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**VIA E-MAIL ONLY**

Dear Dr. Egrie:

The AVMA appreciates the opportunity to provide comments on the following 34 revised documents extracted from the report of the October 2010 meeting of the OIE Aquatic Animal Health Standards Commission (AAHSC). As requested, when we have comments on revised or new 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, to include suggested language, if any, to implement the changes we believe should be made; and
- c. scientific justification or rationale for such changes; or comments if no specific changes are suggested.

When language revisions are suggested, recommended deletions are ~~struck through~~, and recommended additions are underlined.

**SECTION 1—CURRENT CHAPTERS WITH CHANGES RECOMMENDED BY THE CODE COMMISSION (COMMENTS ALLOWED ONLY ON OIE CHANGES INDICATED)**

**DOCUMENTS 1-12:** The AVMA offers no comments on proposed changes.

**13. Introduction to the recommendations for controlling antimicrobial resistance (Chapter 6.2.)**

- a. TEXT: **Article 6.2.1., paragraph 1:** Antimicrobial agents are essential drugs for human and animal health and welfare. The OIE recognises the need for access to antimicrobial agents in veterinary medicine: antimicrobial agents are essential for treating and controlling ~~and preventing~~ infectious *diseases* in *aquatic animals*. The OIE therefore considers that ensuring continued access to effective antimicrobial agents is important.
- b. CHANGES & REVISIONS SUGGESTED: Antimicrobial agents are essential drugs for human and animal health and welfare. The OIE recognises the need for access to antimicrobial agents in veterinary medicine: antimicrobial agents are essential for treating, ~~and~~ controlling, ~~and preventing~~ infectious *diseases* in *aquatic animals*. The OIE therefore considers that ensuring continued access to effective antimicrobial agents is important.

- c. RATIONALE: The change proposed by the AAHSC conflicts with the definition of therapeutic uses of antimicrobials as put forth by the Codex Alimentarius Commission, FDA, and AVMA. The AVMA acknowledges that there is little debate on the use of antimicrobials for treatment of disease in animals. However, prevention and control of disease are also key elements in the practice of veterinary medicine, particularly in aquatic and terrestrial animal agriculture, where the focus is on population health. This concept of disease prevention and control through herd health is analogous to public health efforts. Based on the results of a limited ban enacted in Denmark (ie, the banning of the use of antimicrobials in food animals as growth promotants, but not to prevent or control disease), the AVMA does not believe the public would benefit from such limitations as suggested by the deletion of “prevention of disease” in this article of the OIE Aquatic Animal Health Code. The loss of approved preventative uses of antimicrobials will negatively impact animal health and welfare without significantly or predictably improving public health. Non-science based, broad bans of preventive uses of antimicrobials have the potential to harm public health, such as through increased foodborne disease. Additional information, including a bibliography of relevant scientific literature, is available at [www.avma.org/press/testimonies/hoang\\_testimony\\_080925.asp#3](http://www.avma.org/press/testimonies/hoang_testimony_080925.asp#3).

