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Regulatory Analysis and Development  
U.S. Department of Agriculture  
PPD, APHIS, Station 3A-03.8  
4700 River Road, Unit 118  
Riverdale, MD 20737-1238

**Re: Docket No. APHIS-2008-0096 – National Aquatic Animal Health Plan for the United States**

Dear Sir or Madam:

I am writing on behalf of the American Veterinary Medical Association (AVMA), established in 1863 and the largest veterinary medical association in the world. As a not-for-profit association established to advance the science and art of veterinary medicine, AVMA is the recognized national voice for the veterinary profession. The association's more than 78,000 members comprise approximately 85% of U.S. veterinarians, all of whom are involved in myriad areas of veterinary medical practice including private, corporate, academic, industrial, governmental, military, and public health services.

The AVMA appreciates the opportunity to provide comments on the proposed National Aquatic Animal Health Plan (NAAHP) and applauds the agencies and the National Aquatic Animal Health Task Force (NAAHTF) for this initiative. With aquatic animal diseases now being recognized as the largest obstacle facing commercial aquatic livestock (aquaculture) production and wild fisheries (natural resource) replenishment, a U.S. plan that charts the way forward for dealing with existing and emerging disease threats is imperative.

If appropriately designed and implemented, an effective NAAHP will assist States and the U.S. to develop suitable aquatic animal disease prevention, control and eradication programs; will expedite actions towards the U.S. meeting international standards; and will assist aquatic animal industries. Most importantly, we hope that the NAAHP will guide States in developing harmonious and uniform approaches and regulations, stimulate increased production for both commercial aquatic livestock and harvest fisheries replenishment, and increase and facilitate interstate and international trade.

With that in mind, we offer the following general and specific comments on the proposed National Aquatic Animal Health Plan.

## 1. National Advisory Committee for Aquatic Animal Health (NACAAH)

- While we believe the NAAHP has made admirable strides forward since efforts were initiated in 2001, it is still in its formative stage and is in need of greater refinement before it can be fully implemented. For it to be practical, effective and fully integrated, the NAAHP is a program requiring input from diverse governmental and nongovernmental stakeholders. The AVMA believes the formation of a National Advisory Committee for Aquatic Animal Health is fundamental, and its formation should be the highest priority for the NAAHTF.

When such a NACAAH is formed we recommend membership specifically include individuals that have aquatic animal experience and expertise who hold leadership roles in veterinary medicine or as State animal health authorities experienced in disease regulatory issues. We believe that the AVMA, other veterinary organizations, and the National Assembly of State Animal Health Officials (NASAHO) would readily nominate highly qualified individuals.

## 2. General Nature of the NAAHP

- As a roadmap for the U.S., the NAAHP should cover general principles rather than specific details. Several areas (see below) address specifics that currently may be debated or are unclear. However, as specific information and viable approaches are developed and refined using the primary principles outlined (credible and justifiable science, transparency and collaboration, careful prioritization of limited resources, flexibility to integrate evolving practical State, Federal and international developments—with full involvement of all stakeholders), specifics can be included in a NAAHP “Implementation Manual.”

We therefore recommend that the NAAHP be revised to incorporate only general principles, deferring the specifics to supporting documentation once appropriate approaches are refined with stakeholder input. A similar and very successful approach (the AQUAPLAN and AQUAVETPLAN) has been used by Australia to deal with national responses to aquatic animal diseases. This Australian model has had wide appeal, acceptance, and application by Australian States government agencies. In addition, it has received recognition from international standards setting bodies like the World Organization for Animal Health (OIE) and other countries. It would be prudent for the NAAH Task Force to carefully examine and emulate this model, refining elements as necessary to meet U.S. needs. Finally, we also recommend that the Federal agencies (APHIS, USFWS, NMFS) convene regular stakeholder meetings (perhaps every 6 months) to refine thinking on implementation of specific areas, and that the NAAHP and an “Implementation Manual” be revised on at least an annual basis.

