Dear Dr. Egrie:

The AVMA appreciates the opportunity to provide comments on the following 21 revised documents extracted from the September 2009 meeting of the OIE Aquatic Animal Health Standards Commission (AAHSC). As requested, when we have comments on revised text, our responses are formulated for each document as follows:

a. Identification of the text on which we are commenting;
b. Description of the changes we believe should be made;
c. Suggested language, if any, to implement the changes we believe should be made; and
d. Scientific justification or rationale for such changes.

When language revisions are suggested, recommended deletions are struck through, and recommended additions are underlined. Language revisions suggested by the AVMA are also highlighted to differentiate from revisions included in the original documents.

1. Certification Procedures (Chapter 5.2)

The AVMA has no comments on these revisions.

2. Control of Aquatic Animal Health Hazards in Aquatic Animal Feed (Chapter 4.5)

a. TEXT: Article 4.5.4., point 14 (cross contamination), final two paragraphs.
b. CHANGES: Deletion of language made redundant with revisions included in the original document.
c. REVISIONS SUGGESTED: Procedures, such as flushing, sequencing and physical clean-out.
should be used to reduce the likelihood of contamination between batches of feed or feed ingredient. Procedures such as flushing, sequencing, and physical clean-out should be used to avoid cross-contamination between batches of feed or feed ingredients. National regulations should be followed in order to avoid the use of unauthorised feed ingredients with a risk of cross-contamination.

d. **RATIONALE:** The first sentence in the final paragraph is redundant with the new sentence that now comprises the penultimate paragraph.

3. **Application of Compartmentalisation (Chapter 4.X)**

No revisions (marked text) were noted. However, this chapter has not yet been added to the online version of the OIE *Aquatic Animal Health Code.* In our opinion, this constitutes a new chapter and thus, we offer the following comments.

a. **TEXT:** Entire chapter.

b. **CHANGES:** Refer back to the AAHSC for potential re-incorporation into Chapter 4.1.

c. **REVISIONS SUGGESTED:** None.

d. **RATIONALE:** This new chapter appears to be an expanded extract of Chapter 4.1—Zoning and Compartmentalisation. However, because of the interrelatedness of compartments and zones, we believe that it is more understandable if the two are discussed in a single chapter. This would also help avoid redundancies when discussing concepts and recommendations related to both zones and compartments. If the AAHSC prefers to separate application of compartmentalization from a general discussion of compartmentalization, zoning, and application of zoning, then the separate chapters will need careful review to avoid redundancies and ensure consistent use of all terms (eg, establishments, epidemiological units).

a. **TEXT:** Article 4.x.1, third paragraph, second line.

b. **CHANGES:** Changing “of” to “on” and adding a comma to make the sentence grammatically correct.

c. **REVISIONS SUGGESTED:** None.

d. **RATIONALE:** Editorial changes.

a. **TEXT:** Article 4.x.2, second-to-last line.

b. **CHANGES:** Adding a hyphen to make the sentence grammatically correct.

c. **REVISIONS SUGGESTED:** None.

d. **RATIONALE:** Editorial change.

a. **TEXT:** Article 4.x.5, point 2, final paragraph, first sentence.

b. **CHANGES:** Replace “passive” with “general” and “active” with “targeted.”

c. **REVISIONS SUGGESTED:** An appropriate combination of targeted-active and general-passive surveillance is necessary to achieve the goals described above.

d. **RATIONALE:** General and targeted surveillance are well-defined epidemiological terms, whereas passive and active surveillance are not. Their use in the first sentence of the above paragraph is, therefore, ambiguous, particularly since “targeted surveillance” is used in subsequent sentences.

a. **TEXT:** Article 4.x.6.

b. **CHANGES:** Delete.

c. **REVISIONS SUGGESTED:** None.

d. **RATIONALE:** Diagnostic capabilities and procedures are addressed in other chapters within the OIE *Aquatic Animal Health Code.* To avoid redundancy, a simple reference to the relevant chapter/article can be included within the appropriate text of Article 4.X.5 (surveillance for the disease agent or diseases).
a. TEXT: Article 4.x.7.
b. CHANGES: Modify title.
c. REVISIONS SUGGESTED: Contingency Plans Emergency response and notification
d. RATIONALE: Editorial suggestion for clarity.

a. TEXT: Article 4.x.7., final paragraph.
b. CHANGES: Change word order.
c. REVISIONS SUGGESTED: In the event of a compartment being at risk from a change in the surrounding area, in the disease situation for which the compartment was defined within the area surrounding the compartment, the Veterinary Authority should re-evaluate without delay the status of the compartment and any additional biosecurity measures needed to ensure that the integrity of the compartment is maintained.
d. RATIONALE: Editorial suggestion for clarity. The AVMA also notes that care must be taken in addressing disease suspicion and confirmation within establishments, compartments, and zones as epidemiologic units. Issues to address include the need for increased targeted surveillance, secure quarantine processes, and consistent methods to determine which epidemiological units would lose or retain disease-free certification when a disease is suspected or confirmed.