**DOCUMENT 14:** The AVMA offers no comments on proposed changes.

**15. Principles for responsible and prudent use of antimicrobial agents in aquatic animals (Chapter 6.3.)**

- a. TEXT: **Article 6.3.2., number 1:** maintain the efficacy of *antimicrobial agents* both for veterinary and human medicine and to ensure the rational use of antimicrobials in *aquatic animals* with the purpose of optimising both their efficacy and safety;
- b. CHANGES & REVISIONS SUGGESTED: maintain the efficacy of *antimicrobial agents* both for veterinary medicine and, as applicable, human medicine and to ensure the rational use of antimicrobials in *aquatic animals* with the purpose of optimising both their efficacy and safety;
- c. RATIONALE: Some antimicrobials used in aquatic animal medicine are not used in human medicine and, therefore, would not be expected to affect efficacy/safety in people. An example is hydrogen peroxide, which is approved by the FDA ([www.fda.gov/downloads/AnimalVeterinary/Products/ApprovedAnimalDrugProducts/UCM042860.pdf](http://www.fda.gov/downloads/AnimalVeterinary/Products/ApprovedAnimalDrugProducts/UCM042860.pdf)) and labeled for use in fish against certain bacterial diseases ([www.fda.gov/downloads/AnimalVeterinary/Products/ApprovedAnimalDrugProducts/FOIADrugSummaries/UCM051421.pdf](http://www.fda.gov/downloads/AnimalVeterinary/Products/ApprovedAnimalDrugProducts/FOIADrugSummaries/UCM051421.pdf)). Hydrogen peroxide is not found in FDA’s Orange Book (<http://www.accessdata.fda.gov/scripts/cder/ob/default.cfm>), is not approved as a drug for humans, and would therefore not be associated with failure of any therapeutic use in human medicine.
- a. TEXT: **Article 6.3.2., number 5:** ~~prevent the contamination of animal-derived food with antimicrobial residues that exceed the established maximum residue limit (MRL) occurring in the food;~~
- b. CHANGES & REVISIONS SUGGESTED: ~~prevent the contamination of animal-derived food with antimicrobial residues that exceed the established maximum residue limit (MRL) occurring in the food;~~
- c. RATIONALE: In the United States, Maximum Residue Limits (MRLs) are established for the purpose of human food safety, without stated intent to reduce the risk associated with the selection or dissemination of antimicrobial resistant microorganisms and antimicrobial resistance determinants. There is no evidence that clearly establishes any MRL with a reduction in risks associated with selection or dissemination of resistance or its determinants. Therefore, MRLs have no specific relevance to responsible and prudent use of antimicrobial agents. The AVMA recommends striking the entire sentence, because the statement propagates the misconception that violative residues are

commonplace and are a primary driver of human antimicrobial resistance trends.

- a. TEXT: **Article 6.3.4., final paragraph:** The Competent Authorities should develop effective procedures for the safe collection and destruction of unused or out-of-date antimicrobials.
- b. CHANGES & REVISIONS SUGGESTED: The Competent Authorities should work with relevant stakeholders to develop effective procedures for the safe collection and destruction of unused or out-of-date antimicrobials.
- c. RATIONALE: Effective guidance products in the US have resulted from efforts between the US federal government and stakeholders including the AVMA. A recent example is the AVMA's Best Management Practices for Pharmaceutical Disposal ([www.avma.org/drugdisposal](http://www.avma.org/drugdisposal)), which was developed through close communication between the AVMA and EPA's Office of Water. The AVMA believes that effective, collaborative efforts should be encouraged to develop sound, science-based guidance documents.
- a. TEXT: **Article 6.3.6., paragraph 2, final sentence:** Distributors should ensure that information for the appropriate use and disposal of the antimicrobial agent preparation should accompany all distributed products and should also be responsible for maintaining and disposing off the product under according to the manufacturer recommendations.
- b. CHANGES & REVISIONS SUGGESTED: Distributors should ensure that information for the appropriate use and disposal of the antimicrobial agent preparation should accompany all distributed products and should also be responsible for maintaining and disposing ~~off~~ of the product under according to the manufacturer recommendations.
- c. RATIONALE: Editorial; correction of a typographical error.
- a. TEXT: **Article 6.3.7., paragraph 2:** *Veterinarians* or other *aquatic animal* health professionals should only prescribe or recommend antimicrobial a specific course of antimicrobial treatment for *aquatic animals* under their care.
- b. CHANGES & REVISIONS SUGGESTED: Option 1: "*Veterinarians* or other *aquatic animal* health professionals should only prescribe, dispense, administer or recommend a specific course of antimicrobial treatment for *aquatic animals* under their care." "*Veterinarians* or other *aquatic animal* health professionals should ~~only~~ prescribe, dispense, administer or recommend a specific course of antimicrobial treatment only for *aquatic animals* under their care."
- c. RATIONALE: Two suggested revisions are offered, because it was not clear whether this sentence was meant to convey the idea that veterinarians and other animal health professionals should only prescribe or recommend to treat any animal (Option 1) or whether veterinarians should prescribe and recommend only to treat animals under their care (Option 2). Additionally, veterinarians are allowed to administer and dispense prescription drugs as well as prescribe them. Such roles are supported by various US entities (eg, FDA; see [www.fda.gov/AnimalVeterinary/ResourcesforYou/FDAandtheVeterinarian/ucm077384.htm](http://www.fda.gov/AnimalVeterinary/ResourcesforYou/FDAandtheVeterinarian/ucm077384.htm)). The revisions suggested by the AVMA are also in keeping with its document titled *Judicious Use of Antimicrobials for Treatment of Aquatic Animals by Veterinarians* ([www.avma.org/issues/policy/jtua\\_fish.asp](http://www.avma.org/issues/policy/jtua_fish.asp)). These guidelines are based on carefully reviewed, scientifically sound research and were developed with support and input from the CDC, Infectious Diseases Society of America, the FDA, and the USDA, and through collaboration with species-specific allied veterinary organizations.
- a. TEXT: **Article 6.3.7., paragraph 8, final two sentences:** Suspected adverse reactions, as well as a lack of effectiveness, should be reported to the Competent Authorities. The associated susceptibility data should accompany the report of lack of effectiveness.
- b. CHANGES & REVISIONS SUGGESTED: Suspected adverse reactions, including as well as a lack of effectiveness, should be reported to the *Competent Authorities*. The associated susceptibility data

