as described in 4.X.6.*,* may include *aquatic animal* *disease*s which are listed in Chapter 1.3., as well as other *disease*s which have been identified as being of importance to the country, *zone* or *compartment*.

Also in peacetime, the *Competent Authorities* should take a systematic approach to planning every element of the framework that will be applied from the point at which an important *disease* is suspected during the alert phase, through the activation of the *contingency plan* in the emergency phase, to the point at which the recovery phase begins and the emergency officially ends.

The *Competent Authorities* should consider whether the *contingency plan* and recovery plan elements of the emergency disease preparedness framework apply either to a specific *aquatic animal* *disease* or to a group of such *diseases*. The *Competent Authority* should decide in peacetime, which of these approaches best meets their needs, taking into account *aquatic animal* *diseases* that are listed in their country, the relevant *susceptible species,* and types of production.

**RATIONAL**

We recommend changing “Competent Authority” to “Competent Authorities” since some members have more than 1 agency/group involved in the oversight of these activities.

Article 4.X.4.

General principles

Emergency *disease* preparedness is a core function of the *~~Competent Authority~~*  *Veterinary Authority.* The various elements that are necessary to ensure that the *~~Competent Authority~~*  *Veterinary Authority* is prepared to deal with an *outbreak* of an important *disease*, are elaborated in a framework. The framework is constructed in peacetime before the occurrence of a *disease* *outbreak*.

**RATIONAL**

It is unclear if the responsible authority should be the *Competent Authority,* the *Veterinary Authority*, or both.We recommend changing “Competent Authority” to “Veterinary Authority” for this activity.

The ultimate success of the framework will be influenced by the quality of the preparations which have been made by the *Competent Authority*, and the commitment and coordination of the *Aquatic Animal Health Services*, and relevant industry stakeholders.

The general principles to be considered when developing an emergency disease preparedness framework are as follows:

1) legal provisions and funding should be available to allow ~~a~~ *Competent Authorities* to execute all elements of the framework and to manage disease outbreaks in compliance with the contingency plan, and with the detailed operational measures which are referred to in Chapter 4.Y.;

**RATIONAL**

We recommend changing “Competent Authority” to “Competent Authorities” since some members have more than 1 agency/group involved in the oversight of these activities.

2) risk analysis should be used in advance of, during and after a disease outbreak as described in Article 4.X.6. The risk analysis that is carried out in advance will identify the important aquatic animal diseases which will be subject to emergency measures. The risk analysis that is carried out during and after the disease outbreak will inform the response and recovery actions which will be taken by the Competent Authority, ~~and~~ the Aquatic Animal Health Services, and industry stakeholders;

3) a contingency plan should be developed for a specific aquatic animal disease or group of related aquatic animal diseases, following appropriate consultation with the Aquatic Animal Health Services, which contains at least the components outlined in points (a) to (f) of Article 4.X.7. The contingency plan is:

a) partially activated in compliance with Article 4.Y.4.~~Chapter 4.Y.~~ when the presence of an important *disease* is suspected during the ‘alert phase’;

b) fully activated in compliance with Article 4.Y.5.~~Chapter 4.Y.~~ once the *disease* emergency has commenced during the ‘emergency phase’.

4) simulation exercises should be planned and executed to test, and ultimately to improve, relevant elements of the disease preparedness framework. Simulation exercises support~~ensure that~~ *Competent Authorities* and *Aquatic Animal Health Services* to be~~are~~ trained and properly equipped and resourced~~to manage suspicion and confirmation of an important~~ *~~disease~~* ~~in their~~ *~~territory~~*~~,~~ in accordance with Article 4.X.8.;

5) all elements of the framework should be regularly reviewed and revised as described in Article 4.X.9.;

6) a ‘recovery plan’ should be prepared as described in Article 4.X.11., which will be based on *risk analysis* and on the recovery options which are described in Article 4.X.10.

Article 4.X.5.