## 3. Agency Jurisdiction, Authority and Coordination

- The AVMA recognizes the need to conform to International Standards (OIE Code and Manual) and when necessary utilize terms contained therein. However, the term “Competent Authority” has and will continue to confuse many U.S. governmental and non-governmental stakeholders, particularly the State regulators and producers.
- The use of terms such as “fish pathologist” and “fish specialists” inherently convey within the veterinary profession board certification status and added professional and legal responsibilities and liabilities. Yet, the NAAHP uses such terms to refer to individuals working in the respective fields that may have different training or expertise. It is recommended that the Task Force

consider alternative language in referencing applicable fish experts within the NAAHP.

Hence, the AVMA recommends referring to “Regulatory [State or Federal] Agency” instead of “competent authority”, and referring to individuals authorized to perform regulatory work on behalf of the “Regulatory Agency” as “authorized officials”, “authorized personnel,” or an equivalent term of similar meaning. We believe this language would remove the confusion and can easily be referenced in a footnote or glossary. In addition, we suggest expanding the second sentence within section 1.3.2 on page 16 to specifically include veterinarians, such as “...entities that regulate aquaculture as well as involving the veterinary profession.” This suggestion is made because veterinarians are key stakeholders in animal health and programs related to such.

#### 4. Diseases of Concern

- We appreciate and understand the distinction the agencies have made between “Reportable Aquatic Animal Pathogens (RAAPs)” and “U.S. Program Aquatic Animal Pathogens (PAAPs).” However, we believe that these terms will add to the current confusion of industries and trading partners about which aquatic animal diseases have regulatory or response programs in place and where such programs exist. Despite definitions, few will understand the distinction between “reportable” and “program” diseases. Furthermore, we believe that specifying “pathogens” may encourage non-reporting of clinically diseased animals (or only reporting diseases for which the pathogen is definitively known thereby severely affecting any level of preliminary or syndromic surveillance).
  - i. It is unclear how the Task Force arrived at the “mortality at or above 0.5% per day for any 3 consecutive days during a disease episode is considered significant.” Clarification of this point, which is made on page 24 of the plan, would be most helpful.
  - ii. Both categories are reportable and, by definition, both have some level of control programs in place. A key distinction is whether the disease is of U.S. national or regional (other countries or some U.S. states) concern. Whether or not treatments exist is just one of many control strategies.
  - iii. It is well accepted nationally and internationally that infectious and contagious diseases of humans and animals are caused by pathogens.
  - iv. Currently both RAAPs and PAAPs contain internationally reportable (OIE notifiable) diseases; the distinction of a PAAP disease being exotic to the U.S. will be lost, and it will imply that the U.S. already has an active program in place for its control and eradication.
  - v. To disease responders, international trade partners, and producers, the more important, logical, and understandable method would be to group all Nationally and Internationally reportable diseases (whether found in the U.S. or not) as well as those of concern to U.S. States or regions.
  - vi. It is important that all veterinarians, not just USDA accredited veterinarians, be responsible for notifying their state’s competent authority or Area Veterinarian in Charge if they identify a reportable disease. While not regulated by USDA, non-accredited veterinarians are an important component of disease reporting.

- vii. Reporting diseases based on suspicion is nebulous and has proven difficult to enforce in the past.

Considering the above, we have three basic recommendations.

- i. The program should refer to diseases and not pathogens which supports syndromic surveillance.
- ii. The program could potentially refine disease categorization (page 30) into tiers for applicable reporting requirements or disease severity. It would be beneficial to differentiate between higher priority diseases (i.e. those with potential to cause severe impact or which are new to a geographical area) that need to be reported within 24 hours and lower priority diseases (i.e. endemic diseases) which may only need to be reported every six months.
- iii. Consider defining all reportable diseases using one of the following systems to increase clarity across U.S. and international stakeholders and to move towards a single list of all nationally reportable diseases for the National Animal Health Reporting System.
  - a. Categorizing within Level I, II (and potentially III) Aquatic Animal Disease (not dissimilar from that of the European Union).
  - b. Categorizing by “Nationally Reportable ...” or “Regionally Reportable Aquatic Animal Diseases”.

