

UNITED STATES OF AMERICA – COMMENTS

Annex 11. Item 6.1. – Chapter 1.1. ‘Notification of diseases, and provision of epidemiological information’

CHAPTER 1.1.

NOTIFICATION OF DISEASES, AND PROVISION OF EPIDEMIOLOGICAL INFORMATION

Article 1.1.1.

For the purposes of the *Aquatic Code* and in terms of Articles 5, 9 and 10 of the Organic Statutes of the Office international des Epizooties, Member Countries shall recognise the right of the *Headquarters* to communicate directly with the *Veterinary Authority* of its *territory or territories*.

All *notifications* and all information sent by WOAHP to the *Veterinary Authority* shall be regarded as having been sent to the country concerned and all *notifications* and all information sent to WOAHP by the *Veterinary Authority* shall be regarded as having been sent by the country concerned.

Article 1.1.2.

- 1) Member Countries shall make available to other Member Countries, through WOAHP, whatever information is necessary to minimise the spread and impact of important *diseases* of *aquatic animals* and their *pathogenic agents* and to assist in achieving better worldwide control of these *diseases*.
- 2) To achieve this, Member Countries shall comply with the *notification* requirements specified in Articles 1.1.3. and 1.1.4.
- 3) For the purposes of this chapter an 'event' means a single *outbreak* or a group of epidemiologically related *outbreaks* of a given *disease* that is the subject of a *notification*. An event is specific to a *pathogenic agent* ~~pathogen~~ and *variant strain*, ~~as when~~ appropriate, and includes all related *outbreaks* reported from the time of the immediate *notification* through to the final report. Reports of an event include *aquatic animal host susceptible species*, number and geographical distribution of affected *aquatic animals* and *epidemiological units*.

United States	Category: change Proposed amended texts (or precise suggested deletion): Please see the proposed changes in blue – “An event is specific to a <u><i>pathogenic agent</i></u> pathogen and <u><i>its variant strain</i></u>, as when appropriate, and includes all related <i>outbreaks</i> reported from the time of the immediate <i>notification</i> through to the final report. <u>Notifications</u> Reports of an event include <u><i>aquatic animal host susceptible species</i></u>, <u>the</u> number and geographical distribution of affected <i>aquatic animals</i> and <u>the relevant epidemiological units</u>.” Rationale: The term “reports” should be replaced with “notifications” for consistency with WOAHP use of these terms. Additional grammatical edits are proposed to improve readability.
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- 4) To assist in the clear and concise exchange of information, *notification* reports shall conform as closely as possible to the WOAHP *disease* reporting format.
- 5) The detection of the *pathogenic agent* of a *listed disease* in an *aquatic animal* ~~shall~~ should be notified ~~reported~~, even in the absence of clinical signs. Recognising that scientific knowledge concerning the relationship between *pathogenic agents* and clinical *disease* is constantly developing and that the presence of an infectious agent does not necessarily imply the presence of clinical *disease*, Member Countries shall ensure through their *notification* reports that they comply with ~~the spirit and intention of~~ point 1 above.

United States	Category: change Proposed amended texts (or precise suggested deletion): Please see the proposed changes in blue – “The detection of the <i>pathogenic agent</i> of a <i>listed disease</i> in an <i>aquatic animal</i> shall <u>should</u> be notified <u>reported</u>, even in the absence of clinical signs <u>unless specified otherwise in the disease specific chapters</u>. Recognising that scientific knowledge concerning the relationship between <i>pathogenic agents</i> and clinical <i>disease</i> is constantly developing and that the presence <u>detection</u> of an infectious agent does not necessarily imply <u>indicate</u> the presence <u>occurrence</u> of clinical <i>disease</i>. Member Countries shall ensure through their <u>notification</u> reports that they comply with the spirit and intention of point 1 above.” Rationale: The insertion of “unless specified otherwise in the disease specific chapters” is necessary because as written, it implies that any disease in any aquatic animals should be reported; however, there are listed pathogens for which the Aquatic Code specifies reporting is only required for some species and not others. For example, only reports of infection with ranavirus in amphibians should be reported, not if the infection is found in other non-amphibian aquatic animals. Additional grammatical edits are proposed to improve readability.
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- 6) In addition to notifying ~~events~~ findings in accordance with Article 1.1.3. and 1.1.4., Member Countries shall also provide information on the measures taken to prevent the spread of *listed diseases* and *emerging diseases*. Information shall include *biosecurity* and *sanitary quarantine* measures, including *vaccinations* and restrictions applied to the movement of ~~*commodities*~~ *aquatic animals*, *aquatic animal products*, *biological products* and ~~*fomites*~~ other miscellaneous objects which could ~~by their nature~~ be responsible for transmission of *disease*. In the case of *diseases* transmitted by *vectors*, the measures taken against such ~~vectors~~ shall also be ~~described~~ specified.

