National Aquatic Animal Health Plan for the United States

Prepared by the

National Aquatic Animal Health Task Force

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MISSION

The mission of the National Aquatic Animal Health Task Force on Aquaculture is to develop and implement a National Aquatic Animal Health Plan (NAAHP) for aquaculture in partnership and in cooperation with industry; regional organizations; State, local, and Tribal governments; and other stakeholders. This plan will:

- Facilitate the legal movement of all aquatic animals, their eggs, and products in interstate and international commerce;
- Protect the health and thereby improve the quality and productivity of farmed and wild aquatic animals;
- Ensure the availability of diagnostic, inspection, and certification services; and
- Minimize the impacts of diseases when they occur in farmed or wild aquatic animals.

GOALS

The goal of the NAAHP is to provide recommendations to industry, States, tribes, Federal agencies, and other stakeholders in support of the mission. These recommendations are not part of an overarching regulatory program to be implemented by the Federal government. Rather, the recommendations should be considered by all stakeholders, whose cooperation is essential if the mission of the NAAHP is to be met. Activities addressed in the NAAHP include the following:

- Defining pathogens of national concern;
- Preventing, controlling and managing pathogens and/or the diseases caused by those pathogens;
- Describing and implementing surveillance programs;
- Creating and implementing disease management zones;
- Identifying priority areas for research and development in aquatic animal health, including identification of existing funding structures and recommendations on leveraging resources;
- Describing strategies for continued outreach and awareness regarding national aquatic animal health strategies and the NAAHP;
- Outlining education and training needs for all stakeholders; and
- Implementing the NAAHP.

ACRONYMS AND ABBREVIATIONS

AAHS. Aquatic animal health specialist

AFS. American Fisheries Society

AFS/FHS. Fish Health Section of the American Fisheries Society

AHPA. Animal Health Protection Act

APHIS. Animal and Plant Health Inspection Service of the U.S. Department of Agriculture.

AVIC. Area Veterinarian in Charge (APHIS)

CFR. Code of Federal Regulations

CVO. Chief Veterinary Officer

DOC. U.S. Department of Commerce

DOI. U.S. Department of Interior

EOP. Executive Office of the President

EPA. U.S. Environmental Protection Agency

ESA. Endangered Species Act

FAO. Food and Agriculture Organization (United Nations)

FACA. Federal Advisory Committee Act

FDA. U.S. Food and Drug Administration

FEC. Federal Executive Committee of the Task Force, made of the voting members of the Task Force who represent APHIS (chair), FWS (vice-chair) and NOAA Fisheries (vice-chair).

FWS. U.S. Fish and Wildlife Service of the U.S. Department of the Interior

ICS. Incident Command System

JSA. Joint Subcommittee on Aquaculture**.**

NAAHP. National Aquatic Animal Health Plan

NAAHTF. National Aquatic Animal Health Task Force (*Task Force)* on Aquaculture

NACAAH. National Advisory Committee for Aquatic Animal Health

NMFS. National Marine Fisheries Service (NOAA Fisheries)

NOAA. National Oceanic and Atmospheric Administration of the U.S. Department of Commerce

NVSL. National Veterinary Services Laboratories

OIE. World Organization for Animal Health

OIE Code. Aquatic Animal Health Code of the World Organization for Animal Health.

OIE Diagnostic Manual. Diagnostic Manual for Aquatic Animals of the World Organization for Animal Health.

OSTP. Office of Science and Technology Policy

PAAP. Program aquatic animal disease

PNP. Private nonprofit fishery cooperative

RAAP. Reportable aquatic animal disease

SPS agreement. Agreement on the Application of Sanitary and Phytosanitary Measures, World Trade Organization.

Task Force. The members of the National Aquatic Animal Health Task Force (NAAHTF) on Aquaculture commissioned by the JSA.

U.S.C. United States Code

USDA. U.S. Department of Agriculture

WTO. World Trade Organization

EXECUTIVE SUMMARY

Aquaculture is practiced throughout the United States and its Territories by private, public, and Native tribal entities. This critical economic and environmental activity provides a source of wholesome and healthy food, employment, recreation, supplementation of wild fishery stocks for harvest by commercial and tribal harvesters, and protection and restoration of aquatic animals that face extinction.

Developing and implementing a national aquatic animal health plan has become urgent for two reasons: the growing need to protect our domestic commerce and resources, and the advent of new health regulations by foreign governments that restrict the import of live and processed aquatic animals from the United States.

Economic impacts of infectious diseases

Disease has the potential to pose a great threat to the success of aquaculture. In recent years, outbreaks of infectious salmon anemia (ISA) and spring viremia of carp (SVC) in private U.S. aquaculture operations have resulted in losses of over $10 million. Also recently, a new strain of viral hemorrhagic septicemia (VHS) has impacted several wild populations of fish in the Great Lakes region of the United States. If these or other disease agents are discovered in the United States while the country has limited and disparate supporting infrastructure to diagnose, report, educate, manage, and develop surveillance and control programs, international commerce in some aquatic animals could be restricted or eliminated.

The National Aquatic Animal Health Plan (NAAHP)

In 2001, the Joint Subcommittee on Aquaculture (JSA), under the auspices of the Executive Office of the President (EOP) , Office of Science and Technology Policy (OSTP), commissioned a national task force to develop a national health plan for aquatic animals. The Federal agencies with primary responsibility for aquatic animal health — the U.S. Department of Agriculture (USDA), the U.S. Department of Commerce (DOC), and the U.S. Department of the Interior (DOI) — are leading the Task Force.

Once the JSA commissioned the Task Force to develop the NAAHP, the Task Force recognized that the first outreach activity would be to bring together all interested parties, inform them of the intent to develop a plan, and request their input on content. The input from stakeholders shaped the mission and the objectives for the NAAHP, which was again vetted to interested parties and reviewed by the JSA itself. The mission of the NAAHP is to:

- Facilitate the legal movement of all aquatic animals, their eggs, and products in interstate and international commerce;
- Protect the health and thereby improve the quality and productivity of farmed and wild aquatic animals;
- Ensure the availability of diagnostic, inspection, and certification services; and

- Minimize the impacts of diseases when they occur in farmed or wild aquatic animals

Only after approval of the mission of the NAAHP by the JSA did the Task Force begin soliciting input for the contents of the chapters. Technical group meetings were held at which input was solicited from industry, State, tribal, Federal and academic partners. A total of 12 group meetings were held between January 2003 and November 2006. Many of the technical groups were focused on species-specific disease issues in regards to surveillance and disease management. The Task Force's technical team used input from these groups and other meetings to draft the NAAHP's chapters.

Four principles have been used by the Task Force to develop the NAAHP. They are: 1) Construct the Plan using established scientific principles of fish health management; 2) Develop the plan in an open and visible process in which stakeholders have opportunities for input; 3) Recognize that limited resources are available, therefore the Plan must be affordable, make sense to stakeholders, and be capable of implementation; and 4) Develop standards that are consistent with World Trade Organization (WTO) and World Organization for Animal Health (OIE) guidelines and, to the extent possible, are consistent with Federal, State, and tribal regulations already in existence in the United States.

The goal of this document is to provide recommendations to industry, States, tribes, Federal agencies and other stakeholders to meet the mission of the NAAHP. These recommendations are not necessarily in support of an overarching regulatory program to be implemented by the Federal government. Rather, the recommendations relate to activities for consideration by all stakeholders to meet the mission of the NAAHP.

Recommendations and implementation

While the NAAHP is not a regulation, it provides general principles and guidelines for how the U.S. Federal Agencies with jurisdiction over aquatic animal health (APHIS, NOAA Fisheries, and FWS) should take action to protect our farmed and wild resources, facilitate safe commerce, and make available laboratory testing, training, and other programs available as needed to implement the NAAHP. The key recommendations made by the Task Force are as follows:

- Preventing program aquatic animal pathogens (PAAPs)
- Responding to PAAPs and reportable aquatic animal pathogens (RAAPs)
- Health certification
- Surveillance scheme for PAAPs and RAAPs
- Laboratories, standardized testing, quality testing, and approved personnel
- Education and training

Due to limited resources, the NAAHP must be developed based on the priorities and recommendations identified within this Plan, and implementation of these priorities will be contingent upon funding. However, beyond the NAAHP priorities as outlined throughout this document, continued stakeholder input will be required to ensure that

these priorities and recommendations are current. Therefore, of utmost importance to a successful NAAHP is the establishment of a National Advisory Committee for Aquatic Animal Health (NACAAH).

A NACAAH could be established as a permanent FACA-chartered advisory committee to the Federal Agencies responsible for implementing programs related to the NAAHP. Or, it could be created as a subcommittee of a currently established FACA committee, such as the Secretary's Advisory Committee on Foreign Animal and Poultry Diseases within the USDA. In either case, the Advisory Committee structure can provide input to agencies regarding issues of importance and, in an environment of fiscal conservation, assist the Federal agencies in allocating resources for aquatic animal health issues appropriately. Such an advisory committee would be large enough to ensure broad stakeholder representation, but small enough to ensure its effectiveness. The advisory committee should be composed of a broad representation of stakeholders.

The next step is for the Federal agencies to take the recommendations and suggested actions in the Plan and make them into policies, guidelines, and if appropriate, regulations. Like the development of the NAAHP, implementation must be a collaborative process which includes input from States, tribes, industry and other stakeholders, and the time frame for certain activities may be influenced by available funding.

CHAPTER 1. INTRODUCTION

1.1 Background and Rationale

1.1.1 The need for a national health plan

Aquaculture is practiced throughout the United States and its Territories by private, public, and tribal entities. This critical economic and environmental activity provides wholesome and healthy food, employment, recreation, supplementation of wild fishery stocks for commercial and tribal harvesters, and protection and restoration of aquatic animals that face extinction. Aquaculture also produces many other benefits, including medicines, education (public aquariums), and stress reduction (home aquariums).

Developing and implementing a national aquatic animal health plan has become urgent for two reasons: the growing need to protect our domestic commerce and resources, and the advent of new regulations by foreign governments with stricter requirements for import of live aquatic animals and animal products from the United States.

The JSA commissioned a national task force to develop a national health plan for aquatic animals. The Federal agencies with primary responsibility for aquatic animal health — USDA, DOC, and DOI — are leading the Task Force, which held its first meeting in 2001. The Task Force is chaired by the Animal and Plant Health Inspection Service (APHIS) of the USDA, with co-chairs from the DOI's Fish and Wildlife Service (FWS) and the DOC's National Oceanic and Atmospheric Administration (NOAA). Stakeholder meetings have been held to identify necessary components of the plan and a process for plan development.

This document incorporates feedback from our stakeholders and other Federal partners of the JSA as to what a national plan for aquatic animals should provide. As this plan is developed, reviewed, pilot tested, and implemented, there is an expectation by the JSA that the process will be dynamic, interactive, and transparent with the goal of achieving our mission and providing for the health and safety of our farmed and wild aquatic animal resources.

