Annex 11. Item 6.6. – Draft new Chapter 4.Y. Disease outbreak management

SECTION 4

DISEASE PREVENTION AND CONTROL

**USA COMMENTS IN RED FONT**

CHAPTER 4.Y.

DISEASE OUTBREAK MANAGEMENT

Article 4.Y.1.

Purpose

To provide recommendations concerning the actions which should be taken by the *Competent Authority* and the *Aquatic Animal Health Services* to manage the emergency response to suspicion or confirmation of the presence of an important *aquatic animal disease*, and activate its contingency plans as described in Chapter 4.X.

Article 4.Y.2.

Scope

To provide recommendations concerning the actions to be taken by the *Competent Authority* and the *Aquatic Animal Health Services,* from the point at which an important *disease*, as described in Article 4.X.6., is suspected in a *free country*, *free zone* or *free compartment*, or has been suspected or confirmed in an epidemiologically linked population, to the point at which the recovery phase begins. These actions operationalise the elements described in Chapter 4.X., which are required to manage the *disease outbreak*.

Article 4.Y.3.

General Principles

The successful management of an emergency response should take the following principles into account:

1) the actions to be taken by the *Competent Authority* and the *Aquatic Animal Health Services* should be based on the emergency *disease* preparedness framework which has been developed in accordance with Chapter 4.X;

2) the operational elements of the emergency *disease* preparedness framework should be described in ~~an Operations Manual~~ Contingency Plan. The Competent Authority can rely on the ~~Operations Manual~~ Contingency Plan to provide guidance on all aspects of the response, including actions to be taken during the alert, emergency, and recovery phases;

3) the initial response objective following a disease outbreak is to eradicate the disease, thereby allowing a country, zone or compartment to return to disease freedom. However, should the progression of the outbreak prevent this objective from being achieved, other actions should be described, which will assist the Competent Authority to pursue an alternative pathway to recovery;

4) the actions described in the ~~Operations Manual~~ Contingency Plan should be executed in a timely and co-ordinated fashion, by competent personnel, who have access to all the resources which are necessary to manage the disease outbreak in accordance with the country priorities and resources.

**RATIONALE:** Edits to refer to a ‘contingency plan’ here as stated in Annex 10 Article 4.X.2.

Article 4.Y.4.

Alert phase

The actions to be taken during the alert phase of an emergency should take the following factors into account:

1) the alert phase begins when there is suspicion of the presence of an important disease of aquatic animals, generally as a consequence of active or *passive surveillance* in the country, or in another country, which is a neighbour or a trading partner. During this phase, the *Competent Authority* will take steps to ~~detect the presence of the~~ confirm the agent or *disease* detection and to prevent possible *disease* spread;

2) following the commencement of this phase, an epidemiological investigation should be initiated in order to:

a) confirm or rule out the presence of the disease, in the shortest possible time frame;

b) determine if the disease has spread from or to aquaculture establishments or waterbodies other than the one in which the original suspicion was raised.

3) during the epidemiological investigation:

a) *risk* based *surveillance* is used to prioritise which *aquatic animal* populations, identified through tracing, should be prioritised for sampling. For example, *aquaculture establishments* which are highly connected to the *aquaculture establishment* or waterbody in which the suspicion arose, through movements of live *aquatic animals* and other transmission pathways, as described in Article 4.1.7., should be prioritised for clinical inspection and sampling;

b) the samples should be submitted to laboratories identified in the *Contingency Plan,* as described in Chapter 4.X., as being suitably equipped and staffed to produce reliable results in the shortest possible timeframe.

4) during the alert phase, taking into account Chapter 4.1., the *Competent Authority* should take steps to prevent *disease* spread by implementing *biosecurity* measures in the *aquaculture establishment* or waterbody in question. Additional specific *disease* control measures should also be considered, such as:

a) prohibiting the movement of *aquatic animals* and *aquatic animal products* as well as equipment, *vehicles*, *feed* and *aquatic animal waste* to or from the *aquaculture establishment* or waterbody, unless authorised by the *Competent Authority* based on a risk assessment;

b) extending the measures described above to other *aquaculture establishments* or waterbodies that have an epidemiological link with the *aquaculture establishment* or waterbody in which the suspicion arose.