Similarly we believe utilizing the term “managing diseases” will not clearly indicate active response to a reportable disease and may provide an impression that no response efforts will be attempted. We recommend removal of the term “managing diseases” throughout the document, and suggest referring to these as diseases for which the U.S. has or will have “prevention, control, and (where feasible) eradication” programs in place, as appropriate.

## 5. Diagnostics, Surveillance, Biosecurity

- The plan addresses disease prevention through means of biosecurity plans and quality control efforts; but does not specifically mention the consideration of or need for negative diagnostic test results on incoming animals. We suggest the inclusion of a discussion concerning required diagnostics prior to import. Additionally from page 40, there is concern as to whether or not agencies address bivalves. Should there be consideration for shellfish transported to restaurants (because diseased animals are moved in such cases)? In general there needs to be a greater awareness and clarification concerning the plan’s applicability to bivalves.
- Section 6.3.3, number three on page 40, which addresses interstate movement in the absence of federal interstate regulations, the states should be allowed to implement their own scientifically based requirements for either an aquatic species or pathogen. Pathogen may be included in species, but that is open to interpretation, and it needs to be clarified. Certain pathogens do not have much impact on some states; but, those same pathogens may be devastating to the economy of a different state, depending on the aquatic species raised there. If a pathogen is not important enough nationally to be regulated, the states need to have the right to help protect their aquacultural entities. Again, we recommend the NAAHP consider diseases instead of pathogens.

- A National aquatic disease diagnostic laboratory network with the highest standards of quality assurance and quality control in performing validated and reliable diagnostic assays is imperative for a successful NAAHP. Such a network and uniform reporting of diagnostic assay results is pivotal and fundamental to developing any surveillance, prevention, control, or eradication programs for the U.S. We believe its implementation as well as the database and reporting systems proposed should have high priority. However, we caution that:
  - i. Extreme care needs to be taken to ensure diagnostic assays clearly distinguish suspicion from confirmation of disease or infection.
  - ii. The confidentiality of results be preserved (such as required in veterinary medical records) to prevent stigma associated with unconfirmed suspicion
  - iii. The results of diagnostic assays are reported to clearly fit disease prevention, control, and eradication purposes.
- Similarly, the AVMA believes that a National Aquatic Animal Disease Surveillance system and a common database is necessary, however we again offer caution about the confidentiality of diagnostic results and the possible stigma associated with unconfirmed suspicion of a disease. However, we believe these issues will be resolved through dialogue and consultation with all stakeholders.
- We understand the desire to utilize both the OIE Manual for Diagnostic Tests for Aquatic Animals and the AFS-FHS Bluebook as standard laboratory protocols for diagnostic assays. However, having two standards has and will continue to be confusing to U.S. diagnostic laboratories, service providers, international trade partners, and producers.

We therefore recommend that the OIE Manual be used for Nationally and Internationally reportable diseases and, where necessary, the AFS-FHS Bluebook be used for other diseases of importance.

- When listing the elements of a biosecurity plan, it is recommended that testing be specifically addressed as necessary to biosecurity measures (Section 5.2). Required testing protocols are a source of many producers' objections to disease regulatory programs.
- Utilizing an integrated approach to biosecurity that includes disease hazard identification, prioritization, risk-analysis, diagnostics, surveillance, contingency plans for any epidemiological units (from the farm to the nation including zones, compartments, and establishments) is a sound approach that will have great appeal to industries and regulatory agencies. Additionally, it will encourage public-private collaboration and cooperation as well as government-industry cost sharing. Such a program served as the basis for a recent "International Aquaculture Biosecurity Conference" with strong appeal from industry and government stakeholders from more than 22 countries (see Attachment 1 for an overview of this approach).

## 6. Resources for Refining and Implementing a NAAHP

- We recognize that current Federal, State, and industry financial and workforce resources are limited and will need to be prioritized. Unquestionably, flexibility will be needed in developing and refining programs. Furthermore, effective and practical regulations will require public-private collaboration, partnerships, and cost-sharing approaches.