4. Criteria to Assess the Safety of Aquatic Animal Commodities (Chapter 5.3)
a. TEXT: Revisions from “commodity” to “aquatic animal products” in all article text while retaining “commodity” in chapter title.
b. CHANGES: Clarification of intent of these changes.
c. REVISIONS SUGGESTED: None.
d. RATIONALE: The AVMA understands the proposed changes; however, retaining the word “commodity” in the chapter title but changing this in the body of the articles to “aquatic animal products” may convey the intent that the products under discussion are not live commodities or products (eg, live bivalves intended only for human consumption, gametes, larvae). Thus, if these changes are retained, we believe the AAHSC will need to revise the definition of “aquatic animal products” to clarify intent. We propose the following: “Aquatic animal products means the non-living products or commodities produced from live aquatic animals.”

a. TEXT: Article 5.3.2.
b. CHANGES: Modify article title for clarity.
c. REVISIONS SUGGESTED: Criteria to assess the safety of live aquatic animals or aquatic animal products destined for retail trade for human consumption from a country, zone or compartment not declared free of disease, regardless of country disease status.
d. RATIONALE: Editorial suggestions for clarity.

a. TEXT: Article 5.3.2., first paragraph.
b. CHANGES: Add reference to mollusc/crustacean disease chapters for completeness.
c. REVISIONS SUGGESTED: In all disease chapters, point 1b) of Article X.X.33 (fish disease chapters) and Article X.X.X.11 (mollusc and crustacean disease chapters) lists live aquatic animals or aquatic animal products for retail trade destined for human consumption. The criteria for inclusion of live aquatic animals or aquatic animal products in point 1b) of Article X.X.33 (fish disease chapters) and Article X.X.X.11 (mollusc and crustacean disease chapters) include consideration of the form and presentation of the product, the expected volume of waste tissues generated by the consumer and the likely quantity of viable disease agent in the waste.
d. RATIONALE: In the first and second lines of Article 5.3.2., references are provided to both fish and mollusc/crustacean disease chapters. It appears that the reference to the mollusc/crustacean chapter was missing from the fourth line.
5. Diseases Listed by the OIE (Chapter 1.3)
The AVMA has no comments on these revisions.

6. Disinfected Eggs (Chapter 10.X.X.)
   a. TEXT: Article 10.4.X., 10.5.X., and 10.9.X.; point 2a.
   b. CHANGES: Delete reference to “competent authority of the importing country.”
   c. REVISIONS SUGGESTED: … the egg should be disinfected prior to importing, according to the methods described in Chapter 1.1.3. of the Aquatic Manual or those specified by the Competent Authority of the importing country, and
   d. RATIONALE: The language proposed in point 2a of these new articles defers the decision of what procedures may be acceptable for egg disinfection to the Competent Authority of the importing country. This is ill advised and will result in ambiguous and confusing standards, some of which may not be supported by sound science. It is preferable that the Code specify (either directly or indirectly through reference of the appropriate Manual chapters) disinfectants and disinfectant procedures documented to be effective in eliminating specific pathogenic agents from aquatic animal eggs.

7. Epizootic Haematopoietic Necrosis (Chapter 10.1)
   a. TEXT: Article 10.1.12., point 1 iii).
   b. CHANGES: Define “artificially dried” and/or provide examples of artificial drying methods.
   c. REVISIONS SUGGESTED: 1 iii) artificially dried eviscerated fish (for example, flame-dried) (including air-dried, flame-dried and sun-dried).
   d. RATIONALE: “Artificially dried” fish needs to be defined, and a simple suggestion would be to include examples of what is meant by the phrase “artificially dried fish.”

   a. TEXT: Article 10.1.9., final paragraph.
   b. CHANGES: Greater emphasis is needed to highlight the primary purpose of risk analysis when considering trade (importation) of aquatic animal products for human consumption.
   c. REVISIONS SUGGESTED: For these commodities OIE Members may wish to consider introducing internal measures to address the risk, particularly those related to transmission of EHNV to cultured or wild aquatic animals, associated with the commodity being used for any purpose other than for human consumption.
   d. RATIONALE: The suggested revisions emphasize that a primary purpose of risk analysis is to mitigate/prevent transmission of EHNV to cultured or wild aquatic animals. Similar revisions may be desired elsewhere in this chapter, and for this reason, the AVMA recommends further AAHSC review to ensure that articles focusing on live aquatic animals and aquatic animal products for human consumption emphasize that the intent of risk analysis and mitigation is to address transmission of pathogenic agents to cultured or wild aquatic animals and to assure public health.

