Annex 10. Item 6.6. – Draft new Chapter 4.X. Emergency disease preparedness

SECTION 4

DISEASE PREVENTION AND CONTROL

**USA COMMENTS IN RED FONT**

CHAPTER 4.X.

EMERGENCY DISEASE PREPAREDNESS

**GENERAL COMMENTS:** We appreciate the Commission’s work drafting this important new chapter. Please see the suggested changes below which we feel are less prescriptive and more in line with the Terrestrial Code chapters addressing this same topic. We recommend that authors review the terrestrial chapters and mirror the more flexible language.

Article 4.X.1.

Purpose

To describe the essential elements of an emergency disease preparedness framework which a *Competent 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.

**RATIONALE:** Edits mirror the text found in Terrestrial Code chapters, specifically Chapters 4.1 and 4.19.

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* 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.

**RATIONALE:** Competent authorities should have the flexibility to consider these elements and others as practical.

Introduction

*Effective prevention and control of transmissible animal diseases, including zoonoses, is a central mandate of the Competent Authority of each Member Country.*

*The chapters in this section describe modern tools to prevent, control and even eradicate transmissible animal diseases, and recommendations for disease prevention and control. Aquatic animal health authorities should consider developing measures based on the recommendations in this section, considering various factors including their impact on trade, animal welfare, public health and environment.*

*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 environmental factors, increased *aquaculture* production and *international trade*. This chapter provides recommendations for a *Competent Authority* 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 Authority*, 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 Authority* 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 Authority* 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.

**RATIONALE:** Edits mirror the text found in Terrestrial Code chapters, specifically Chapters 4.1 and 4.19.

Article 4.X.4.

General principles

Emergency *disease* preparedness is a core function of the *Competent Authority.* The various elements that are necessary to ensure that the *Competent 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*.

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*.

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 Authority 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.;

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;

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 Chapter 4.Y. when the presence of an important *disease* is suspected during the ‘alert phase’;

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

4) simulation exercises should be planned and executed to test relevant elements of the disease preparedness framework. Simulation exercises ensure that *Competent Authorities* and *Aquatic Animal Health Services* are trained and properly equipped 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.

Although the general principles described in this section are applicable to multiple diseases, Competent Authorities of Member Countries should adapt them to their circumstances because characteristics of the pathogenic agents and the situations in which they occur differ between diseases and between geographic areas and environments. To this end, recommendations in this section should be read in conjunction with listed disease-specific recommendations in Sections X to Y.

**RATIONALE:** Edits mirror the more balanced tone and text found in Terrestrial Code chapters, specifically Chapters 4.1 and 4.19.

Article 4.X.5.

Legal provisions and funding

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

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

**RATIONALE:** Edits mirror the text found in Terrestrial Code chapters, specifically Chapters 4.1 and 4.19.

Article 4.X.6.

Risk analysis in Disease Outbreak Situations

**RATIONALE:** Edits clarify the important distinction between an import risk analysis (covered under a different chapter) and disease outbreak risk analysis. While the approach to evaluating risk should be the same for imports and disease outbreaks, the reason for conducting these assessments is different.

*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 Authority* to ensure that the emergency disease preparedness framework can be efficiently executed.

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 ~~continual~~ regular review by the *Competent Authority*. The *risk analysis* should ~~take into account~~ utilize 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.*

**RATIONALE:** Editorial changes.

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, 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.

**RATIONALE:** If a listed pathogen is detected as part of these surveillance activities, then this should be reported to the Competent Authority.

~~Response actions during the~~ *~~disease~~* ~~emergency~~

~~As part of preparedness planning,~~ *~~risk assessment~~* ~~protocols should be developed to support decision making by the~~ *~~Competent Authority~~* ~~during an~~ *~~outbreak~~*~~. 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 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 assessment~~* ~~should be completed to determine if further~~ *~~risk~~* ~~mitigation measures are required to prevent reinfection of the new stock of~~ *~~aquatic animals~~*~~.~~

RATIONALE: These two items should be moved to the section on general principles and risk assessment respectively or covered in Annex 11. The bulk of the response actions are in the contingency plan sections that follow so the “response actions...” language is out of place here.

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*. This cooperation should:

a) ensure that all actions 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 a framework that ensures that response authorities are appropriately recognized and technical support for all aspects of the response are provided

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

a) ~~central and local~~ *~~disease~~* ~~control centres~~ national disease response structure;

b) laboratories;

c) equipment;

d) trained personnel;

e) data management or information systems;

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);

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 ~~comply with~~ follow the guidance of the measures which are described in Chapter 4.1. Coordination of control measures with neighbouring countries with shared waterbodies should be taken into account;

**RATIONALE:** Edits made to address overly prescriptive guidance and to allow more flexibility.

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*. 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 *fallowing* of a number of *aquaculture establishments*, 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 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* 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.

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.

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* that 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, 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* to respond to the elements of the emergency disease preparedness framework that were tested during the exercise.

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 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, improvements in technology or relevant 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* ~~within an agreed timeframe~~.

**RATIONALE:** Edits to address unneeded verbiage.

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 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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