Therefore, we reiterate the need and our recommendation for the formation of a Federal Advisory Committee and regular updates of the NAAHP. In addition, the creation of non-governmental aquatic animal health working groups to discuss and offer recommendations to the NAAHTF or the NACAAH would provide additional expertise and insight.

## 7. Interactions, Outreach, and Awareness

- It is imperative to include the National Assembly of State Animal Health Officials, the World Aquatic Veterinary Medical Association, other aquatic veterinary organizations, and the National Shellfish Association in the outreach program for the NAAHP. These organizations should be added to the list of “Animal Health Organizations” provided on page 46 of the plan.
- If there is to be a focus on expanding curricula in veterinary schools, the Association of American Veterinary Medical Colleges should also be included.

## 8. Education, Training, and Service Providers

- Training in proper sample collection in order to meet regulations is definitely an immediate need.
- The AVMA requests correction of the misspelling of its name in the last paragraph on page 50, kindly change the word “Medicine” to “Medical” within our name.
- We appreciate the NAAHP for acknowledging the roles of producers (“aquaculturists”), veterinarians, and para-veterinarians (non-veterinarian aquatic animal health professionals including “Fish Pathologists, “Inspectors”, and veterinary technicians) and the ongoing need for education and training. There appears to be a general misunderstanding surrounding the following issues mentioned in the NAAHP, including:
  - i. The roles of each of these professionals in implementing requirements outlined in the NAAHP.
  - ii. These professionals’ availabilities, abilities, potential conflicts-of-interest, and legal and professional liability issues in providing services within diagnostic laboratories to State and Federal aquaculture facilities as well as to aquatic livestock producers.
  - iii. The practical and ethical implications of identifying “specialists.”
  - iv. The development of core curricular and continuing education programs with the assistance of AFS-FHS, non-veterinary University programs, and any of the AVMA-accredited veterinary schools.

It is AVMA’s recommendation that a non-governmental Task Force (potentially consisting of representatives of AFS-FHS, AVMA, AAVMC, and other suitable bodies involved with veterinary medical professional licensure and Board certification) be established to discuss and resolve the above issues. Recommendation from this Task Force, possibly considered by either a NACAAH or the NAAHTF, would be a constructive approach for refining the NAAHP.

In conclusion, we compliment the agencies for collaborating on developing a general plan for dealing with diseases in aquatic livestock and wild fisheries, and we recommend that the NAAHP is updated regularly. We assert that for a NAAHP to be effective:

- Jurisdiction for aquatic livestock (commercial aquaculture) diseases should be within Federal and State agriculture agency purview and wild (natural resource) animal diseases fall under the jurisdiction of Federal and State natural or wildlife agencies. There should be close collaboration to ensure harmonized approaches and unified outcomes.
- To meet the NAAHP's stated four objectives (credible and justifiable science, transparency and collaboration, careful prioritization of limited resources, flexibility to integrate evolving practical industry, state, federal and international developments), and to implement a NAAHP that does not disrupt the development and growth of aquaculture and commerce while fulfilling and integrating natural resource objectives, it is imperative to establish a Federal Advisory Committee, convene regular stakeholder meetings to provide general input to the FAC, and to update the NAAHP on at least an annual basis.

We thank you for the opportunity to provide input on this important matter. Should you have additional questions please feel free to contact me or Dr. David Scarfe ([dscarfe@avma.org](mailto:dscarfe@avma.org); 847-285-6634).