8. General Obligations Related to Certification (Chapter 5.1)
   a. TEXT: Article 5.1.1., second-to-last paragraph.
   b. CHANGES: Modifications needed to accommodate current effective certification methods.
   c. REVISIONS SUGGESTED: Certificates should be issued and signed by a single competent official authorized by the Veterinary Authority or other Competent Authority to perform inspections, and endorsed through signature and/or official stamp of the Veterinary Authority or other Competent Authority. The certification requirements should not include conditions for diseases that are not transmitted by the commodity concerned. There should only be one signing certifying official for one certificate.
   d. RATIONALE: The suggested revisions still address the need for certificates to be signed by a single official, yet now accommodate current processes that have been used effectively for many decades in many countries, particularly those that have a national veterinary accreditation or similar program that accredits veterinarians to perform health and disease inspections and issue certificates of veterinary inspection (eg, US, UK, Canada, Australia, New Zealand, and many European countries).
9. Glossary

a. TEXT: Protection Zone
b. CHANGES: “Pathogenic agent” (at end of third line) may need to be defined
c. REVISIONS SUGGESTED: None
d. RATIONALE: We note some inconsistency in the use of the terms “disease,” “disease agent,” and “pathogenic agent” throughout these documents. “Disease” and “disease agent” are defined elsewhere in the Aquatic Code glossary, whereas “pathogenic agent” is not. However, “pathogenic agent” may be a more all-encompassing term than “disease agent,” because the definition of “disease agent” in the Aquatic Code does not take into account non-organismic agents of disease (eg, prions). We also encourage close review of the Aquatic Code to ensure use of terms is consistent throughout and matches glossary definitions.

a. TEXT: Competent Authority.
b. CHANGES: Need to better differentiate “Veterinary Authority” from “Competent Authority.”
c. REVISIONS SUGGESTED: Competent Authority means the Veterinary Authority or, in the absence of a Veterinary Authority, other Governmental Authority of an OIE Member having the responsibility and competence, across the whole territory, for ensuring or supervising the implementation of aquatic animal health and welfare measures, international health certification and aquatic animal health and welfare measures and other standards and recommendations described in the Aquatic Code in the whole territory.
d. RATIONALE: We note the terms “Veterinary Authority” and “Competent Authority” are used somewhat interchangeably throughout the Aquatic Code. However, we understand that an expressed intent of the OIE is that in countries lacking a veterinary government body to oversee animal health (ie, a Veterinary Authority), a non-veterinary government body would be recognized to oversee the implementation of OIE standards (ie, a Competent Authority). As such, we suggest the above additional revision to explicitly state this intent. Because the terms “Veterinary Authority” and “Competent Authority” should not be used interchangeably, we also respectfully recommend that the phrase “Competent Authority” be replaced with “Veterinary Authority or, in the absence of a Veterinary Authority, other Competent Authority” throughout the Aquatic Code as appropriate.

da. TEXT: Pathological material.
b. CHANGES: Consistency in use of terms needed.
c. REVISIONS SUGGESTED: Pathological material means samples obtained from live or dead aquatic
animals, containing or suspected of containing infectious or parasitic pathogenic agents, to be sent to a laboratory.

d. **RATIONALE:** We believe “pathogenic agent” describes both infectious and parasitic agents. Thus, it is a more encompassing term and its use is also consistent with use elsewhere in the Aquatic Code and with earlier comments regarding proposed “Protection zone” language.

10. **Infection with Abalone Herpes-like Virus (Chapter 11.X)**
The AVMA has no comments on these revisions.

11. **Introduction to the Recommendations for Controlling Antimicrobial Resistance (Chapter 6.1)**
The AVMA has no comments on these revisions.

12. **Measures Concerning International Aquatic Animal Disease Agents & Pathological Material (Chapter 5.9)**
The AVMA has no comments on these revisions.