1.1.2 Aquaculture in food production

Traditional capture of wild aquatic animals will not meet the growing demand for seafood (consumed fresh- and saltwater animals) worldwide. Over 30 percent of the seafood consumed in the world is now of aquaculture origin and it is projected that by the year 2030 over half of all seafood consumed will be from aquaculture[1]. As more scientific evidence demonstrates the health benefits from eating seafood, the demand is likely to grow. Wild stocks are already overtaxed in many regions of the world and fisheries are reduced or closed. Meeting the demands of consumers will only be accomplished by a significant increase in output from aquaculture.

The United States has a vision to meet the challenge of supplying increasing amounts of

seafood to its citizens. This vision is expressed in the Aquaculture Act of 1980 and in the National Aquaculture Development Plan (most recent draft dated 2000) created by the JSA. The goals identified in the plan include protecting the health of our farmed and wild aquatic animals from the introduction of foreign animal pathogens, reducing the proliferation and impact of diseases already existing in the United States, and developing and implementing programs of pathogen spread and disease prevention. The plan states: "Without marked improvements in aquatic animal health management, U.S. aquaculture will not remain competitive in international markets." Perhaps more dire than not competing successfully in the world markets would be the introduction of diseases into the United States that could deplete or eliminate important farmed and wild stocks.

1.1.3 Economic value of aquaculture in the United States

Aquaculture is a rapidly expanding economic activity in the United States. It is estimated that production of farmed aquatic animals more than doubled between 1985 and 1999, from approximately 400 million pounds to 987 million pounds, with a farm-gate value in 1999 of $842 million[2]. That value increased to $958 million by 2005[3]. In 1992, aquaculture provided for 181,000 jobs nationwide and a total annual economic value of $5.6 billion[4]. The total economic value of recreational fisheries is estimated to be over $30 billion annually, a large portion of which is a direct result of aquaculture production at public, tribal, and private hatcheries[5].

Table 1 provides an estimate of the volume and farm-gate value of selected species from 2005. New pilot offshore production programs have been started since that year, and data for ornamental propagation programs other than Florida are not available. Taking these factors into account, the data in table 1 probably underestimates the total national production of farmed aquatic animals by 10 to 20 percent.

TABLE 1.—*Summary of Aquaculture Products Sold By Species and Size Category, United States, 2005. (Source: USDA: The Census of Agriculture; 2005)*

Species farmed	Volume (pounds)	Farm-gate value
Catfish	618,000,000	$462,000,000
Tropical fish	unknown	51,300,000
Mollusks	269,000,000	203,183,000
Tilapia	17,300,000	31,334,000
Salmon	21,000,000	41,164,000
Baitfish	11,535,000	38,000,000
Hybrid bass	11,200,000	31,472,000
Shrimp*	8,000,000	20,724,000
TOTAL	1,019,035,000	958,459,000

* Saltwater

Often overlooked in assessing the value of aquaculture is its contribution to wild fisheries. In the western United States, hatchery production is critical in providing opportunity to commercial harvesters (Table 2). In Alaska, hatcheries operated by the

State and private, nonprofit (PNP) fishery cooperatives provide a significant amount of salmon. While in some areas harvest is primarily of wild origin, in other areas — particularly terminal fisheries operated by PNPs — virtually all the salmon harvested originated from their aquaculture operations. In States such as California, Oregon, and Washington, where many stocks of salmon are listed as threatened or endangered under the Endangered Species Act, harvest opportunities for commercial harvesters would not exist were it not for hatchery releases.

TABLE 2.—*Estimated economic value of cultured Pacific salmon harvested by commercial fishers in the United States in 2000. (Sources: PSMFC Review 2002; Alaska Salmon Enhancement Report, ADFG, March, 2003.)*

State	Salmon harvested	Salmon of hatchery origin	Ex-vessel value	Income impact*
Alaska	137,163,000	29,794,000	$59,699,000	(Not available)
Washington	1,534,000	825,000	4,278,000	$301,000**
California***	479,000	335,000	7,212,000	15,892,000
Oregon***	148,000	104,000	2,145,000	4,600,000
Total	**139,324,000**	**31,058,000**	**73,334,000**	**20,793,000**

* Income impacts (2002 dollars), are per pound per day estimates provided from output of the Fishery Economic Assessment Model for commercial ocean troll fisheries for cultured Chinook and Coho salmon.
** Ocean troll fishery data only included in table. Approximately 90% of salmon harvested in Washington are of hatchery origin and the income impact for the total amount of salmon harvested as a result of hatchery fish could approach $40 million.
*** Harvested number of salmon in Oregon and California are ocean troll caught only, 98 percent of which are Chinook salmon in 2000.

The economic value for recreational salmon fishery in the Western United States for 2001 was over $625 million (table 3). During 2002-2003, survival to adulthood of some species of salmon, particularly Chinook salmon, reached historical highs. The result of these high survival rates has been an increase in harvest opportunities, which in turn translates to an even higher economic impact than those listed in table 3. As with commercial salmon harvesting, recreational salmon fishing would not exist in most States were it not for hatchery production.

TABLE 3.—*Estimated economic value of recreational salmon fishery in U.S. Pacific region 2001. (Source: 2001 U.S. National Fishing and Hunting Survey, DOI/DOC; PSMFC annual reports)*

State	Total Angler Fishing Days*	Salmon of Hatchery Origin**	Ex-vessel value **	Income impact**
California	15,063,000,000	4,568,000	$334,335,000	$234,034,000
Washington	4,048,000,000	5,065,000	339,400,000	179,882,000
Oregon	3,463,000,000	2,756,000	187,444,000	131,210,000
Alaska	348,766,000	2,509,000	370,774,000	80,538,000
Total	**22,922,766,000**	**14,898,000**	**1,231,953,000**	**625,664,000**

* Anglers 16 years and older. Data from the 2006 U.S. National Fishing and Hunting Survey.
** Economic value of recreational salmon fishery is based on proportion of wild to enhanced catch in commercial fishery.

The total value of recreational fishing in the United States is estimated to exceed $42.2 billion annually. Of that total, over $26.3 billion is for freshwater fishing[6]. It is difficult to determine the portion that is a result of aquaculture production, but it is substantial. Nationwide, an estimated 83 million trout angler days occur annually, a significant portion of which is a result of cultured fish; as an example, trout hatchery activity in the southeastern United States adds nearly $265 million to the economy (table 4).

TABLE 4—*Annual economic effects as a result of trout production at national fish hatcheries in Southeast United States. (Source: FWS. 1999. Trout Fishing in the United States.)*

Hatchery Name	Annual Trout Angler Days	Total Economic Effects	Federal and State Tax Revenue	Annual Hatchery Budgets
Norfolk, AR	1,306,000	$91,162,000	$4,069,000	$694,000
Dale Hollow, TN	698,000	57,269,000	2,722,000	526,000
Greer Ferry, AR	648,000	45,723,000	2,025,000	346,000
Wolf Creek, KY	445,000	40,029,000	2,236,000	285,000
Chattahoochee, GA	360,000	30,416,000	1,532,000	262,000
Total	**3,457,000**	**264,599,000**	**12,584,000**	**2,113,000**

1.1.4 Intangible benefits of a healthy aquatic ecosystem

While the economic value of aquaculture based on production of aquatic animals for food and harvest by commercial and recreational fishers has been demonstrated, other benefits provided by aquaculture are difficult or impossible to measure. For example, a dollar value cannot be placed on the restoration and rehabilitation of an aquatic animal that is on the brink of extinction, the recreational value of fishing, or the enjoyment from home aquariums. All of these activities are a result of aquaculture or are impacted in some way by the general aquatic animal health in the United States.

1.1.5 Impact of infectious diseases on aquaculture

Disease has the potential to pose a great threat to the success of aquaculture. Infectious diseases can cause significant losses to aquatic animals, both farmed and wild, and the consequences can range from decreased productivity in an aquatic farm to complete depopulation of infected stocks[7]. In recent years, outbreaks of infectious salmon anemia (ISA) and spring viremia of carp (SVC) in private U.S. aquaculture operations have resulted in losses of over $10 million. Global losses in shrimp aquaculture due to white spot shrimp virus disease (WSSV) are estimated to be as high as $3 billion annually[8].

Disease outbreaks can result in significant economic loss even if few animals die during the disease event. The discovery of certain disease agents in the United States may result in import restrictions by international trading partners, and thus lost trade for producers. Live and processed seafood exports total an estimated $4.2 billion in 2005, but may be more[9]. The United States currently has an annual deficit of approximately $8.116 billion

in international seafood trade[10], and our goal is to reduce that deficit. This can only be accomplished by protecting the health of aquatic animals.

1.1.6 Impact of infectious disease on native aquatic wildlife

Disease events caused by infectious agents are not restricted to cultured aquatic animals. There are documented cases of severe mortality in wild populations caused by both endemic and exotic diseases. For example, naturally occurring infectious hematopoietic necrosis (IHN) virus causes loss in wild Pacific salmon. A new strain of viral hemorrhagic septicemia (VHS) recently affected several wild populations of fish in the Great Lakes region. In Norway, the parasite *Gyrodactylus salaris* was introduced via the importation of infected smolts from the Baltic Sea to a government hatchery, and wild populations of Atlantic salmon on the west coast of Norway were severely impacted as a result. With the Norwegian scenario in mind, basic health and survival of aquatic species are closely tied to larger global issues such as import, export, risk assessment, and disease surveillance.

1.2 Long-Term Goals

There are four long-term goals for the development and implementation of a national aquatic animal health plan:

- Support aquaculture as a viable business activity in the United States;
- Protect our nation's farmed and wild aquatic resources from the unwanted introduction or spread of devastating infectious diseases;
- Provide for effective interstate and international trade; and
- Meet the United States' national and international legal obligations.

1.2.1 Support aquaculture as a viable business activity

To control production costs and increase profitability, farmers must improve efficiency and protect the health of their animals. The implementation of the NAAHP will provide a variety of benefits to producers, including:

- Comprehensive pathogen and disease prevention, diagnosis, and treatment programs;
- Research to prevent and/or treat disease outbreaks;
- Training to provide a cadre of health professionals to service private operations; and
- An outreach and awareness program to inform the public about the safety of seafood and the protection of natural resources.

1.2.2 Protect cultured and wild resources

Federal agencies have stewardship responsibilities for cultured and wild species alike. One of the primary objectives of the NAAHP is to identify the elements of a health management plan that will provide for the protection of wild and cultured resources while enabling effective and efficient aquaculture.

1.2.3 Provide for effective interstate and international trade

The intra- and international movement of live aquatic animals is essential if aquaculture is to successfully occur in the United States. However, the movement of any animals raises the concern that infectious diseases will be introduced or spread. Implementation of the NAAHP will create the framework for ensuring the safe movement of aquatic animals, thus supporting safe, efficient and predictable commerce.

1.2.4 Meet the United States' national and international legal obligations

Companies that export live aquatic animals must meet the requirements of the country to which they are shipping. The United States currently does not have an infrastructure established that meets all the requirements of our trading partners. Likewise, programs necessary to limit or prevent inappropriate imports of high-risk animals into the United States are not in place. Further, rules of interstate commerce in the United States may not meet our obligations under the World Trade Organization (WTO) because some States' animal health regulations constitute non-tariff trade barriers. The NAAHP will bring the United States closer to the recommendations of the World Organization for Animal Health (OIE), the regulations of other countries including those in the European Union (EU), and the rules and polices under the North American Free Trade Agreement and WTO.