5) whilst awaiting the outcome of the epidemiological investigation described above, the *Competent Authority* ~~should~~ may communicate with the ~~emergency management group,~~ members of the response framework as described in Chapter 4.X.~~,~~ and review the ~~and convene a meeting to advise them of developments and review the~~ *Contingency Plan*. The objectives of this review are to:

a) reinforce the structure of the chain of command and the framework for cooperation which are described in Article 4.X.6.;

b) ensure the *Contingency Plan*, as described in Chapter 4.X., is ready to be fully activated should the presence of the *disease* in question be confirmed in the country, *zone*, *compartment*; and

c) make any updates which are necessary to ensure the *Contingency Plan* is ready for immediate activation.

6) whilst confirmation of the presence of the *disease* in question is ongoing, the *Competent Authority* ~~should~~ may communicate with relevant personnel, laboratories, and contractors, putting them on alert to ensure they review their readiness to act quickly in compliance with the *Contingency Plan*, should the *disease* be confirmed. Such communications are made using the contact details which are kept in accordance with Chapter 4.X.;

7) the *Competent Authority* should endeavour to ensure that the alert phase is short enough to minimise *disease* spread, and long enough to ensure the suspicion has been accurately confirmed or ruled out;

8) should the suspicion not be confirmed, the alert phase is terminated, and any outcomes which warrant review of the *Contingency Plan*, are made;

9) the alert phase ends when the presence of an important *disease* is either confirmed or ruled out by the *Competent Authority.* Relevant actors in the *Aquatic Animal Health Services* should be communicated with to advise them that the alert phase is being terminated, and that the situation is either moving back to peacetime or forward to the emergency phase as described in Article 4.Y.5.

**RATIONALE:** Edits intended to address overly prescriptive language and provide flexibility to Member Countries.

Article 4.Y.5.

Emergency Phase

The emergency phase of *disease outbreak* management commences when the presence of an important *disease* has been confirmed. The steps which should be taken during the emergency phase are set out in the *Contingency Plan*, ~~and the associated detailed actions are set out in the Operations Manual,~~ taking the following factors into account:

1) the chain of command as described in Article 4.Y.6.;

2) the appropriate facilities, skills, resources as described in Article 4.Y.7.;

3) the *Biosecurity* and other *disease* control measures as described in Article 4.Y.8.

**RATIONALE:** Edits intended to simply language.

Article 4.Y.6

Chain of command

As soon as the *disease outbreak* has been confirmed, the *Competent Authority* ~~convenes a meeting of the emergency management group~~ should activate the response framework as described in Chapter 4.X., and the activation of all elements of the *contingency plan* commences.

~~The first meeting of the emergency management group should considers at least t~~ The following issues should be considered~~, with the assistance of relevant specialist sub-groups~~:

1) the most up-to-date epidemiological information available concerning the *disease* emergency, including:

a) location of confirmed case(s) including grid references and maps;

b) inventory of species kept in the infected *aquaculture establishment(s)* ~~and the numbers and weights of the~~ *~~aquatic animals~~*;

c) clinical situation including description of clinical signs and estimates of morbidity and mortality;

d) identification of the index *case*;

e) details of *susceptible species* in the vicinity of the confirmed case(s);

f) outcomes from preliminary tracing and *surveillance*;

g) outcome from preliminary *~~risk assessment~~* risk evaluation.

2) immediate response objectives and options, taking into account the available epidemiological information referred to above, including:

a) official confirmation of the *disease outbreak* to the operators concerned;

b) international notification in accordance with Chapter 1.1.;

c) the reinforcement of the preliminary *biosecurity* measures which were put in place during the ‘alert phase’, the imposition of new *disease* control measures, or both.