Most sincerely,

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W. Ron DeHaven, DVM, MBA

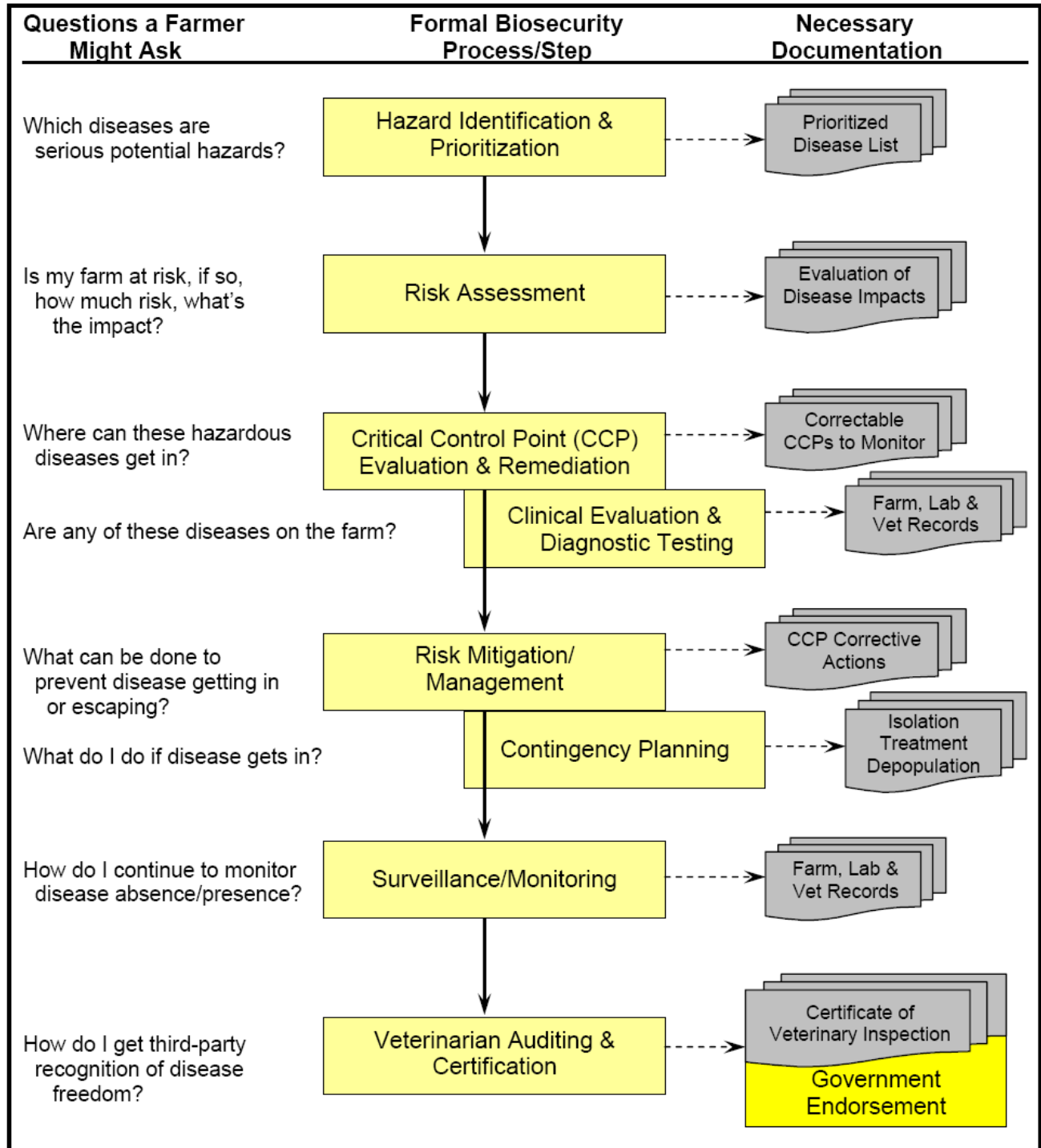
CEO/Executive Vice President

American Veterinary Medical Association

WRD/AqVMC/ADS/KH/HC

**Attachment 1**

Integrated steps for developing, implementing, auditing and certifying a biosecurity program intended to prevent, control and possibly eradicate disease in any epidemiological unit<sup>1</sup> (a tank/pond, farm, state/province, zone, region or country).



<sup>1</sup> Epidemiologic Unit— a defined population of animals, separated to some degree from other populations, in which infectious and contagious diseases can be transmitted