United States	Category: change Proposed amended texts (or precise suggested deletion): Please see the proposed changes in blue – “In addition to notifying events <u>findings</u> in accordance with Articles 1.1.3. and 1.1.4., Member Countries shall also provide information on the measures taken to prevent the spread of <u><i>listed diseases</i> and <i>emerging diseases</i></u>. This <u>information</u> shall include <u><i>biosecurity</i> and <i>sanitary quarantine</i></u> measures, <u>including <i>vaccinations</i></u> and restrictions applied to the movement of <i>commodities</i> <u><i>aquatic animals</i>, <i>aquatic animal products</i>, <i>biological products</i></u> and <i>fomites</i> <u>other miscellaneous objects</u> which could by their nature be responsible for transmission of <i>disease</i>. In the case of <i>diseases</i> transmitted by <i>vectors</i>, the measures taken against such <u>those</u> <i>vectors</i> shall also be described <u>specified</u>.” Rationale: Grammatical edits are proposed to improve readability.
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- 7) The Headquarters shall communicate to *Veterinary Authorities* all notifications received and other relevant information.

Article 1.1.3.

Notification of listed diseases

The *Veterinary Authority* shall, under the responsibility of the Delegate, send to the *Headquarters*:

- 1) in accordance with Chapter 1.3. and the definition of the *listed disease* ~~relevant provisions~~ in the disease-specific chapters, *notification*, through the World Animal Health Information System (WAHIS) or other electronic correspondence under the authority of the Delegate ~~by fax or e-mail~~ within 24 hours of the confirmation of any of the following events:
 - a) first occurrence of a *listed disease* in a country, a *zone* or a *compartment*;
 - b) recurrence of a *listed disease* in a country, a *zone* or a *compartment* following the final report that declared the last event ~~outbreak~~ ended;

- c) first occurrence of a listed disease due to a new variant~~strain~~ of a *pathogenic agent of a listed disease* in a country, a *zone* or a *compartment*;
- d) recurrence of a listed disease due to an eradicated variant of a pathogenic agent in a country, zone or compartment following the final report that declared the last event ended;
- e) a sudden and unexpected change in the geographical distribution or increase in incidence or virulence of, or morbidity or mortality caused by the pathogenic agent of a listed disease, present within a country, a zone or a compartment;

United States	Category: change Proposed amended texts (or precise suggested deletion): Please see the proposed changes in blue – 1) in accordance with <u>Chapter 1.3. and the definition of the listed disease</u> relevant provisions in the disease-specific chapters, <i>notification, shall be submitted</i> through the World Animal Health Information System (WAHIS) or <i>other electronic correspondence under the authority of the Delegate by fax or e-mail</i> within 24 hours of <u>the confirmation of</u> any of the following events: a) first occurrence of a <i>listed disease</i> in a country, <i>a-zone</i> or <i>a-compartment</i>; b) recurrence of a <i>listed disease</i> in a country, <i>a-zone</i> or <i>a-compartment</i> following the final report that declared the <u>last event</u>outbreak ended; c) first occurrence of <u>a listed disease due to a new variant</u>strain of a <i>pathogenic agent of a listed disease</i> in a country, <i>a-zone</i> or <i>a-compartment</i>; d) <u>recurrence of a listed disease due to a previously</u>an eradicated variant of a <i>pathogenic agent in a country, zone or compartment following the final report that declared the last event ended;</i> e) <u>a sudden and unexpected change in the geographical distribution or increase in incidence or virulence of, or morbidity or mortality caused by the pathogenic agent of a listed disease, present within a country, a-zone or a-compartment;</u> Rationale: Grammatical edits are proposed to improve readability and ensure consistency throughout this chapter and across others within the Aquatic Code.
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- f) occurrence of a listed disease in a new host species;