3) trade issues which are likely to arise, both within the country and with trading partners elsewhere;

4) review of legal, administrative and financial arrangements to ensure all relevant enablers are in place to immediately manage the disease emergency. This should include:

a) details of the legal instrument which supports the provision of funding for the management of disease emergencies concerning *aquatic animals*;

b) contact details for the relevant department which will process the request for funds once the *contingency* *plan* has been activated;

c) details concerning the mechanisms by which the funds will be transferred, in addition to the frequency of transfer and the personnel who are authorised to draw down the funding.

5) format for, and timing of, communications with the *Aquatic Animal Health Services* who are responding to the emergency, relevant trading partners, and the public. Those communications are based on generic draft press releases and letters to the *Aquatic Animal Health Services* which have been prepared in peacetime, and which are appropriately fine-tuned to meet the current circumstances;

6) a schedule for future meetings throughout the emergency phase of the response, allowing for flexibility to schedule meetings at short notice, should this be required.

**RATIONALE:** Edits made to better align with Terrestrial Code chapters covering the same topics (Article 4.19.3 and 4.19.5). Language in this aquatic chapter is more prescriptive and affords less flexibility to the Member Country.

Specific to point 1b – level of detail is excessive and not commiserate with Terrestrial chapters. We recommend referencing the life stage instead.

For point 1g, we need to differentiate risk assessment vs. evaluation. Currently the term ‘risk assessment’ is defined by the Aquatic Code as something specific to hazard introduction or spread. We recommend that for emergency response, WOAH consider a new or different term such as “risk evaluation” while using the same tools/approach as risk analysis.

Article 4.Y.7.

Appropriate facilities, skills, resources

1) ~~Disease control centres~~ Implement National Disease Response Structure

a) The *~~Competent Authority~~* ~~establishes a central~~ *~~disease~~* ~~control centre and where necessary, an appropriate number of local~~ *~~disease~~* ~~control centres. Those centres,~~ response structure identified in the *Contingency Plan,* should be capable of providing at least the following:

i) appropriate information technology and telecommunication infrastructure;

ii) information systems to manage data collection concerning *aquaculture establishments*, details of sample collection and associated laboratory results, as well as the imposition of *disease* control measures on *aquaculture establishments* and transporters;

iii) ~~space for preparing and storing sampling kits for dispatch to the field~~ a framework that provides administrative management of the operational needs for a response including leadership, safety, communications, planning, operations, logistics and funding;

~~iv)~~  ~~disinfection points for staff who are involved in sampling and inspection of~~ *~~aquaculture establishments~~*~~;~~

~~v)~~ ~~storage area for fields kits, personal protective equipment, cleaning and disinfection materials;~~

~~vi)~~ *~~biosecurity~~* ~~measures which are appropriate for the specific facilities and the purpose for which they are used.~~

~~b)~~ ~~The personnel from the~~ *~~Aquatic Animal Health Services~~* ~~who staff the central and local~~ *~~disease~~* ~~control centres have been identified in the~~ *~~Contingency Plan.~~* ~~Operationally, this group includes technical, administrative and legal personnel, as necessary, who are fully trained to complete the following tasks in accordance with detailed standard procedures which are set out in the Operations Manual:~~

~~i)~~ ~~clinical inspections of aquaculture establishments, and wild aquatic habitats, as relevant;~~

~~ii)~~ ~~sample collection;~~

~~iii)~~ ~~preparation and issuance of legal notices;~~

~~iv)~~ ~~management of general biosecurity measures and other specific disease control measures;~~

~~v)~~ ~~communications with relevant personnel and stakeholders.~~

2 ) Laboratories

a) During the emergency, the *Aquatic Animal Health Services* should submit samples to the laboratories which have been identified in the *Contingency Plan.* Those laboratories provide rapid and accurate testing and reporting, which is dependent on the following resources:

i) appropriately trained and competent staff;

ii) appropriate equipment, which has been suitably serviced and is fit-for-purpose;

iii) a sufficient range and quantity of consumables;

iv) appropriate informationsystems to ensure sample traceability and reporting of laboratory results;

v) *biosecurity* measures which are suitable to contain the *pathogenic agent* in question.