1.3 Guiding Principles

The Task Force set forth four principles by which the elements of the NAAHP have been developed, described in 1.3.1 to 1.3.4 below. The following sources contributed to these principles:

- OIE Aquatic Animal Health Code (2002)
- A business case in support of a national aquatic animal health program. (DFO, Canada. 2002)
- Salmonid disease control policy of the fisheries co-managers of Washington State. (WDFW, 1998)
- Manual of procedures for the implementation of the Asia regional technical guidelines on health management for the responsible movement of live aquatic animals. (FAO/NACA, 2001)

1.3.1 Science-based standards

The elements of the NAAHP are constructed using established scientific principles of fish health management. To the degree possible, the latest scientific research and publications were incorporated into this document. Stakeholder groups composed of scientific experts, such as the American Veterinary Medical Association, the American Fisheries Society, and government management agencies, have provided reviews and comments under the highest level of scientific scrutiny and professionalism.

One science-based method involves evaluating the pathogen and disease risks associated

with the movement of product. This analysis must be conducted in a transparent fashion so that the exporting country/zone clearly understands the concerns of the importing country/zone, and the difference between scientific facts and subjective opinion is clearly delineated.

Risk analysis is preferable to a zero-risk approach because it encourages a more objective decision-making process and provides opportunity for relevant regulatory entities to discuss proposed transfers. Pursuant to the WTO's Agreement on the Application of Sanitary and Phytosanitary Measures, it continues to be the right of any managing entity to accept or reject the import of live aquatic animals into its management area. However, when an entity rejects an import, it must be prepared to justify that decision. This standard applies not only to international trade but also to inter- and intrastate commerce.

1.3.2 Transparent and collaborative process

The development of the NAAHP must be an open and visible process in which stakeholders have opportunities for input. Further, participants in the process must represent a broad range of interests from the aquaculturists (private, Federal, State, and tribal) who own and operate aquaculture facilities to the Government and tribal entities that regulate aquaculture. By holding stakeholder workshops and broadly distributing reports during the development of the plan, the NAAHP was developed in a transparent and collaborative manner.

1.3.3 Essential, logical, and feasible guidelines

Limited resources are available to manage the health of our nation's aquatic animal resources. It is the intent of the JSA to develop an aquatic animal health framework that will allow safe and productive aquaculture yet will include only the essential elements for success. In addition to being affordable, the plan must make sense to stakeholders and be capable of implementation. If the NAAHP does not make logical sense or is too onerous or complicated, it will not achieve its goal of enabling safe, effective, and efficient aquaculture in the United States.

1.3.4 Consistency with international standards

Trade with international partners is at risk because of the limited and inconsistent guidelines and rules for the management of fish diseases and pathogens. Foreign countries with disease control programs in place, such as members of the EU, are reluctant to import live aquatic animals that may present a risk to their aquatic animals. The aquatic animal health standards of the United States must be brought into line with the rest of the world. The standards proposed in this document are consistent with WTO and OIE standards and, to the extent possible, consistent with Federal, State, and Tribal regulations already in existence in the United States.

1.4 Process for Developing the NAAHP

The process for developing the NAAHP was approved by the Federal Executive Committee of the Task Force, which is composed of the voting members of the Task Force who represent APHIS (chair), FWS (vice-chair) and NOAA Fisheries (vice-chair).

In 2001, the Joint Subcommittee on Aquaculture established the Aquatic Animal Health Task Force on Aquaculture (Task Force) with the charge of developing the NAAHP. The Task Force recognized that the first outreach activity would be to bring together all interested parties, inform them of the intent to develop a plan, and ask their input on content. Two meetings were held: in Washington, DC, in December 2001, and in Tucson, AZ, in June 2002. The input from the stakeholders shaped an outline for the NAAHP, which was again vetted to all interested parties and reviewed by the JSA itself. Only after approval by the JSA did the Task Force begin soliciting input for the contents of the chapters.

The next step in the process was to hold technical group meetings at which input was solicited from industry, State, tribal, Federal, and academic partners. Twelve group meetings were held between January 2003 and November 2006. Many of the technical groups focused on species-specific disease issues in regards to surveillance and disease management. Minutes of the meetings were shared with the JSA and posted on the APHIS aquaculture Web site.

The Task Force's technical team used input from the technical groups and other meetings to draft chapters. Once the executive committee of the Task Force approved the chapters, the completed draft of the NAAHP was then reviewed and approved at the agency level within APHIS, FWS, and NOAA. The NAAHP is being released as a joint document prepared by APHIS, FWS, and NOAA. This meets the charge given to the Task Force to develop a NAAHP.

CHAPTER 2. ROLES, RESPONSIBILITIES, AND AUTHORITIES

2.1 Introduction

The National Aquaculture Act of 1980 (Public Law 96-362, 94 Stat. 1198, 16 U.S. Code (U.S.C.) 2801, et seq.) defines aquaculture as "the propagation and rearing of aquatic animals in controlled or selected environments," and includes species of "finfish, mollusk, crustacean, or other aquatic invertebrate, amphibian, reptile, or aquatic plant." In addition to covering a wide range of animals, aquatic animal health issues cross multiple jurisdictional boundaries, and there are multiple roles for various stakeholders, from private aquaculturists to State, tribal and Federal agencies.

For the NAAHP to be successful, it is vital that all stakeholders understand their respective roles and responsibilities in the area of aquatic animal health. For example, for the NAAHP to facilitate safe and uninterrupted commerce, stakeholders need to be aware of requirements for movement across jurisdictional boundaries as well as the appropriate agencies and contacts involved in that movement. For those stakeholders with legal responsibilities, termed the *competent authority*, it is imperative that aquatic animal health activities fit within the scope of their legal authorities. *Competent authority* is seen as the State, tribal, or Federal entity with the legal responsibility for ensuring or supervising the implementation of aquatic animal health measures. Therefore, the goal of this chapter is to define the current roles, responsibilities, and, where appropriate, the legal authorities of private industry, State, tribal and Federal governments in administering national aquatic animal health programs in the United States.

2.2 Current Roles, Responsibilities, and Legal Authorities

2.2.1 Industry

Roles and responsibilities: The NAAHP recommends how aquatic animal health should be managed in the United States. The primary role of industry should be to actively participate in the development and review of the NAAHP; industry representatives will continue to be invited to stakeholder meetings and their contributions are critical.

Once the NAAHP is developed, it is the responsibility of industry to be an active team member in its implementation. More detail on how industry will participate in implementing the NAAHP can be found in chapter 10.

2.2.2 States and Territories

Legal authorities: In general, and consistent with federal law, States and U.S. Territories have authority over aquatic animal health issues within their borders. Animal health regulations may be administered by one or more agencies in each State. The regulating State agencies are typically the departments of agriculture, fish and wildlife, and/or natural resources. Individuals responsible for administering and enforcing State aquatic animal health regulations may have a diverse background to include fishery biologists,

fish pathologists, veterinarians, ecologists, and others.

States are responsible for managing wild fishery resources within their jurisdictional boundaries. While States have regulatory authority over controlling introduction of animals across their borders from other States or countries, these existing regulations might not be in harmony with other States or with existing Federal regulations or new regulations proposed in the NAAHP. It is critical that States collaborate in the development and implementation of the NAAHP to ensure harmony between Federal and State regulations.

Roles and responsibilities: Animal health programs vary from State to State, with some being very complex while others rely on Federal agencies for their services. Many States have integrated aquatic animal health programs that include health protection regulations, field health services, extension specialists, and diagnostic and inspection laboratories for testing for diseases and pathogens. Some of these State laboratories are operated by the State agency with regulatory authority. Others are operated within aquatic animal health departments of academic institutions. Many of these laboratories are recognized and approved by Federal agencies.

2.2.3 Federally recognized Native American tribes

Legal authorities: Federally recognized Native American treaty tribes have legal authority within their respective areas to manage fishery resources, including aquaculture and aquatic animal health. While tribes have regulatory authority over controlling introduction of animals into their borders from other States or countries, these existing regulations might not be in harmony with existing State and Federal regulations or new regulations proposed in the NAAHP. It is critical that tribes collaborate in the development and implementation of this plan to ensure harmony between Federal, State, and tribal regulations.

Roles and responsibilities: Animal health programs vary among tribes with some being very complex while others rely on Federal agencies for their services. Many tribes or groups of tribes have integrated aquatic animal health programs that include health protection regulations, field health specialists, and diagnostic and inspection laboratories for testing for diseases and pathogens. These laboratories are recognized and may be approved by Federal agencies.

2.2.4 Federal agencies

A brief description of the current legal authorities of the Federal agencies involved in aquatic animal health follows.

Joint Subcommittee on Aquaculture

Legal authorities, roles, and responsibilities: The JSA is one of the subcommittees of the Committee on Science of the Executive Office and serves as the Federal interagency coordinating body for increasing the effectiveness and productivity of aquaculture research, technology transfer, and coordination and communication between Federal agencies involved in aquaculture. The JSA was established as part of the National Aquaculture Act of 1980. While the JSA has no defined regulatory authority over animal health, it provides an important forum to discuss issues and plans such as the NAAHP. The National Aquatic Animal Health Task Force is one of the many technical groups under the JSA and is charged with developing a national aquatic animal health management plan.

Animal and Plant Health Inspection Service

Legal authorities: APHIS is the lead agency for preventing, controlling, and eliminating animal diseases and for providing Federal oversight to health programs in livestock. Authority of USDA for aquatic animals is found in the Animal Health Protection Act (AHPA, 7 U.S.C. 8301 et seq.). The Act gives the U.S. Secretary of Agriculture regulatory authority over all aquatic animal pests and diseases that have the potential to affect livestock, including farmed aquatic animals.

In regard to private commercial aquaculture, the U.S. Secretary of Agriculture has authority to regulate imports, exports, and interstate commerce of all animals should they pose a risk to other livestock. The Secretary has the authority to hold, seize, treat, or prohibit and restrict the movement of any farm-raised animals should the Secretary deem necessary.

The Virus-Serum-Toxin Act of 1913, as amended in 1985 (21 U.S.C. 151 et seq.), gives the USDA the authority to regulate veterinary biologics. The Act requires that both products and facilities be licensed, and that products distributed in the United States are not worthless, dangerous, contaminated, or harmful. APHIS is the Federal agency responsible for licensing domestic manufacturers of veterinary biological materials (biologics), such as vaccines, and issues permits allowing biologics from other countries to be imported into the United States. The interstate and international movement of pathogens, organisms, and vectors for research or for the production of biologics are regulated by APHIS.

APHIS, in coordination with other Federal, State, and private entities, is the U.S. agency responsible for reporting the occurrence of certain notifiable aquatic animal pathogens to the World Organization for Animal Health (OIE) in Paris, France. This reporting occurs through the Deputy Administrator for APHIS in Charge of Veterinary Services, also known as the Chief Veterinary Officer (CVO).

National Marine Fisheries Service (NOAA Fisheries)

Legal authorities: Several laws give NOAA Fisheries responsibility and authority over activities affecting aquatic animal health. The National Aquaculture Act (16 U.S.C. 2801

et seq.) directs the U.S. Secretaries of Commerce, Interior, and Agriculture to develop, periodically review and revise, and implement an aquaculture program. It also directs the Secretaries to undertake a continuing assessment of aquaculture in the United States.