Legal provisions and funding

There are certain pre-requisites for an emergency disease preparedness framework including~~. Such pre-requisites include~~ that the *Competent Authorities have*~~has~~:

1) ~~recourse to~~ *aquatic animal* health legislation which underpins the execution of all the elements and actions that are necessary to manage suspicion and confirmation of an *outbreak* of an important *aquatic animal* *disease* as described in Article 4.X.6.*;*

2) access to emergency resources including funds which are sufficient to allow the execution of the relevant elements of the *disease* preparedness framework as well as the operational measures which are set out in Chapter 4.Y.

Any delay in the ability of the *Competent Authorities* to rely on legal provisions, or to access finance, can hamper the effective management of a *disease* emergency. Delays should be avoided, or at least minimised, by ensuring that all the administrative steps that must be followed to transmit the necessary funds from the central funding authority to the *Competent Authority* are identified.

**RATIONAL**

We recommend changing “Competent Authority” to “Competent Authorities” since some members have more than 1 agency/group involved in the oversight of these activities.

Article 4.X.6.

Risk analysis

*Risk analysis* plays an important role before, during and after a *disease outbreak*. It is therefore, of critical importance that this expertise is available to the *Competent Authorities* to ensure that the emergency disease preparedness framework can be efficiently executed. This article elaborates the principles described in Chapter 2.1 and applies them in the context of emergency *disease* preparedness.

**RATIONAL**

We recommend changing “Competent Authority” to “Competent Authorities” since some members have more than 1 agency/group involved in the oversight of these activities.

Identification of aquatic animal diseases which will be subject to emergency measures

*Risk analysis* should be used by the *Competent Authority* to determine which important *diseases* of *aquatic animal*s present a threat and should, therefore, be subject to emergency measures in the event of a *disease* *outbreak*.

The *risk analysis* should take account of a country’s circumstances. In particular, the knowledge of relevant wild and farmed *aquatic animal* species in the *territory*, as well as their geographic distribution, *disease* status and economic and trade importance, are critical to the completion of an effective *risk analysis*. Such *risk analysis* should also include information on the most important routes of introduction, transmission pathways, life cycle stages, persistence in the environment, likelihood of eradication, which will inform *disease* control strategies and response options which are referred to in Article 4.X.10.

The list of important *aquatic animal* dise*ases* that may be subject to emergency measures should be under regular~~continual~~ review by the *Competent Authority*. The *risk analysis* should utilise~~take into account~~ the latest relevant scientific findings and should be repeated regularly to assess the threat of *emerging diseases.* Changes in the species farmed, and in the distribution or virulence of known *pathogenic agents* should inform changes in national *disease* listings. *Competent Authorities* should ensure they collate the data required for completing and updating *risk analysis.*

Surveillance activities

Suspicion of an outbreak of an important aquatic animal disease, which is subject to statutory control, often results from surveillance activities. Therefore, emergency disease preparedness systems are heavily reliant on the surveillance and reporting activities carried out by the Aquatic Animal Health Services, and relevant industry stakeholders in accordance with Chapter 1.4. The outcomes from an emergency disease preparedness framework are fundamentally reliant on the quality of *surveillance* and reporting activities.

In addition, when the presence of an important aquatic animal disease is suspected or has been confirmed, risk analysis has a crucial role to play in prioritising surveillance activities as part of forward and backward epidemiological tracing, and establishing *protection zones* and *infected zones*.

Response actions during the *disease* emergency

As part of preparedness planning, *risk analysis~~assessment~~* protocols should be developed to support decision making by the *Competent Authority* during an *outbreak*. The *risk analysis* should be able to identify the *risk* mitigation measures and protocols that~~Protocols~~ are required to cover a range of *disease* control options e.g. the possibility to on-grow stock on an infected *aquaculture* *establishment* to slaughter weight (which will include an assessment of the *risk* of spread within a particular water body), and the possibility to move live *aquatic animals* within *infected* *zones*.