should accompany the report of lack of effectiveness, as applicable.

- c. RATIONALE: In the US, lack of effectiveness is a type of adverse event, and is to be reported to the federal government, using the same form as used to report other types of adverse events ([www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/AnimalDrugForms/ucm048817.pdf](http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/AnimalDrugForms/ucm048817.pdf)).

**DOCUMENTS 16-18:** The AVMA offers no comments on proposed changes.

**19. Welfare aspects of stunning and killing of farmed fish for human consumption (Chapter 7.3.)**

- a. TEXT: In Article 7.3.7., statement appearing under “Summary table of some stunning/killing methods for fish and their respective welfare issues” as follows: Note: the terms, small, medium and large fish should be interpreted relative to the species in question.
- b. CHANGES & REVISIONS SUGGESTED, DEPENDING ON INTENT OF THE AAHSC: Option A: Note: The terms ‘small,’ ‘medium,’ and ‘large’ fish should be interpreted relative to the species in question to apply to differently sized fish within a given species. Option B: Note: The terms ‘small,’ ‘medium,’ and ‘large’ fish should be interpreted relative to the species in question. to apply to fish species that are considered to be ‘small,’ ‘medium’ and ‘large.’
- RATIONALE AND COMMENTS: We are still unclear as to whether ‘small,’ ‘medium,’ or ‘large’ applies to relatively sized fish within a given species (i.e., variously sized fish of that particular species) or whether the distinctions refer to entire species considered to be ‘small,’ ‘medium’ or ‘large.’ Thus, we offer two suggested revisions for clarity, depending on the intent of the AAHSC.

**DOCUMENTS 20-32:** The AVMA offers no comments on proposed changes.

SECTION 2—NEW CHAPTERS (COMMENTS ALLOWED ON ALL TEXT)

**DOCUMENT 33:** The AVMA offers no comments on proposed new chapter.

**34. Killing of farmed fish for disease control purposes (Chapter 7.4.)**

- a. GENERAL COMMENTS: When using drugs or chemicals to kill animals, carcasses should not be used for human food or animal feed, and contaminated carcasses need to be appropriately disposed of to prevent environmental contamination. We respectfully recommend careful review of this chapter to ensure inclusion of such considerations. In addition, we may have additional comments on article 7.4.7. after completion of the aquatic chapters of the new AVMA Guidelines on Euthanasia, which is currently under development.

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. Beth Sabin, International Coordinator and Assistant Director in our Education and Research Division ([esabin@avma.org](mailto:esabin@avma.org); 800-248-2862, ext 6675).

Sincerely,



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

*WRD/eas/ads/gcg/cnb/law*