Under the Lacey Act Amendments of 1981, 16 U.S.C. 3371-3378, the Secretaries of Commerce and Interior must jointly promulgate regulations for the marking and labeling of containers or packages containing fish or wildlife in transport, import, and export.

The Fish and Wildlife Coordination Act (16 U.S.C. 661-666c) provides authority for Commerce and DOI to conduct cooperative programs with NOAA Fisheries and other agencies.

The Saltonstall-Kennedy Act, (15 U.S.C. 713c-3), requires the Secretary of Commerce to make grants from a fund established under this section to persons carrying out research and development projects addressed to any aspect of United States fisheries, including aquaculture.

The following statutes provide additional legal authorities that pertain to aquaculture and aquatic animal health generally: the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act, 16 U.S.C. 1801 et seq.); the Endangered Species Act (16 U.S.C. 1531 et seq.); the Atlantic Coastal Fisheries Management Act of 1993 (16 U.S.C. 71 et seq.); and the Fish and Wildlife Act of 1956 (16 U.S.C. 742a et seq.).

Fish and Wildlife Service (FWS)

Legal authorities: FWS' primary authority in aquatic animal health is based on the Lacey Act (18 U.S.C. 42) which prohibits the possession or importation of any animal or plant deemed to be injurious to human beings, wildlife, or wildlife resources, or to the interests of agriculture, horticulture, forestry, or to wildlife or the wildlife resources of the United States. DOI is charged with enforcement of this Act.

FWS' regulations promulgated under the Lacey Act (50 CFR Part 16.13, known as "Title 50"), protect wild and cultured fish in the United States from viruses that may be imported with live or dead salmonids or their products. These regulations requires live or dead uneviscerated fish of the *Salmonidae* family and their live fertilized eggs or gametes to be tested and found free of certain viral pathogens before import into the United States. A Title 50 inspector must issue a signed statement attesting that these commodities have been tested and found free of the listed pathogens. Additionally, the importation into the United States of live salmonid fish requires the written permission of the Director of FWS, who maintains a list of approved Title 50 inspectors.

FWS has additional regulatory authority in the areas of fish and wildlife. The Fish and Wildlife Act of 1956 (16 U.S.C. 742f) requires the Department of the Interior (DOI) to take steps "required for the development, advancement, management, conservation, and protection of fishery resources." In addition, the Endangered Species Act of 1973 (16

U.S.C. 1531-1544), the Wildlife Coordination Act (16 U.S.C. 661-666c), and the Anadromous Fish Conservation Act (16 U.S.C. 757a – 757g) each authorize DOI to enter into cooperative agreements with stakeholders to protect and conserve fishery resources.

Environmental Protection Agency

Legal authority: The Environmental Protection Agency (EPA) is authorized to regulate aquaculture operations under the Clean Water Act (33 U.S.C. 1251 et seq.). This law gives EPA the authority to require a National Pollutant Discharge Elimination System (NPDES) permit for aquaculture operations in the United States. The EPA has established regulations for concentrated aquatic animal production, or farm-raised fish facilities. The regulation applies to certain facilities that generate wastewater from their operations and discharge that wastewater directly into waters of the United States. This rule helps reduce discharges of conventional pollutants, primarily total suspended solids. It also helps reduce nonconventional pollutants such as nutrients.

Health and Human Services - Food and Drug Administration

Legal authority: The primary authority of the Food and Drug Administration (FDA) lies in the Food, Drug and Cosmetic Act (21 U.S.C. 301 et seq.) This act gives FDA the responsibility for ensuring that all food is safe and wholesome to eat. In regard to this plan, the approval of drugs for use on aquatic animals falls under the regulatory purview of FDA. In this context, the word "drug" means any compound that alters or affects the health or physiological state of an animal, but does not include biologics under the authority of USDA.

State Department and U.S. Trade Representative

The State Department and the U.S. Trade Representative (USTR) negotiate treaties and agreements with foreign countries.

2.2.5 National and international advisory bodies

The contributions of national and international animal health-related organizations are crucial in developing the NAAHP. Several are profiled here. Other more specialized organizations also provided valuable expertise on aquatic animal issues.

OIE: The OIE is the international advisory group that recommends processes and procedures by which animal health is managed and coordinated in all countries of the world (though not every country is a member of the OIE). Pathogen and disease data on all animals are maintained by the OIE and shared with member countries. The Aquatic Animal Health Standards Commission of the OIE is responsible for authoring the OIE Aquatic Animal Health Code and the OIE Diagnostic Manual for Aquatic Animals.

American Fisheries Society, Fish Health Section (AFS/FHS): The Fish Health Section,

founded in 1972, is charged with promoting the health of aquatic animal resources in the United States. The section has established an accreditation program to recognize professionals in the field of aquatic animal health. The section publishes a manual, "Suggested Procedures for the Detection and Identification of Certain Finfish and Shellfish Pathogens," also known as the Blue Book, for the detection of certain aquatic animal pathogens which includes a segment specific for inspections. The newest edition contains a section specifically addressing standardized procedures for hatchery health inspection and was co-produced and published with the FWS.

American Veterinary Medical Association (AVMA): The AVMA represents the interests of veterinarians who practice aquatic animal medicine in the United States. Policies on aquatic animal issues are developed in the AVMA's Aquatic Veterinary Medicine Committee (AVMC, previously the Aquaculture and Seafood Advisory Committee). Draft policies are forwarded from AVMC to the AVMA Executive Board for review and approval, as the AVMC functions only in an advisory capacity.

The United States Animal Health Association (USAHA): USAHA is a forum for communication and coordination among State and Federal governments, universities, industry, and other concerned groups on issues such as animal health and disease control, animal welfare, food safety, and public health. It is a clearinghouse for new information and methods that may be incorporated into laws, regulations, policy, and programs. USAHA develops solutions based on science, new information and methods, public policy, risk/benefit analysis, and the ability to develop a consensus for changing laws, regulations, policies, and programs.

The Association of Fish and Wildlife Agencies (AFWA): The AFWA is the collective voice of North America's fish and wildlife agencies at every level of government. The Association promotes sound management and conservation, and speaks with a unified voice on important fish and wildlife issues. The Association also provides management and technical assistance to both new and current fish and wildlife leaders.

CHAPTER 3. AQUATIC ANIMAL PATHOGENS AND DISEASES OF CONCERN

3.1 Introduction

A primary element of a national animal health management program is the rapid identification of economically and biologically important diseases and their causative agents. Rapid identification of such diseases or pathogens is important in order to rapidly respond and thereby reduce any potential deleterious effects on aquatic animal resources, whether public or private. A list of pathogens and diseases is a starting point for establishing surveillance and monitoring efforts, developing management regions or zones, and creating the infrastructure necessary for implementing a health management program. This chapter will identify those known infectious diseases around which the NAAHP could initially be built with further stakeholder input.

3.2 U.S. Reportable Aquatic Animal Pathogens (RAAPs)

The United States has a responsibility to report to the OIE, within certain parameters, the occurrence of any aquatic animal disease, or the presence of the disease agent, designated by the OIE as notifiable. Other pathogens may be considered reportable because of their significance in the United States. The list of RAAs is included in the NAAHP so that practitioners and laboratories will know which pathogens need to be reported to government officials.

Reporting the presence of pathogens that are listed only as RAAPs will not necessarily lead to Federal regulatory actions. Such reports might be important for State or regional control programs, epidemiological studies, scientific investigations, or other non-Federal regulatory purposes. The reporting process is described in section 4.4.2.

3.2.1 Criteria for RAAPs

Identification (confirmed occurrence) or suspicion (observation of clinical signs or preliminary tests indicative of the presence of a pathogen) of any disease which fits the following criteria should be reported to the Federal competent authorities:

A. A disease on the current list of OIE aquatic animal diseases (see section 3.4 and the most recent edition of the OIE Aquatic Animal Health Code)

OR

B. An emerging disease of previously unknown etiology which has the potential to seriously impact aquatic animal health and meets the following four criteria:
   1. The disease has been demonstrated to cause significant production losses due to morbidity or mortality. Mortality at or above 0.5 percent per day for any 3 consecutive days during disease episode is considered significant; OR, the

disease has been demonstrated, or there is strong scientific evidence which suggests, that it negatively affects wild aquatic populations;
2. Infectious etiology has been proven, or an infectious agent is strongly associated with disease but etiology is not yet known, and there is a potential for spread via live animals or their products;
3. A repeatable, robust means of detection or diagnosis exists; and
4. Consensus is reached among the Federal competent authorities for listing the emerging disease as a RAAP.

OR

C. A disease not on the current list of OIE aquatic animal diseases (see the most recent edition of the OIE Aquatic Animal Health Code), but deemed nationally important by consensus of the Federal competent authorities and unevenly distributed in the United States.

Control of regionally significant pathogens, such as bacterial kidney disease (*Renibacterium salmoninarum*), whirling disease (*Myxobolus cerebralis),* and infectious pancreatic necrosis, would benefit from national standardized reporting; the resulting data could support scientifically based regulations or epidemiological investigations on the spread of these pathogens.

3.3 U.S. Program Aquatic Animal Pathogens (PAAPs)

A PAAP is a RAAP for which specific measures have been put in place by the Federal Government to contain, eradicate, or otherwise manage and control its spread. This could be in the form of eradication and control programs, such as for ISA and SVC, or interstate or international movement controls, such as for VHS and Title 50 pathogens.

Pathogens that would warrant some type of Federal action were discussed at several technical group meetings. Additionally, each aquatic animal commodity stakeholder group was also asked to provide input on what animal health concerns are specific to that commodity and what types of actions should be taken to address those concerns. Based on these recommendations and the criteria listed below, the Task Force has developed a proposed list of PAAPs. Implementation of programs for these pathogens will need to be based on continued input from stakeholders and input from an NACAAH (if one is formed), and be in line with available funding.

3.3.1 Criteria for PAAPs

In addition to recommendations from technical groups and stakeholders, the decision to list a disease as a PAAP is based on the following criteria:
1. The disease is caused by a U.S. RAAP.
2. The pathogen is exotic to the United States, or its distribution is limited and is restricted to one or a few specified geographic regions or zones, or the pathogen exists in wild populations and not in aquacultured populations.

3. Measures can be implemented which have been demonstrated to successfully eradicate, control, and/or limit further dissemination of the pathogen or disease.
4. No effective treatment is known for the disease.

3.4 List of U.S. RAAPs and PAAPs

The 36 pathogens and diseases listed in column 1 of table 1 qualify as RAAPs. The pathogens marked in column 2 are current PAAPs, and column 3 indicates additional recommended PAAPs. This determination is based on the criteria in section 3.3 and on discussions throughout the NAAHP technical groups. This list will be updated to accommodate emerging diseases or as appropriate.