A *risk analysis~~assessment~~* of depopulation activities should be undertaken to ensure that they are carried out with the minimum risk of *disease* spread. In addition, prior to repopulation, a *risk analysis~~assessmen~~t* should be completed to determine if further *risk* mitigation measures are required to prevent reinfection of the new stock of *aquatic animals*.

Article 4.X.7.

Contingency plan

The *Competent Authority* should decide whether the *contingency plan* applies either to a specific *aquatic animal* *disease* or to a group of such *diseases* which, because of their similarity to each other, may be managed effectively using the same principles e.g. certain finfish *diseases* that occur in freshwater, certain mollusc *diseases* that occur in seawater.

The *Competent Authority* should also consider that because of the nature of *emerging diseases*, the *contingency plan* and the recovery plan, which are devised for such *aquatic animal* diseases, should be generic. Such generic plans will, however, require rapid and effective fine-tuning, once the details of the *emerging disease* have become known, and the *Competent Authority* has assessed that the *disease* in question should be subject to emergency *disease* preparedness measures.

The contingency plan should include at least the following components:

1) the establishment of a clear chain of command within the country, from the central level to the regional and local levels, with the *Competent Authority* in overall command. This chain of command should include decision makers from the *Aquatic Animal Health Services* who may not deal directly with *aquatic animal* health, but who play a role in the emergency disease preparedness framework;

2) a framework for cooperation between the *Competent Authority*, ~~and the~~ *Aquatic Animal Health Services* and industry stakeholders. This cooperation should:

a) ensure that all actions, and roles and responsibilities which form part of the plan are well understood and discussed in advance of and during, any *disease* *outbreaks*, thereby ensuring that rapid and effective decisions can be made when necessary;

b) result in the establishment of at least the following groups which meet at frequencies which may vary depending on the phase of the emergency:

i) a formally recognised emergency management group which is chaired by the *Competent Authority*;

ii) specialist sub-groups which will provide specific advice to the emergency management group~~Emergency Task Force~~ for consideration e.g. epidemiology group, laboratory group, logistics group, communications group, environmental group, producers’ group, mental health and psychological support group.

3) identification of, and arrangements for access to, appropriate:

a) central and local *disease* control centres;

b) laboratories;

c) equipment;

d) trained personnel;

e) communications and media liaison;

f) data management or information systems;

g~~f~~) additional materials and resources that may be required, including for instance, telecommunications, transport, vaccines, experts (e.g. in the areas of logistics, fisheries management, environmental protection);

h~~g~~) service providers (e.g. waste disposal contractors, Personal Protective Equipment (PPE) suppliers, chemical suppliers, standby generators).

4) the general *biosecurity* and *disease* control measures which will be taken in the event of suspicion or confirmation of the presence of an important *aquatic animal* *disease* to which the *contingency plan* applies. The general *biosecurity* measures which will apply to *aquaculture establishments* should follow the guidance on~~comply with~~ the measures which are described in Chapter 4.1. Coordination of control measures with neighbouring countries with shared waterbodies should be taken into account;

5) concerning specific *disease* control measures, the duration of the *fallowing* period that may apply following de-population, cleaning and *disinfection*, should be considered~~, using~~ *~~risk~~**~~assessment~~*. The duration of the fallowing period~~Such an assessment~~ should take into account relevant factors such as the nature of the relevant *pathogenic agent*, the type and extent of the production system, hydrographical factors and the nature of local wild *aquatic animal* populations. ~~The~~ *~~risk assessment~~* ~~should also inform the need for synchronised~~Synchronised *fallowing* of a number of *aquaculture establishments*, should be considered in certain circumstances;

6) possible response options that can be applied to manage a *disease* *outbreak*, based on *risk assessment*. Such response options would depend on the progression of the *disease* *outbreak* and could include measures such as eradication, containment through *biosecurity* measures, mitigation of *disease* consequences, or no *disease* response;

7) *risk communication* strategy which will apply during each stage of the process, both within and between the various authorities and services and with relevant stakeholders. For example, the *contingency plan* should set out the nature and timing of communications with the personnel who are described in points 2(b)(i) and (ii) above, as well as taking community engagement into account, where appropriate. The *risk communication* strategy should be based on the principles of *risk communication* described in Chapter 2.1.