13. **Model International Aquatic Animal Health Certificates (Chapter 5.10)**
   a. **TEXT:** Deletion of references to gametes, eggs, and larval aquatic animals in Article 5.10.1: Box I.5., Box I.9., Box I.17, Box I.22, Box I.24. and Article 5.10.2: title
   b. **CHANGES:** Retain all reference to gametes, eggs and larval aquatic animals.
   c. **REVISIONS SUGGESTED:** Retain all reference to gametes, eggs and larval aquatic animals.
   d. **RATIONALE:** It is well documented that numerous aquatic animal diseases are transmitted through gametes, eggs and juveniles, and a large number of aquatic animal gametes, eggs and juveniles are moved internationally. Importing countries, including the US, should require that these life stages are documented and certified to be free of OIE-listed diseases. Further, although the above reference to gametes, eggs, and larva were deleted, we note that in Article 5.10.2., Box II/IIa, “gametes” was not deleted so that the Certifying Official still affixes his/her signature to certify that the aquatic animals and gametes described in the certificate meet all health/disease requirements.

14. **Necrotising Hepatopancreatitis (Chapter 9.X)**
The AVMA has no comments on this new chapter.

15. **Quality and Evaluation of Competent Authorities (Chapter 3.1)**
   a. **TEXT:** Article 3.1.1, paragraph 1
   b. **CHANGES:** Add “regulatory” to “legislative.”
   c. **REVISIONS SUGGESTED:** The quality of Competent Authorities depends on multiple factors that include fundamental principles of an ethical, organisational, legislative, regulatory, and technical nature. Competent Authorities should conform to these fundamental principles, regardless of the political, economic or social situation of their country.
   d. **RATIONALE:** The AVMA recognizes that some countries mandate industry action through governmental legislation while others do this through legislation and regulation. The AVMA, therefore, recommends that all mention of “legislative” or “legislation” be replaced with “legislative and regulatory” or “legislation and regulations,” as appropriate.
   a. **TEXT:** Article 3.1.1, paragraph 4
   b. **CHANGES:** Add “regulations” to “legislation.”
   c. **REVISIONS SUGGESTED:** The quality of Competent Authorities, including aquatic animal health legislation and regulations, can be measured through an evaluation, the general principles of which are described in Article 3.1.3. and in Article 3.1.4.
   d. **RATIONALE:** The AVMA recognizes that some countries mandate industry action through governmental legislation while others do this through legislation and regulation. The AVMA, therefore, recommends that all mention of “legislative” or “legislation” be replaced with “legislative and regulations,” as appropriate.
and regulatory” or “legislation and regulations,” as appropriate.

a. TEXT: Article 3.1.2., point 6.
b. CHANGES: Add “regulations” to “legislation” and clarify or delete the final sentence.
c. REVISIONS SUGGESTED:
   Aquatic animal health legislation and regulations
   If quality as they support good governance and provide the legal framework for all key activities of the Competent Authority.

   Legislation and regulations should be suitably flexible to allow for judgments of equivalence and efficient responses to changing situations. In particular, they should define and document the responsibilities and structure of the organisations in charge of the animal identification system, control of aquatic animal movements, aquatic animal disease control and reporting systems, epidemiological surveillance and communication of epidemiological information.

   A similar demonstration should be made by Competent Authorities when they are in charge of veterinary public health activities.

d. RATIONALE: The AVMA recognizes that some countries mandate industry action through governmental legislation while others do this through legislation and regulation. The AVMA, therefore, recommends that all mention of “legislative” or “legislation” be replaced with “legislative and regulatory” or “legislation and regulations,” as appropriate. Deletion or clarification of the final sentence is recommended, because as written, its intent is not at all clear. Because its intent is not clear to us, we cannot offer editorial changes and so recommend deletion.

a. TEXT: Article 3.1.2., point 7, line 1.
b. CHANGES: Add “regulations” to “legislation.”
c. REVISIONS SUGGESTED: Competent Authorities must be able to demonstrate by means of an appropriate legislation and regulations…
d. RATIONALE: The AVMA recognizes that some countries mandate industry action through governmental legislation while others do this through legislation and regulation. The AVMA, therefore, recommends that all mention of “legislative” or “legislation” be replaced with “legislative and regulatory” or “legislation and regulations,” as appropriate.