 Contact details of the staff which are referred to in point (i) and the companies which provide the services and goods, which are referred to in points (ii), (iii) and (iv), are detailed in the Operations Manual.

b) For *listed diseases*, laboratory methods should follow the relevant chapter of the WOAH Aquatic *Manual.* For diseases other than *listed diseases*, a procedure identified in the Operations Manual should be utilised, or another method which has been validated for the purpose of use.

3) Service Providers

a) ~~The availability of r~~Relevant service providers identified during the preparedness and planning phase are critically important during the emergency phase. These providers should be utilized as outlined in the contingency plan. is of crucial importance, in particular, considering that a *disease outbreak* may extend to multiple *aquaculture establishments* in dispersed locations, and potentially to wild *aquatic animals*. Action should, therefore, be taken to ensure the availability of:

**RATIONALE:** Edits made to address overly prescriptive language, guidance that is unnecessary, and duplicative with other sections, which also may not be possible for all Member Countries.

i) mortality management providers involved in retrieval and/or transport, who have capacity for the required daily tonnage;

ii) sanitary slaughter facilities, which can cater for the required daily tonnage;

iii) telecommunications providers;

iv) providers of laboratory equipment and consumables who have an acceptable lead-in time for delivery of new and replacement items;

v) companies which service relevant laboratory equipment and which have an acceptable response time for critical pieces of equipment;

vi) providers of vaccines/ veterinary medicines, who can supply an appropriate number of doses and have a suitable lead-in time for delivery;

vii) experts in areas which are relevant to the successful management of the emergency, and who have appropriate skills (e.g. in the areas of logistics, fisheries management, environmental protection, vaccination or treatment of *aquatic animals*), and who are available to deal with emergency situations;

viii) back-up providers for each type of service, should they be required for an extensive *disease outbreak*.

 Contact details of the providers referred to in points (i) to (viii) above are detailed in the Operations Manual.

Article 4.Y.8.

Biosecurity and other disease control measures

The actions which the *Competent Authority* should take~~s~~ concerning *biosecurity* and other *disease* control measures during the emergency phase, are described in the Operations Manual and may include:

**RATIONALE:** Edits in introduction made to soften language.

1) defining the *infected zone* and *protection zones* which apply in freshwater or marine environments, as relevant, following confirmation of a *disease outbreak*, and taking into account the recommendations of Chapter 4.2.;

2) providing maps which will demonstrate the *infected zone* and the surrounding *protection zone*, as well as the *aquaculture establishments* which are located within those *zones*;

3) coordinating actions concerning *biosecurity* and other *disease* control measures with other *Competent Authorities*, when the establishment of such *infected zone* or *protection zones* impacts neighbouring countries;

4) specifying relevant *biosecurity* and other specific *disease* control measures including:

a) controlling the movement of aquatic animals, *aquatic animal products*, *feed* and equipment to or from the infected establishment(s), unless authorised by the *Competent Authority* following *risk assessment*;

b) extending the movement controls referred to above, to other *aquaculture establishments* or waterbodies which have an epidemiological link with the *aquaculture establishment* in which the suspicion arose;

c) exemptions from the movement prohibitions described above, should *risk assessment* have indicated that these represent an acceptable *risk*, or alternatively that more stringent movement measures are required due to the developing disease situation;

d) specifying the procedures to be used when *aquatic animals* are slaughtered or killed, depending on their species, size and the number of *aquatic animals* involved, including:

i) details of the equipment and where relevant, veterinary products to be used, and their suppliers;

ii) the appointment of a named Welfare Officer to ensure that procedures are carried out to the highest possible standards, and in the case of fish, to ensure that slaughtering or killing is carried out in accordance with Chapter 7.4.;

iii) details of the *biosecurity* measures required to ensure the slaughter or killing process does not cause *disease* spread. This includes measures which apply to *vehicles* which are authorised to move animals or products from the infected establishments (or from additional establishments, as directed by the *Competent Authority*), to processing factories or animal by product establishments;

~~iv)~~ e) the vaccination options that may be employed, depending on the circumstances of the *disease* *outbreak*, ~~including~~:

* no vaccination;
* vaccination which is implemented in *aquaculture establishments* within the *infected zone* i.e. suppressive vaccination, the aim of which is to reduce the spread of *disease* from the *infected zone*;
* vaccination which is implemented outside the *infected zone* where the *disease* has not been suspected or confirmed i.e. protective vaccination, the aim of which is to prevent the spread of the *disease* in populations of *aquatic animals* which are at *risk* of infection;
* a combination of suppressive and protective vaccination.