TABLE 1. *RAAP and PAAP categories*

RAAP	Current PAAPs	Recommended PAAPs
Fish		
Epizootic hematopoietic necrosis (EHN)		X
Infectious hematopoietic necrosis	X	
Oncorhynchus masou virus disease	X	
Spring viremia of carp	X	
Viral hemorrhagic septicemia	X	
Viral encephalopathy and retinopathy		X
Infectious pancreatic necrosis	X	
Infectious salmon anemia	X	
Red sea bream iridoviral disease		X
White sturgeon iridoviral disease		
Bacterial kidney disease (*Renibacterium salmoninarum*)		
Piscirickettsiosis (*Piscirickettsia salmonis*)		
Epizootic ulcerative syndrome		
Gyrodactylosis (*Gyrodactylus salaris)*		
Koi herpes virus		
Whirling disease (*Myxobolus cerebralis)*		
Mollusks		
Bonamia exitiosus		X
Bonamia ostreae		X
Marteilia refringens		X
Marteilia sydneyi		X
Marteilia chungmuensis		X
Mikrocytos roughleyi		X
Perkinsus olseni/atlanticus		X
Candidatus Xenohaliotis californiensis		X
Haplosporidium nelsoni		X
Haplosporidium costale		X
Perkinsus marinus		X
QPX		X
Crustaceans		
Taura virus syndrome		X
Yellowhead disease		X
Spherical baculovirosis (Penaeus monodon-type)		X
Infectious hypodermal and hematopoietic necrosis		X
White spot disease		X
Tetrahedral baculovirosis (Baculovirus penae)		X

Crayfish plague (*Aphanomyces astaci*)		X
Necrotizing hepatopancreas disease (HPD)		X

CHAPTER 4. SURVEILLANCE

4.1. Introduction

For the purposes of the NAAHP, surveillance is a systematic series of investigations of defined populations of aquatic animals, conducted to detect the occurrence, prevalence, or incidence of pathogens and disease. Surveillance information is used for a variety of purposes discussed in this chapter, such as supporting aquatic animal movement controls and providing guidance for responding to adverse aquatic animal health events.

This discussion of surveillance will span from the national level to farmer, facility, and site-specific surveillance. Surveillance activities for pathogens and diseases may range from casual observations of the general health of aquatic animals in a single rearing container to a sophisticated ongoing sampling and testing scheme to identify one or more species of pathogen in all susceptible aquatic species in a geographic region as large as a continent. All levels of surveillance are critical to the basic tenets of the NAAHP and support science-based decisions to improve the safe trade of aquatic animals and to protect aquatic animal resources.

From the national perspective, surveillance activities are necessary to conform to international reporting expectations, to take appropriate regulatory actions when needed, and to accurately defend international and interstate trade activities. Farmer, facility, and site-specific surveillance activities provide data upon which regulatory actions, when necessary, are based. Therefore, accurate data from a well-planned national surveillance strategy can help regulators take effective, appropriate action.

Some attributes of successful surveillance are voluntary participation; cooperation among all major entities, starting at the producer/resource manager level; and flexibility of disease lists. Other existing Federal and State animal disease control programs can serve as models for effective surveillance.

It is not the intention of the NAAHP to provide a detailed surveillance scheme and action plan for each species of aquatic animals and each PAAP or RAAP. Rather, this chapter will provide reasons for conducting surveillance, general guidelines for developing a surveillance plan, and ways that surveillance data can support other functions of the NAAHP.

4.2 Surveillance Objectives

There are several objectives of a surveillance program. Some objectives are more relevant to individual farmers or facilities, and others are relevant to regulators.

- **To provide information on the occurrence (incidence, prevalence, and geographical distribution) of or freedom from a PAAP or RAAP.**

  A surveillance program provides a process to rapidly detect a new occurrence or change in prevalence or incidence of specified aquatic animal pathogens and diseases, or potentially

previously unknown emerging diseases, within the United States and it territories. It also allows farmers and producers to quickly respond, as appropriate, to manage, control, or eradicate pathogens and diseases, and prevent the spread of infected animals.

Surveillance data may be used to demonstrate zones, compartments, or facilities that are free from PAAPs and RAAPs. Such information could be used for the issuance of health certificates or to otherwise allow interstate and international movement of products.

- **To inform the OIE and trading partners of the status of reportable pathogens in the United States.**

  International commerce and interstate movement of healthy and sanitary aquaculture products, including live animals, are central to the economic success and production goals (including stock enhancement) of aquaculture farmers. Government entities have guidelines or regulations that define the required health status of animals intended for import or interstate movement into their jurisdictions. As a signatory to the WTO and a member of the OIE, the United States must carry out its responsibilities to regulate movement of animals as outlined in the tenets of these organizations.

- **To scientifically support import restrictions based on health status of imported animals.**

  The demonstration, through surveillance activities, that the United States (or regions or aquaculture facilities within it) is free of specific diseases would enable the United States to require other countries wishing to export to the United States to test and issue health certificates for live aquatic species that could be carrying these pathogens.

- **To facilitate planning of national control and eradication programs and strategies.**

  A sound surveillance system enables the competent authorities and resource managers to determine appropriate, science-based responses to disease detections.

- **To provide epidemiological data for research and management purposes.**

  While understanding the distribution of pathogens in a country or zone is justification for a surveillance program, the value of the information goes beyond answering a yes/no question of disease freedom. By conducting and reviewing structured surveillance, the etiology, variability, transmission risks, and potential mitigations and control of both enzootic and emerging pathogens and diseases may be better understood. Epidemiologic review of surveillance data can also provide estimates of diagnostic test accuracy, and may lead to additional surveillance protocols or recommendations for the improvement and adaptation of existing surveillance and control efforts.

4.3. Guiding Principles

The following principles should provide guidance in developing specific surveillance plans.

- Commodity-specific surveillance programs should be developed with stakeholder input to support effective disease management programs for both cultured and wild stocks of aquatic animals.
- Surveillance requires supporting infrastructure and resources in the form of appropriately trained personnel, adequately equipped laboratories, legal support structures, transport, and communication networks. Effective application of this infrastructure requires knowledge of susceptible and carrier host populations, pathogens and diseases to which they are susceptible, and their environments. All of this information should be captured, analyzed, and communicated to relevant stakeholders to complete the objective of disease management.
- Demonstration of "disease freedom" in the strict sense is impossible. Rather, surveillance can offer some degree of certainty that a country, zone, or compartment is free from a disease. The degree of certainty in a survey result has to be determined using a scientifically based evaluation process, which should assess the survey methodology, the testing procedures, and the animal health infrastructure of the competent authority.
- The process should incorporate as much as possible a quantitative statistical assessment of the various approaches so that they can be compared and objectively evaluated.
- Surveillance programs should focus on RAAPs. Pathogens that merit consideration for federally supported surveillance and zoning programs are primarily of international trade significance, cause infectious diseases of ecologic and economic significance, and are emerging diseases.

4.4. General Surveillance Procedures

The specific objective of a surveillance plan will dictate appropriate procedures for sampling, testing, and reporting. For example, if the purpose of surveillance is to collect data for the issuance of an export health certificate, one set of procedures may dictate the process. If the purpose of surveillance is to manage an enzootic pathogen, other procedures may be suitable.

There are three components to a surveillance plan:
- Collecting and testing samples
- Reporting occurrences and communicating results to stakeholders
- Analyzing and storing surveillance data

4.4.1 Collecting and testing samples

The sampling process should be driven by the objective of the surveillance program and the species being sampled. Consider the following elements when developing sampling protocols for surveillance:
- Consistency with methods prescribed by the OIE Manual of Diagnostic Tests for Aquatic Animals or the AFS Blue Book (Suggested Procedures for the Detection and Identification of Certain Fish and Shellfish Pathogens)
- Confidentiality of information
- A statistically and epidemiologically justifiable approach

- Adequate training for personnel

Should surveillance programs develop from the NAAHP, it is crucial for sampling protocols to be standardized to ensure consistency and transparency. Development of such surveillance programs should include input from relevant stakeholders. Such input may be gathered through technical or advisory groups. Models for such groups exist in federally sponsored surveillance programs such as the Interstate Milk Shippers Conference, the Interstate Shellfish Sanitation Conference, and the National Poultry Improvement Plan.

Pathogen testing for aquatic animals takes place in public, private, and tribal laboratories throughout the United States. Diagnostic findings by these laboratories are an important source of data for disease management for all entities, governments, and private industry. Many laboratories testing for pathogens may do so for the sole purpose of providing information to better manage their own animal stocks. Efforts should be made to share the information generated by those laboratories, which can be integrated into a Federal regulatory network, when a suspect finding of a RAAP or PAAP is made.

The Federal competent authorities recognize the need for resources to enable laboratories to become approved (including establishing Federal laboratory approval and audit teams) and to assist in conducting ring testing in conjunction with the National Veterinary Services Laboratories (NVSL). Reliable media and reagents must be available to laboratories for accurate and consistent testing results. The establishment of a national aquatic animal health laboratory network is a high priority.

The NAAHP may use the National Animal Health Laboratory Network (NAHLN) model for establishing approved laboratories to collect surveillance information, recognizing that laboratories conducting testing for export health certificates must be approved by the Federal competent authorities.

4.4.2 Reporting occurrences and communicating results to stakeholders

Timely and accurate notification of Federal competent authorities of the occurrence of a RAAP is critical to implement disease management measures and inform other entities that may be affected by the event. Such notification process should take place in accordance with article 1.2.1.3. of the OIE Aquatic Code so that the Federal competent authorities can fulfill their responsibilities as signatories to the OIE. Further, the U.S. veterinary administration (CVO, APHIS) has the responsibility to notify the OIE upon diagnosis of an OIE-listed disease. The timing of the notification varies between 24 hours after confirmation and biannually, depending on the particular pathogen and its status in the United States.

Partnerships need to be established between the Federal competent authorities and all entities conducting testing for PAAPs or RAAPs to facilitate the reporting of suspect findings. Upon notification, the competent authorities would cooperate with the laboratory and producer or resource manager to further investigate and verify the suspect isolation.

Confirmation or suspicion of a RAAP should be required within 24 hours if any of the following

conditions occur:

A. A new detection in the United States in a specified geographic zone (see chapter 6) or a recurrence in the United States or zone previously considered to be free of that disease;
B. Occurrence in a new host species;
C. New pathogen strain or disease manifestation;
D. Potential for international spread; or
E. Potential for zoonotic spread.

Below is a stepwise process for reporting the preliminary diagnosis or suspicion of a RAAP and the subsequent confirmation of the disease. This procedure is consistent with APHIS Veterinary Services Memorandum 567.6: Reporting of Aquatic Diseases to the OIE.

1. Aquatic animal health specialists, diagnostic laboratories (including FWS Fish Health Centers and NOAA diagnostic laboratories), or USDA-accredited veterinarians notify the office of the AVIC upon suspicion or confirmation of a RAAP.
    a. FWS Fish Health Centers should also contact the National Aquatic Animal Health Coordinator for the FWS.
    b. NOAA Diagnostic Laboratories should also contact the National Aquatic Animal Health Task Force Technical Representative for NOAA.
2. The AVIC immediately notifies the State veterinarian, the State director(s) of the regulatory agency responsible for aquatic animal health (if not the State veterinarian), the tribal representative if occurrence is on tribal land, and others in the APHIS infrastructure as appropriate.
3. Upon receiving the initial information, the competent authority should notify her/his counterparts in the other agencies.
4. Following notification, the regulatory authorities will work with the diagnostic laboratory to ensure the proper steps are taken to confirm the preliminary finding, including submission of suspect material to a U.S. or OIE reference laboratory.
5. Upon confirmation of a RAAP and meeting the reporting requirements above, the AVIC should immediately notify the person making the original report/submission, the State veterinarian, the State director(s) of the regulatory agency responsible for aquatic animal health (if not the State veterinarian), tribal authorities (if on tribal property), and other APHIS personnel as appropriate.
6. APHIS staff will notify their counterparts in FWS and NOAA Fisheries.
7. The APHIS CVO will notify OIE as appropriate.