16. Welfare of Farmed Fish During Transport (Chapter 7.2)
The AVMA has no comments on these revisions.

17. Sample for Importing Aquatic Animal Products
The AVMA has no comments on these revisions.

18. Sample for Importing Live Aquatic Animals
The AVMA has no comments on these revisions.

19. Import Risk Analysis (Chapter 2.2)
The AVMA has no comments on these revisions.

20. Zoning and Compartmentalization (Chapter 4.1)
a. TEXT: Article 4.1.3., point 2.
b. CHANGES: Further review is needed to clarify the use of “epidemiological measures,” “intensified movement control,” “special identification” and “raised awareness.”
c. REVISIONS SUGGESTED: None.
d. RATIONALE: The added text explaining the use of “epidemiological measures,” “intensified movement control,” “special identification” and “raised awareness” are so ambiguous as to make
standardized implementation by any country impossible. As written, the AVMA cannot support this change. Please also see AVMA comments under number 9—Glossary (above) for suggested changes to the new definition of “protection zone.” The AVMA also re-emphasizes our earlier comments under number 3—Application of Compartmentalisation (above). If the central concept developed by OIE for preventing, controlling and possibly eradicating any disease on increasing larger epidemiological units (establishments, compartments, zones), it is imperative that both the Aquatic and Terrestrial Codes clearly define establishments, compartments and zones, explain how they are integrated, and clearly explain how a country can define and certify disease freedom for each. As currently written, these areas remain ambiguous.

21. Slaughter of Farmed Fish for Human Consumption (Chapter 7.3)
The AVMA finds that this new chapter addresses most of the procedures necessary to humanely stun finfish before slaughter and processing. However, we believe language needs to be clarified and this chapter can be simplified to address the core components that result in standard practices for humane stunning of finfish. The AVMA, therefore, respectfully recommends that the new chapter 7.3 be referred back to the AAHSC for further review and revision. We offer the following specific comments:

a. TEXT: Title and other text.
   b. CHANGES: Change “fish” to “finfish” throughout.
   c. REVISIONS SUGGESTED: Slaughter of Farmed Finfish for Human Consumption
   d. RATIONALE: As several countries use the term “fish” to apply to many species of aquatic organisms (including invertebrates), it is preferable if the term “finfish” were used throughout this chapter to remove any ambiguity. The revision suggested here is only for the title; additional revisions will be needed throughout this new chapter to ensure consistent use of the term “finfish.”

a. TEXT: Throughout chapter; see, for example 7.3.4., point 2 and 7.3.5., point 2c.
   b. CHANGES: Clarification of ambiguous terms.
   c. REVISIONS SUGGESTED: None.
   d. RATIONALE: In many places, ambiguous terms are used or not defined (eg, “certain number of fish,” “suitable,” “where feasible,” “preferable,” water quality”). If this chapter is to establish standardized guidelines for humanely stunning finfish, acceptable procedures need to be described in greater detail before its inclusion in the Aquatic Code.

a. TEXT: Article 7.3.5., point 2g.
   b. CHANGES: Clarification is needed.
   c. REVISIONS SUGGESTED: None.
   d. RATIONALE: We question which “emergencies” during unloading, transferring and loading fish prior to slaughter will need “contingency plans,” and, further, what might be included in these plans. Clarification is needed to remove any ambiguity and assure standard application of these new Code recommendations.

a. TEXT: Article 7.3.6.—Stunning and killing methods.
   b. CHANGES: Practical stunning and slaughter approaches for small farmed finfish establishments need to be added.
   c. REVISIONS SUGGESTED: None.
   d. RATIONALE: The new chapter, and in particular, this article, tends to emphasize sophisticated processes and procedures easily accommodated by large commercial farmed finfish establishments, but completely neglects practical approaches for small establishments. Although Article 7.3.6, point 4 (Other stunning and killing methods) suggests that carbon dioxide or chilling may “result in poor welfare,” it is unclear what alternatives OIE suggests for small farmed finfish establishments. Alternatives should be provided to assure small establishments can comply with OIE recommendations.
a. TEXT: Entire chapter.

b. CHANGES: Additional information is needed to address actual slaughter methods that precede processing.

c. REVISIONS SUGGESTED: None

d. RATIONALE: Although this new chapter addresses stunning methods that will result in rendering finfish unconscious, it does not address the final piece of the story—the actual slaughter process (killing) that precedes processing. It is the AVMA’s opinion that such information needs to be added to this chapter.

As always, we appreciate the opportunity to provide input. Should you have questions or require additional information about our comments, please do not hesitate to contact Dr. David Scarfe, Assistant Director in our Scientific Activities Division (dscarfe@avma.org; 800-248-2862, ext 6634), or Dr. Beth Sabin, International Coordinator and Assistant Director in our Education and Research Division (esabin@avma.org; 800-248-2862, ext 6675).

Sincerely,

[Signature]

W. Ron DeHaven, DVM, MBA
Executive Vice President and Chief Executive Officer