 ~~e~~ f) the decontamination options which are available, taking into account the recommendations of Chapter 4.4.. A list of the cleaning agents, *disinfectants* and equipment that are appropriate to use, are commercially available and which meet the decontamination requirements concerning the pathogenic agent in question, should also be specified;

 ~~f~~ g) procedures for the containment of wastewaters which are produced following *disinfection*, which have been drawn up in accordance with the instructions of the *Competent Authorities* with responsibility for discharges to the environment.

**RATIONALE:** Edits made to correct the numbering system in this section. Vaccination issues should be listed as a separate item “e”) because vaccination should not be part of slaughter considerations.

Article 4.Y.9.

Recovery phase

The recovery phase of *disease outbreak* management is activated when the end of the emergency has been declared by the *Competent Authority*. This phase takes into consideration the recovery plan described in Chapter 4.X., and the associated detailed actions which are set out in the Operations Manual.

1. In cases where the recovery phase includes the ambition to return to *disease* freedom in accordance with Pathway 4 as referred to in Chapter 1.4., either for the entity (country, *zone* or *compartment*), which was previously *disease* free, or to make a *self-declaration of freedom from disease* for a smaller entity or entities (*zone*(s) or *compartment*(s)); this phase should begin with a review of the basic biosecurity conditions which applied before the disease outbreak occurred. This review will determine if additional sanitary measures are required to strengthen the basic biosecurity conditions which will apply in the entity for which the new declaration of freedom will be made. This step will be followed in due course, by the re-population of *aquatic animals* and the re-commencement of trade. The ultimate aims of the recovery phase are to successfully return to peacetime operations.

2. In cases where the recovery phase does not include the ambition to return to disease-freedom, the actions which are necessary to either contain the disease, or to mitigate the impacts of the disease, should be identified and set out in the Operations Manual.

a) Where the aim of the recovery plan is to contain the disease, the following measures may be described:

i) movement controls;

ii) biosecurity measures, as described in Chapter 4.1.;

iii) disinfection of *aquaculture establishments* and equipment, as described in Chapter 4.4.;

iv) periodic *fallowing*, as described in Chapter 4.7.;

v) handling, disposal and treatment of *aquatic animal waste*, as described in Chapter 4.8.

b) Where the aim of the recovery plan is to mitigate the impact of the *disease*, the following measures may be described:

i) vaccination, using one or more of the strategies, which are referred to in Article 4.Y.5.;

ii) the possibility to change to the production of a species of aquatic animals, which are not susceptible to the disease which caused the emergency;

iii) the possibility to change production and husbandry practices, so that risk factors which are known to result in morbidity or mortality of *susceptible species* are minimised as far as possible;

iv) training which may be provided to operators to create improved awareness of the *disease* in question, as well as the steps that can be taken at establishment level to mitigate its impact.

3. In addition, the recovery plan may include details of:

a) the steps that are necessary to:

i) allow relevant movement controls to be partially or completely lifted (including permitting arrangements), so that affected trade may recommence within the country;

ii) start communications with producers and international partners, with a view to supporting an early recommencement of *international trade*, or to seek alternative trading partners.

b) any increased *surveillance* or *biosecurity* measures which may apply as trade recommences within the country and with international partners;

c) any resources that the *Competent Authority* intends to provide including research, monetary, technical, or other relevant supports;

d) any review of national legislation and disease outbreak management procedures that may be required to underpin the recovery plan that has been developed concerning the *disease outbreak* in question;

e) ongoing communication with *Aquatic Animal Health Services* to explain relevant details of the recovery plan and to reinforce the role the *Aquatic Animal Health Services* play in future *disease* prevention and control.

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