The actions necessary to operationalise points 1 to 7 above are described in Chapter 4.Y.

Article 4.X.8.

Simulation exercises

Simulation exercises are a crucial component of emergency *disease* preparedness. The objectives of such exercises are to validate and test the functionality and suitability of the *contingency plan* and the operational measures which are described in Chapter 4.Y. Simulation exercises will also validate and test the capacity of *Competent Authorities*, ~~and~~ *Aquatic Animal Health Services*, and industry stakeholders to respond to an important *aquatic animal* *disease*. The emergency disease preparedness framework should include a requirement for the regular completion of simulation exercises to test that all personnel are adequately trained and prepared for the tasks which have been allocated to them. An outcome report should be produced following each simulation exercise, describing the actions necessary to close any gaps which have been identified in the *contingency plan*, or other amendments which are required to the operational measures which are described in Chapter 4.Y.

The *Competent Authority* should set a minimum frequency for the completion of such exercises, to ensure readiness to efficiently execute the various elements of the *contingency plan,* should it be activated. Simulation exercises may be organised within a country or among the *Competent Authorities* and *Aquatic Animal Health Services* of countries or zones with shared waterbodies where relevant.

A simulation exercise should have clearly defined objectives with respect to the elements of the emergency disease preparedness framework or outbreak response capability that is being evaluated. The objectives will inform the type of exercise, participation and the exercise design.

The planning, organisation, and completion of simulation exercises should take account of the following points:

1) different types of exercises may be used e.g. tabletop, limited field exercises or more extensive field exercises;

2) the scale, frequency and scope of the exercises should be based on *risk* prioritisation, which has been completed by the *Competent Authority,* taking account of any new *risk* factors which have been identified;

3) exercises should include the *Competent Authority* at different administrative levels, as well as the *Aquatic Animal Health Services,* and relevant industry stakeholdersthat will be involved in the application of the *contingency plan* in the event of a *disease* emergency;

4) exercises should test the capacity of the *Competent Authority* to manage every element of the emergency disease preparedness framework, from the initial *disease* alert to the end of the recovery phase;

5) once completed, each simulation exercise should be thoroughly evaluated by the organiser, and an outcome report should be prepared, with the objective of identifying:

a) the elements of the emergency disease preparedness framework that are fit-for-purpose, and those that are not;

b) the readiness and capacity of the *Competent Authority*, ~~and~~ the *Aquatic Animal Health Services*, and industry stakeholders to respond to the elements of the emergency disease preparedness framework, that were tested during the exercise.

c) any gaps/issues raised and any actions to be taken forward, including a timeframe within which these should be addressed.

Article 4.X.9.

Revision and review

The *Competent Authority* should establish a mechanism to improve its emergency disease preparedness framework through regular review, and where necessary, revision of its various elements.

The list of *aquatic animal diseases* which are subject to the emergency disease preparedness framework should be under regular~~continual~~ review, as described in Article 4.X.6.

Review and revision of the *contingency plan* and the operational measures which are set out in Chapter 4.Y. should take into account, the outcomes from the evaluation of the simulation exercises described in Article 4.X.8., and the implementation of an emergency *disease* response, where this is relevant.

The review process consequently may necessitate a revision of the *contingency plan* or other elements of the emergency disease preparedness framework. Such exercises and responses should also be used to highlight the training needs of personnel from the *Competent Authority* and the *Aquatic Animal Health Services,* and to inform the possible revision of the legislation which underpins the framework.

The regular review and revision of the emergency disease preparedness framework should also take into account measures to strengthen the *contingency plan* or to prevent another *disease* emergency event~~,~~ (e.g. updated scientific information including diagnostic tests, improvements in technology or relevant industry practices, as well as any other new elements which will improve the overall suitability and effectiveness of the framework).