The following information should be provided to the AVIC upon preliminary findings or suspicion of a RAAP. As appropriate, details of the finding should remain confidential.

- Name, phone number, and address of person reporting
- The location of the finding (address and GPS, if known), and name and phone number of person in charge of facility/resource area
- The disease suspected or diagnosed
- The species of aquatic animal affected
- Approximate number of animals affected
- Measures being taken to prevent the spread of the disease
- Restrictions or quarantines, if any, placed on the facility or zone

The dissemination of information back to stakeholders completes the surveillance cycle. The information provided must be accurate and distributed in a timely fashion.

4.4.3 Analyzing and storing surveillance data

Analyzing surveillance data: Collecting and reporting data to a central point are not sufficient to complete the needs of a surveillance program. Surveillance data must be summarized and analyzed. Surveillance analyses have previously been conducted on farmed terrestrial animal disease surveillance data within the existing National Animal Health Monitoring System and Centers for Epidemiology and Animal Health (CEAH) programs within APHIS. Surveillance data from NAAHP programs could be appropriately placed within CEAH.

Storing surveillance data: Many different locations and systems are used to store information on the occurrence of pathogens and diseases in aquatic animals in the United States. These systems range from records kept at an individual facility to national databases maintained by FWS and APHIS (National Surveillance Unit). Accurate, secure, and reliable data storage is essential to conduct epidemiological studies, to implement disease prevention and control programs, and to provide information to interested and affected parties in a timely manner.

As an example, APHIS operates the National Animal Health Reporting System (NAHRS) and the National Animal Health Surveillance System (NAHSS) by which information on pathogens and diseases important to terrestrial animals in the United States is collected, managed, and reported, as appropriate, to stakeholders and organizations such as the OIE through the Federal competent authorities. These systems are located in Ft. Collins, Colorado.

FWS operates a database, located at Montana State University, to store the information from its National Wild Fish Health Survey. All data are entered by personnel at the FWS Fish Health Centers, although actual fish samples can be submitted to the Fish Health Centers by many different entities.

States, tribes, and individual facility operators or resource managers also maintain disease reports. While this plan encourages the gathering of detailed health information, resources require that information submitted to a central, Federal database be restricted at this time to RAAPs.

The Task Force places a high priority on the development of a single, centrally located and managed Federal data system. As APHIS' CEAH has existing infrastructure to support such a system, such as the NAHSS and NAHRS systems, the Task Force will work with CEAH in developing a primary location for storing information on reportable aquatic pathogens. The FWS; NOAA Fisheries; other Federal, State, and tribal agencies; and private industry could support this effort by developing, in conjunction with the NAAHP, a common format to submit data to this centrally located and managed system to make the process consistent and effective.

CHAPTER 5. DISEASE PREVENTION, CONTROL, AND MANAGEMENT

5.1 Introduction

The first goal of any aquatic animal health program is to prevent the introduction of pathogens that cause disease, and this chapter will discuss a variety of strategies that relate to disease prevention. However, it is also critical to prepare for possible disease outbreaks. Thus, this chapter also provides information on disease response, including control, management, and eradication, to ensure that any disease response is predictable and appropriate and includes stakeholder input.

5.2 Biosecurity

Biosecurity[11] is the protection from transmission of infectious diseases, parasites and pests among and between animals and pathogen sources. Biosecurity measures are implemented to prevent the introduction or mitigate the spread of pathogens to protect a resource or industry. Biosecurity embodies all of the measures that should be taken to exclude or reduce disease transmission, and it is fundamental to disease containment.

Biosecurity plans are designed to mitigate risk factors for pathogen spread by both direct and indirect pathogen transmission. Direct pathogen transmission is mitigated by controlling contact with an infected animal or its products, such as blood, secretions, excretions, and vectors. Indirect pathogen transmission is mitigated by controlling animal contact with contaminated feed, water, fomites, people, or animals that are contaminated but not infected or susceptible to disease expression.

Elements of biosecurity plans include cleaning and disinfection; controlling movement of people, animals, vehicles and equipment; quarantining of new and returning animals; controlling effluent discharges; evaluating the effectiveness of the biosecurity plan; monitoring of potential vectors and reservoirs; and treating and/or excluding disease vectors and reservoirs. Biosecurity plans address these general areas but can be tailored to specific pathogens and the animals they affect.

The following concepts were developed with stakeholder input and are considered fundamental parts of a biosecurity plan. However, it is understood that these concepts are inherently commodity and facility specific, and aquatic disease programs should work with stakeholders to develop biosecurity measures for future Federal programs.

5.2.1 Plans

Aquaculture biosecurity is a broad topic. Specific plans will vary significantly among commodities, and may vary among pathogens. It is not the intent to summarize all of the biosecurity measures necessary for reportable pathogen exclusion. Rather it is to emphasize that progressive improvements to biosecurity measures are fundamental to the success of U.S. aquaculture industries, and that every facility should have a biosecurity plan in place.

5.2.2 Morbidity and mortality data

Monitoring, recording, and analyzing morbidity and mortality data are fundamental to effective biosecurity.

5.2.3 Sanitation and disinfection

5.2.3.1 Animals and products

Much research has been conducted on salmonid egg disinfection with iodophor (PVP-polyvinylpyrrolidone-buffered iodine) to reduce the associated pathogen load, but this process may not be appropriate for other commodities or life stages. Regardless of the specific processes, the proper sanitation and disinfection of animals and products is a primary step in preventing the introduction of pathogens into a facility.

5.2.3.2 Equipment

Typical disinfectants and dosages recommended for aquaculture equipment have been well established and successfully used in various aquaculture commodity groups for years. These disinfection procedures are used to reduce or eliminate pathogens from equipment and other potential fomites and vectors, including diving gear and boats. While these standards may not be appropriate for all commodity groups, common disinfectants and dosages[12] are:

- Chlorine (20 mg/l active ingredient for 10 minutes)
- Iodophor (100 mg/l active ingredient for 10 minutes)
- Quartenary ammonium compounds (1200 mg/l active ingredient for 10 minutes)
- Virkon S[13] (1 percent solution)

5.2.3.3 Personnel

Facility personnel are the key to the success of biosecurity plans, particularly sanitation and disinfection procedures. Personnel movements around a facility can rapidly and efficiently transmit pathogens. Sanitation and disinfection procedures for personnel will depend on the commodity, facility infrastructure, and disease status of the animals.

5.2.3.4 Fallowing

Fallowing is the process by which aquatic animal premises are kept vacant for a period of time for the control and management of aquatic animal pathogens. The period of time will vary according to the pathogens being managed and the environmental conditions at the aquaculture site. The fallowing period commences after the rearing site has been de-populated of aquatic animals. Typically, after depopulation (including harvest), all equipment, nets, and gear are cleaned so as to remove potential pathogen reservoirs and fomites. The intent of fallowing is to decrease the numbers of pathogens in the surrounding environment, to the extent that the risk of infection will be reduced when aquatic animals are reintroduced into the rearing site. The success of fallowing relies on the decrease of

pathogens in the environment by natural mortality, the absence of carrier animals or fomites re-entering the area during fallowing, and the pathogen-free status of the animals used to restock the site.

There is no standard optimal fallowing period for all commodities and pathogens. Recommended fallowing periods will vary considerably. Fallowing periods should be of adequate length such that there is a reasonable scientific expectation that the reservoir of organisms will be significantly reduced in a manner that reduces the occurrence or re-occurrence of a disease of concern.

5.3 Response to a PAAP or RAAP

This section presents a general overview of recommended actions that should be taken in response to finding a PAAP or RAAP in the United States. Commodity-specific contingency plans could be developed as the NAAHP evolves.

An effective response to a RAAP or PAAP must be swift, collaborative, and comprehensive; such a timely action is rarely achieved if a contingency plan is not in place before the finding occurs. Initial responses by the Federal government could, depending on the pathogen and the epidemiological information, follow the Incident Command System (ICS) to engage all appropriate parties as much as possible. The ICS structure provides a consistent nationwide management system, or template, to enable government, industry, and nongovernmental organizations to work together during domestic incidents. The ICS works under five major sections: Command, Operations, Planning, Logistics, and Finance/Administration.

5.3.1 Administration

Under the legal authorities described in chapter 2, each individual agency should establish or strengthen its aquatic animal health infrastructure, working closely with the other Federal, State, tribal, and private entities, to be able to prepare for and respond to future PAAP findings.

The response to the finding of a PAAP, including implementing a plan and initiating the ICS, should be led by the Federal agency with primary regulatory authority over the type of affected aquatic animals. Regardless of the lead Federal agency for a particular response, the APHIS CVO will continue to be the contact point for reporting OIE reportable pathogens to the OIE, as described in section 4.4.2.

Upon receiving notification of a suspected or confirmed RAAP or PAAP, aquatic animal health contacts for APHIS, FWS, and NOAA Fisheries are responsible for forwarding pertinent information within their respective agencies and to other State, tribal, industry, academic, Federal and other stakeholders. This channeling of information through selected contacts is intended to facilitate correct information dissemination, not to impede communication. However, these established communications channels should not discourage stakeholder contact at all levels when necessary.

The aquatic animal health contacts are responsible for ensuring a coordinated response. As such,

the implementation of agency contingency plans related to PAAPs and RAAPs should be the responsibility of the Federal aquatic animal health contact.

5.3.2 Identification and confirmation

The finding of a PAAP or RAAP may be considered a serious animal health event and may result in regulatory actions. Therefore, rapid and accurate pathogen identification and confirmation is necessary to avoid regulatory actions based on incorrect or premature information.

Once a lead Federal agency for a PAAP response has been identified, it is the responsibility of this agency to orchestrate the steps needed to confirm suspicion. As a PAAP event requires, by definition, a Federal response, the lead Federal agency should expect logistical, and, if necessary, personnel support to rapidly acquire the necessary diagnostic samples for pathogen identification and confirmation.

The identity of the suspected pathogen should be rapidly confirmed by a reference or other appropriate laboratory. This confirmation is necessary because a positive finding may result in regulatory actions and reporting to the OIE with possible subsequent trade implications.

5.3.3 Biosecurity responses

Perhaps the most important lesson learned from previous reportable disease incidents, whether caused by terrestrial or aquatic pathogens, is the need to act quickly and decisively when these pathogens are first observed. The first observation of a pathogen in a population may occur in concert with routine surveillance in clinically healthy fish, but often it results from investigations of disease events. Once detected, though, it is possible that pathogen dissemination may be limited if control efforts have been planned.