United States	Category: change Proposed amended texts (or precise suggested deletion): Please see the proposed changes in blue – “occurrence of a <i>listed disease</i> in <i>an new host</i> unexpected species;” Rationale: We have significant concerns with the use of the term “new host species” here for several reasons: 1) The term “new host” is not currently defined. In some cases, this might be interpreted as a detection in a susceptible species not previously indicated for a given disease. Alternatively, this might be interpreted as an occurrence in a new species to a Member for a given disease (e.g., it had been detected in goldfish, but now it has also been detected in koi). 2) Some pathogens are reportable at a taxonomic level greater than species. Depending on the Member’s health status, the occurrence of a listed disease in a new species may or may not be notifiable within 24 hours, as described. 2) Grammatical edits are proposed to improve readability and ensure consistency throughout this chapter and across others within the Aquatic Code. We therefore propose replacing “new host species” with alternative wording such as “an unexpected host” to convey that the intent of point f) is to notify WOA and member countries of epidemiologically significant changes in host distribution of listed diseases. In order to reduce reporting burden, the inclusion of point f) should not be solely to build scientific evidence for inclusion of species as known susceptible species for diseases with known broad host ranges. Gathering evidence for the inclusion of additional susceptible species can be accomplished through six-monthly reports, Article 1.1.5. reports and published literature.
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- 1) weekly reports subsequent to a *notification* under point 1 above, to provide further information on the evolution of the event which justified the *notification*. These reports ~~shall~~should continue until either the disease has been eradicated or is considered stable which means its incidence, morbidity, mortality and spread have stabilised. In the latter situation, the situation has become sufficiently stable so that six-monthly reporting under point 3 shall apply. will satisfy the obligation of the Member Country. For each event notified, and for both situations (eradication and stabilization), a final report ~~shall~~should be submitted;
- 2) six-monthly reports on the absence or presence and evolution of *listed diseases* and information of epidemiological significance to other Member Countries;
- 3) annual reports concerning any other information of significance to other Member Countries.

Article 1.1.4.

Notification of emerging diseases

The *Veterinary Authority* shall, under the responsibility of the Delegate, send to the *Headquarters*:

- 1) a *notification* through WAHIS or by electronic correspondence under the authority of the Delegate fax or email, when an *emerging disease* event has occurred in a country, ~~a zone or a compartment~~;
- 2) at least monthly periodic reports subsequent to a *notification* of an *emerging disease* should continue:

United States	Category: change Proposed amended texts (or precise suggested deletion): Please see the proposed changes in blue – "<u>at least monthly periodic</u> periodic reports subsequent to a <i>notification</i> of an <i>emerging disease</i> should continue:" Rationale: We do not agree with the removal of "periodic" reports because depending on the event, monthly reporting may or may not be appropriate. This language is maintained in Article 1.1.4. of the Terrestrial Code. One example (from the terrestrial side) which illustrates why "periodic" and not "at least monthly" is more appropriate is SARS Co-V in animals; while the detection of this pathogen was initially concerning, it proved to be sporadic and not epidemiologically significant. Monthly reports were appropriate at the onset of the event, but as the event progressed, less frequent reporting accurately captured sporadic and seasonal disease occurrence. Members should have the discretion to determine reporting frequency for sporadic, seasonal and episodically occurring emerging disease events. Alternatively, "at least semi-annually" would be a more specific reporting timeframe that could provide sufficient update on emerging disease events coinciding with other required six-monthly reporting.
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a) ~~—~~for the time necessary to ~~have reasonable~~reasonably ~~demonstrate~~certainty that:

a) i) the *disease* has been eradicated; or

b) ii) its incidence, morbidity, mortality and spread have stabilised; in this situation information shall continue to be sent through the six-monthly reports; the situation has become stable;

OR

~~b) —~~until sufficient scientific information is available to determine whether it meets the criteria for inclusion in the WOA list as described in Chapter 1.2.;

- 1) a final report once requirements in point 2 a) or b) are met.

The requirements for notification of an *emerging disease* will continue until sufficient scientific information is available to determine whether it meets the criteria for inclusion in the WOA list as described in Chapter 1.2.

Article 1.1.5.

Other important animal health information

- 4) Although Member Countries are only required to notify *listed diseases* and *emerging diseases*, they are encouraged to provide WOAHA with other important *aquatic animal* health information such as findings of variants of *pathogenic agents of listed diseases* that are not included in the definition of the *disease*, or findings of non-listed diseases of interest to Member Countries.
 - 2) ~~The Headquarters shall communicate by email or through the interface of WAHIS to Competent Authorities all~~
~~notifications received as provided in Articles 1.1.2. to 1.1.4. and other relevant information.~~
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