All revisions which are made as a result of the review process described above should be communicated to the *Aquatic Animal Health Services* and industry stakeholderswithin an agreed timeframe.

Article 4.X.10.

Response Options

The *Competent Authority* should take into account that the initial objective of successfully completing an eradication programme and re-gaining *disease* freedom in a country, zone or compartment following a disease outbreak, may change as *the outbreak* develops.

While the purpose of the recovery plan, may be to re-establish the *disease-free* situation which existed before the *disease* *outbreak* occurred, it should be considered that in certain cases, the *aquatic animal health status* which is achieved after the emergency has ended, may not be the same as the one which existed before the *outbreak* occurred. Various response options should, therefore, be set out in the emergency disease preparedness framework, upon which the recovery plan can be based, depending on the epidemiological situation which exists at the end of the emergency.

Concerning the *aquatic animal* *diseases* which are listed in Chapter 1.3., and taking into account Chapter 1.4., the possible options the *Competent Authority* could consider as part of their recovery plan are as follows:

1) demonstrate the re-establishment of disease freedom at country, zone or compartment level;

2) establish a disease free zone in a previously disease free country;

3) establish a redefined (reduced) disease free zone;

4) establish one or more disease-free compartments;

5) relinquish disease free status and take measures to contain the disease;

6) take measures which are designed to mitigate the impacts of the disease;

7) accept that none of the options outlined above are feasible and no official disease control measures will be applied.

If *disease* control operations are halted before regaining the pre-*outbreak* *disease* free status at country or *zone* level, the recovery plan should set out how the *Competent Authority* could explore the potential to establish redefined *disease* *free zones* or *compartments.*

Where the options described in points 1 to 6 above are not possible for epidemiological, logistical or economic reasons, the *Competent Authority* may accept an evolution from the original *disease* free status, to one where the *disease* has become endemic, but where the epidemiological situation is stable.

Concerning important *aquatic animal* *diseases* which are not listed in Chapter 1.3., but which are listed in the national legislation of a country, the *Competent Authority* may decide to apply a similar range of options to those described in points 1 to 4 above. However, these would not fall within the scope of the official *disease free* statuses that may be established for a country, *zone* or *compartment*, as described in Chapter 1.4.

Article 4.X.11.

Recovery plan

The Competent Authority should decide whether the recovery plan applies either to a specific aquatic animal disease or to a group of such diseases which, because of their similarity to each other, may be managed effectively using the same principles e.g. certain finfish diseases that occur in freshwater, certain mollusc diseases that occur in seawater.

The recovery plan should be activated when the end of the emergency has been declared by the Competent Authority. The point at which the emergency ends, and the nature of the recovery plan, will be determined by risk analysis~~assessment~~, which will take account of the following factors as well as the options described in Article 4.X.10.:

1) the current geographic distribution of the *pathogenic agent;*

2) whether or not, the disease has become established in wild *aquatic animal* populations;

3) the costs and feasibility of establishing and maintaining *disease*-freedom at the level of country, *zone* or *compartment,* taking into account hydrological and epidemiological connections;

4) the socio-economic impact of the possible recovery option(s);

5) any *risk* the *disease* may pose to vulnerable wild *aquatic animal* populations in the infected or adjacent areas.

Concerning the response options described in points 1 to 6 of Article 4.X.10., the recovery plan should include details of the actions which the *Competent Authority* and the operators of aquaculture establishments should take to:

6) prepare a self-declaration of freedom from disease, as referred to in points 1 to 4 of Article 4.X.10.; or

7) put in place appropriate biosecurity measures in compliance with Chapter 4.1., to ensure the disease is contained, as referred to in point 5 of Article 4.X.10.; or

8) put in place the mitigation measures which are referred to in point 6 of Article 4.X.10.~~,~~ (e.g. vaccination, change of production species, or change in husbandry practices);

9) consider research requirements to support the actions referred to in points 6 to 8.

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