Biosecurity efforts within an aquaculture facility can be divided into three parts: preventing pathogens from entering a facility, moving within a facility, and moving out of a facility. Ideally, biosecurity protocols are sufficient to prevent PAAP incursions, but if a pathogen that causes a PAAP enters a facility or there is the suspicion of a PAAP, biosecurity contingency plans should be enacted to prevent the spread of the pathogen. Balancing continued business and trade operations while awaiting pathogen confirmation and implementing strict biosecurity may be difficult. This balance will need to be addressed on a case-by-case basis as events arise, and rapid decisions based on qualitative risks to national, regional, and local aquatic animal resources.

5.3.4 Control measures

Federal responses to a PAAP will vary according to the pathogen in question and the facility, zone, or location of the incident. Specific programs will need to be developed in conjunction with industry, States, tribes, and relevant stakeholders.

A Federal response will likely be in the form of one of three actions: control, manage, or

eradicate. Control and management strategies can vary, and include limiting the exposure of infected animals to avoid further dissemination of a disease. These animals may be allowed to be moved to other areas of equivalent disease status, may be moved for slaughter and processing, or may be held for other purposes.

Eradication is the most severe response and involves total depopulation of an affected population and potentially any populations linked to the diseased animals as identified through an epidemiologic trace. When eradication in a private facility is mandated by the Secretary of Agriculture (Title7, Section 8306), the producer must be compensated for the animals de-populated. The Department of Agriculture must work with the affected parties and subject matter experts to determine the most effective means to undertake the eradication and is responsible for effectively depopulating and then cleaning and disinfecting the affected premises.

5.3.5 Communication and public awareness

Communication regarding PAAP events is important to both the facility or industry affected and the general public. To facilitate this communication, the competent Federal agencies should prepare fact sheets in advance. These fact sheets would include information regarding the pathogen, signs of the disease, risks to human health, and contact points for further information.

Federal regulatory actions may have negative impacts on a facility or industry. It is recommended that potentiall affected individuals and industries be informed of and understand Federal actions. It is difficult for industry to conduct business if potential regulatory actions are unknown. Commodity- and pathogen-specific response and surveillance plans, developed with industry and stakeholder input, should include recommendations for Federal responses.

5.3.6 Post-event evaluation and ongoing surveillance

Following a PAAP event, the lead Federal authority of the particular event should conduct an evaluation of the implementation of the PAAP plan, effectiveness of the measures taken, and further actions to be taken, including ongoing surveillance. The evaluation of the implementation and effectiveness of the lead authority's actions should be transparent and open to input from all Federal, State, local and tribal governments, industry, and stakeholders. The intent of this evaluation is to improve future implementation of other PAAP plans and Federal actions.

CHAPTER 6. ZONATION

6.1 Introduction

This chapter will discuss how surveillance data can be used to establish zones based on the presence or absence of pathogens in areas of the United States. Zonation can limit the adverse affects of disease outbreaks and facilitate trade by delineating areas of distinct disease status.

For facilities engaged in the culture and subsequent movement of live aquatic animals, the ability to certify those animals as free from certain pathogens and diseases can increase market access. For example many salmonid egg producers, mollusk producers, and shrimp broodstock producers already have disease prevention, control, and management strategies in place in order to declare themselves as "disease-free" from specific pathogens. Consequently, the relevant State and/or Federal competent authorities are able to issue health certificates that provide opportunities for interstate and international trade.

A number of factors affect the distribution of an aquatic pathogen in a geographical area. Typically, a country's borders do not scientifically reflect that distribution. Some factors which influence the distribution of pathogens include hydrological conditions, presence of susceptible species, ecosystem factors, facility or compartment biosecurity, pathogen management in wild and cultured stocks, and historical movement of live aquatic animals within the country or zone in question.

For example, in the marine environment in both the Pacific Northwest and the Atlantic Maritime area, water, fish, and other mobile organisms and fomites move without restriction back and forth between the waters of the United States and Canada. It is clear that a pathogen present in the open ocean on one side of the border would also eventually be found on the other side. This situation is illustrated in the case of ISA in the Atlantic Maritime region, where it was first observed in New Brunswick and subsequently in Maine. Though infected live salmon may not have been purposefully moved across the borders, water currents or other fomites could have easily transported the virus. On the other hand, ISA has never been detected in the Pacific Northwest. Due to the separation of the Atlantic and Pacific regions of North America, and procedures to restrict the movement of ISA-infected fish between the two areas, it is unlikely that ISA would be transported to the Pacific Northwest. This example illustrates that a zonal approach better reflects the distribution of ISA rather than a designating both the United States and Canada as entirely positive countries.

6.2 Types of Zones

The OIE Code identifies three types of zones: free zones, surveillance zones, and infected zones. These zones are determined on a pathogen-specific basis. To remain within current scientific knowledge and maintain international norms, standards for identifying and declaring zones should defer to the current edition of the Aquatic Animal Health Code of the OIE.

In general, a free zone can be a country or an area within a country (that can be as small as an individual premises) where no cases of a specific notifiable pathogen has occurred within a

specified time frame, and which is within OIE parameters for recommended surveillance programs and levels of prevalence. The establishment of a free zone is contingent upon its separation from infected zones, the prevention of importation of infected animals from infected zones into the free zone, and the separation of the free zone from infected zone by a surveillance zone.

A surveillance zone is a limited area that is free of a specific pathogen but adjacent to or near an area where a notifiable pathogen has been isolated. To maintain a surveillance zone, an active pathogen surveillance program should be conducted, and importations of aquatic animals into that zone should be carefully controlled.

An infected zone is a country, region, or facility positive for the presence of a specific pathogen.

6.3 Commerce in Aquatic Animals and their Products

One rationale for the NAAHP, as described in Chapter 1, is to provide for efficient and safe commerce of aquatic animals and their products. Commerce of live animals always involves some degree of risk of importing diseases. For that reason, a process known as risk analysis should be used to identify and evaluate 1) the potential hazards of importing aquatic animals into the United States; and 2) the potential impacts of pathogens that could be introduced into the United States or into regions previously free of the pathogen. Approaching pathogen and disease status through risk assessment rather than risk avoidance allows commerce to continue in a way that is scientifically supportable.

6.3.1. Risk analysis as a tool to evaluate proposed commerce

Information on import risk analysis is available from the 2006 OIE Aquatic Animal Health Code. Chapters 1.4.1 and 1.4.2 of the Code describe international standards of risk assessments which the NAAHP could follow. As a signatory to the Agreement on the Application of Sanitary and Phytosanitary Measures, the United States should follow these guidelines. These OIE chapters do not provide the detail by which a risk analysis is conducted, but rather give an outline of the basic steps.

As paraphrased from the Code, import risk analyses (whether qualitative or quantitative) provide an objective and defensible method of assessing the risks of pathogen spread associated with commerce of aquatic animals and products. Each analysis, in part, considers an evaluation of the competent authorities and zoning and surveillance systems for monitoring aquatic animal health in the exporting country. The objective is to manage risk appropriately to ensure that a balance is achieved between the need to minimize the likelihood or frequency of pathogen incursions and the need to import aquatic animal commodities and fulfill international trade obligations. The process should be transparent so that all information, decisions, and scientific data are made available to stakeholders to openly and fairly evaluate the process.

Surveillance provides the points of reference for the status of pathogens in zones. These reference points, along with risk analysis data, can then be used to determine if inter- or intra-zone movements present acceptable levels of risk to avoid the introduction of pathogens into a

previously free zone.

6.3.2 Guidelines for international, intrastate, interstate, interzonal, or intercompartmental movement

This section will suggest general guidelines and procedures for aquatic animal movements during international, intrastate, interstate, inter-zonal, and inter-compartmental commerce. This guidance may be incorporated in future Federal aquatic animal health programs. The primary goal is to prevent the introduction or spread of RAAPs, recognizing the authorities of the various legal jurisdictions where the movements occur, and to make movements as efficient as possible. Guidelines will vary significantly among commodities, and may vary among pathogens for the same commodity.

Guidelines for movements of animals and animal products:

1. No live animals or animal products infected with or exposed to a RAAP should be transferred into U.S. territorial waters or outside the immediate boundaries of a facility, except to a bio-secure research laboratory or a processing facility that has biosecurity measures in place to prevent viable pathogens from entering the surrounding environment.
2. The shipping and receiving facilities should maintain records of the lot, number of animals, and date of each shipment that enters a facility. These records may need to be made available to the competent authorities in the event of a disease investigation.
3. Animals from pathogen-free zones can move into zones of similar or lesser health status.

6.3.3 Health inspections, certificates, and associated transfer permits

1. An import permit, which has information on the health status of the animals to be moved and is issued by the appropriate regulatory agencies, is the legal vehicle by which all imports should be reviewed and approved.
2. A health certificate issued by the appropriate regulatory agencies is the legal vehicle by which all movements of animals for international, interstate, and inter-zonal commerce should occur.
3. In the absence of Federal interstate regulations for the movement of aquatic species, individual States are free to implement scientifically based aquatic animal health requirements. Whenever possible, regulatory agencies should coordinate and streamline the permit and certification requirements for interstate or international movements.
4. The health permits required by State and Federal competent authorities for aquatic animal movements should be searchable online with an electronic application process to improve efficiency.
5. Harmonized guidelines should be adopted by States and Federal agencies regulating imports and interstate movements for the purpose of consistency in management of aquatic pathogens.

CHAPTER 7. RESEARCH AND DEVELOPMENT

7.1 Introduction

Three of the central goals of the NAAHP are to protect the health of farm-raised aquatic animals; ensure the availability of diagnostic, inspection, and certification services; and minimize the impacts of disease when they occur in farmed or wild aquatic animals. Ultimately, these goals support the larger goal of enhancing aquaculture, including economic feasibility and safety. To meet these goals it is necessary to advance research and development (R&D) of aquatic animal health issues.

The purpose of this chapter is to address how existing funding mechanisms for aquatic animal health R&D might be optimized to meet the research needs of the NAAHP and its stakeholders.

7.2 Research Funding

Multiple Federal agencies have grant programs that provide funding for research related to aquatic animal health.

7.2.1 USDA

The USDA has various funding opportunities, including the Cooperative State Research Education and Extension Services (CSREES) and the Agriculture Research Services (ARS). Both work cooperatively with APHIS to identify research needs in support of APHIS animal health programs

CSREES research priorities are based on multiple sources. State and regional research needs are reported via regional aquaculture centers to CSREES. CSREES also consults the JSA R&D plan.

ARS research prioritization is based on stakeholder input from major commodity groups. Meetings with these commodity groups are held at regular intervals. Technology transfer is an important component of the research agenda, and Cooperative Research and Development Agreements are important in ensuring research is utilized (e.g., vaccine development).

7.2.2 DOI

There is no extramural funding within DOI. However, science support can be carried out at the FWS fish health centers or technology centers. Research at fish health centers is field-related; that is, it is focused on localized issues. Research priorities are driven by the FWS regions.

The DOI U.S. Geological Survey (USGS) conducts research primarily in support of natural resource needs that have been forwarded to the USGS from other DOI Agencies, such as FWS. The research is therefore a service provided internally within the Department, although some of those research concerns may be similar or the same as those of industry.

7.2.3 DOC

The DOC has various funding opportunities including the Sea Grant program, the National Marine Aquaculture Initiative, the Advanced Technology Program (ATP), and the Small Business Innovative Research (SBIR) Program.

NOAA Sea Grant funding is distributed to State programs that fund research, extension, and education, as well as to some larger national programs. National programs that are funded are either identified in a strategic plan or have been made through congressional earmarks. Sea Grant State programs tend to be smaller, quick response-type programs while national projects tend to be larger and are often multi-State and multi-institutional. Sea Grant looks to the JSA R&D plan and to other stakeholder groups for prioritization of R&D projects.

The National Marine Aquaculture Initiative (NMAI), funded through the Office of Oceanic and Atmospheric Research, directs funds for research in marine aquaculture in the areas of policy and regulatory development, outreach and education, demonstration for the development of marine aquaculture in the United States, aquatic health management, and other related areas. The purpose of funding these projects is to develop a highly competitive, sustainable marine aquaculture industry that will meet growing consumer demand for aquatic foods and products that are of high quality, safe, competitively priced and are produced in an environmentally responsible manner.

The SBIR program and ATP program at the DOC's National Institute for Science and Technology were established to connect to industry and therefore must have industry partners. The ATP projects tend to be highly innovative and are often not supported by traditional grant programs.

7.2.4 State, regional and industry funding sources

Cooperative funding may be useful for implementing future programs. Funding from groups such as the Great Lakes Fishery Commission and industry associations should be considered.

7.3 Research Planning

7.3.1 JSA Research and Technology Task Force

The new Research and Technology (R&T) Task Force under the JSA is charged with updating the 1994 JSA R&T strategic plan and enhancing interagency cooperation and collaboration in research.

A 2-year timeline is expected to update the R&T strategic plan. All Federal agencies involved in aquaculture research will be represented on the R&T Task Force to ensure all needs are reflected in the updated strategic plan. Research needs identified by the NAAHP Task Force as well as those identified by other stakeholders will be considered. The goal is to be responsive to stakeholders' needs yet remain broad based. There will be overlap of members of the R&T Task Force with the NAAHP Task Force to further ensure awareness of the needs of the NAAHP.

7.3.2 Databases of research projects

Information on all research projects funded by CSREES or conducted by ARS is stored in the Current Research Information System (CRIS). This system is used only by ARS and CSREES. Data on Sea Grant supported programs is stored by the States; there is no national listing of all Sea Grant projects. Information on SBIR and ATP programs is not readily accessible, and confidentiality is an issue as these projects are often related to a business idea. However, some basic information on these projects would be useful to the research community and should be available in a database without compromising confidentiality. This data accessibility benefits research by eliminating or reducing duplicate research projects, thereby increasing the funds available for other projects. The CRIS or similar system could be expanded across agencies and would then facilitate collaboration on aquaculture-related research across agencies.

7.3.3 Databases of researchers and major research interests

There is no single source of information on aquaculture researchers and their major areas of interest. Development of a database that could store such information would be useful. If an immediate research question arises, one would have access not only to what research is currently being done, but what researchers may be able to assist in addressing the question based on historical projects and interests.

7.4 Research Needs Assessment

Areas in which research is needed were determined from technical group meetings and stakeholder comments. Industry, States, tribes, and other stakeholders may need to work together to prioritize these needs.

7.4.1 Industry needs

Commodity groups have expressed specific research needs for their area of interest. However, many of the research needs related to aquatic animal health are similar for crustaceans, mollusks, and finfish. General areas needing basic research include the following:

- Epidemiology and identification of risk factors
- Routes of transmission
- Identification of reservoir hosts and sources of infection
- Host range
- Breeding genetics
- Innate immunity
- Pathogenesis factors
- Evolution of pathogens
- Efficient diagnostic tests for emerging pathogens and PAAPs
- Range of aquatic animal pathogens (PAAPs and RAAPs) in the United States
- Easily deliverable, efficacious vaccines and gathering of field vaccine efficacy data (including cost-effective mass immunization strategies)

- Susceptibility to PAAPs and RAAPs that are new to the United States
- Accurate risk assessment techniques
- Cost-effective fish health enhancement via diets and/or immuno-stimulants
- Increased knowledge in molluskan immunology

7.4.2 Natural resource needs

Research needs for aquatic animal health from the natural resource perspective are focused on how to prevent entry or control pathogen spread once it has entered the environment. Related to these needs are host and geographic range of PAAPs and RAAPs, species susceptibility to PAAPs and RAAPs, environmental fate of pathogens, and risk assessment techniques.

7.4.3 Federal priorities

National research priorities need to focus on information to support NAAHP activities and will include the priorities listed for both industry and natural resources. However, within those needs, NAAHP research priorities will focus on pathogens listed as PAAPs and emerging diseases.

7.4.4 State, tribal and regional priorities

Pathogens of regional importance that do not meet the listing criteria outlined in chapter 3 but that are of importance to both natural resources and industry will not be included as PAAPs in the NAAHP. Therefore, it is important that regional organizations or States that deal with these pathogens ensure that their research priorities are sent forward via the JSA R&D task force or through other venues.

7.4.5 Long-term vs. short-term needs

Most extramural funding is based on a relatively short time frame to address research questions. Some examples include projects related to species susceptibility for ISA or SVC. Short-term projects may range from 1 to 4 years in length and usually address issues of immediate concern. There may be long-term issues that need to be addressed and would involve a multiyear, multi-institutional, high-investment approach. Such projects may include basic immunology of aquatic animals or basic assessment of a pathogen.

7.5 Interagency Collaboration and Cooperation

The JSA R&T Task Force is the primary avenue through which interagency collaboration and cooperation in aquatic animal health are coordinated. Updating the R&D strategic plan will involve the key Federal agencies and will provide the template for broad-based areas of aquaculture research. All Federal agencies with an involvement in aquatic animal health may have a representative on the R&D task force.

7.6 Recommendations

7.6.1 Interactions with JSA Research and Technology Task Force

The R&T Task Force and the National Aquatic Animal Health Task Force on Aquaculture (NAAHTF) each have a liaison to the other. Crossing membership across JSA task forces ensures that NAAHTF research needs are considered, and these liaison positions should be maintained.

7.6.2 Forum for input from stakeholders

Stakeholders and the NAAHTF should meet on a set schedule to discuss areas of research priorities. An R&T advisory committee similar to those described in section 4.4.1 would allow for input from all stakeholders. The NAAHTF could then solicit stakeholder input and report back to the JSA R&T task force.

7.6.3 Shared databases with research project information

As discussed in section 7.3.2, the CRIS database maintains data on current USDA intramural (ARS) and extramural (CSREES) research on aquaculture. The Task Force recommends that either CRIS be expanded or a new database developed that would allow access to information on current research projects related to aquatic animal health, conducted by Federal and other agencies. The information in this database should be made available to stakeholders.

In addition to this database, the Task Force also recommends that a second database, or a subset of the research database, be developed for names of aquatic animal health researchers and their main areas of research interest, cross-referenced to the research database that would show current projects. This database would enable all stakeholders to find information on research that is being conducted in aquatic animal health, and would assist Federal and State agencies that either conduct or support extramural research to ensure that research efforts are not duplicated.

CHAPTER 8. OUTREACH AND AWARENESS

8.1 Rationale for Outreach

Outreach is paramount to ensure that development of animal health programs is transparent and that stakeholders are provided a venue for input. This chapter describes how the Task Force and the agencies involved in implementing the NAAHP will continue to solicit input from stakeholders.

8.2 Interactions with Animal Health Organizations

The following is a list of many of the associations that the Task Force or Federal aquatic animal health contacts visit at least annually:

Domestic:
Joint Subcommittee on Aquaculture
National Aquaculture Association
"Aquaculture America" annual meetings
American Fisheries Society, Fish Health Section – regional and national meetings
Association of Fish and Wildlife Agencies
Native American Fish and Wildlife Society
American Veterinary Medical Association, both national meetings and the Aquatic Veterinary Medicine Advisory Committee
U.S. Animal Health Association
U.S. Trout Farmers Association
Catfish Growers of America
Pacific Northwest Fish Health Protection Committee
Rocky Plains Fish Pathologists
Great Lakes Fish Health Committee
National Association of State Aquaculture Coordinators
United States Animal Health Association

International:
World Organization for Animal Health
Food and Agriculture Organization (FAO) of the United Nations.

8.3 Other Outreach Strategies

- **Oral presentations at meetings and conferences.** Task Force members attend over 20 meetings each year.
- **Web page.** The Task Force maintains an NAAHP section on the APHIS Web site (www.aphis.usda.gov/animal_health/animal_dis_spec/aquaculture/). One agency was chosen to host these pages in order to ensure consistency and accuracy, and links are maintained on the NOAA Fisheries and the FWS Web sites. The Web site contains minutes of the technical group meetings from which the chapters were developed.
- **Newsletter.** The Task Force publishes one to two newsletters annually to present the latest activities and progress on the plan. The newsletter is also posted on the Web page.

- **Brochure.** The Task Force created an informational brochure (hard copy and Web based) to provide information on the Task Force and the NAAHP. These brochures are distributed at stakeholder meetings.

Other possible outreach vehicles include informational articles in aquaculture and aquatic health publications, newspaper interviews, and video clips (prepared with assistance of professional outreach staff in partner agencies).

CHAPTER 9. EDUCATION AND TRAINING

9.1 Introduction

The implementation of a successful national aquatic animal health plan requires appropriately educated aquatic animal health professionals to meet the needs of today and of the future. It is also essential that aquaculturists have access to education in aquatic animal health to ensure they have knowledge to make informed management decisions regarding their animals when a disease event occurs, or they know when to contact an aquatic animal health professional and where they can find such an individual. Because the topic of education is so broad and further stakeholder input is needed, this chapter can only present general needs and how to address them. In the long term, Federal and State agencies, veterinary schools, and other educational institutions must constantly assess the evolving need for education as aquaculture continues to expand.

9.2 Training Needs

According to input from NAAHP technical groups, the needs for education are as follows:

- Increasing core and elective education in health management of aquatic animals for veterinary schools.
- Ensuring the competency of agencies with regulatory responsibility for aquatic animal health through aquatic animal training for veterinarians and other aquatic animal health professionals employed by State and Federal agencies.
- Expanding extension services for the producer and all others involved in aquatic animal health services. Animal health providers need to be educated in the critical needs of industry, and producers need to be educated on the different roles of animal health professionals.
- Training in sample collection by the methods specified by the competent authority. This training, which may be the most critical need, includes not only ensuring that the sample is collected according to regulations, but also providing third-party verification that the sample is a true representative of the premises.
- Training for laboratory personnel in standard methods and procedures for pathogen testing as well as quality control and quality assurance.

9.3 Roles and Training of Aquatic Animal Health Providers

In the long term, a strategy to ensure the availability of qualified and educated professionals to support national aquatic animal health efforts must be developed. These individuals may include aquaculturists, veterinarians, aquatic animal health specialists, veterinary technicians, and laboratory personnel.

A discussion of the level and type of education, training, and certification recommended for the various aquatic animal health providers first requires an understanding of the potential roles people might play. Some examples of these roles and ways to provide further training are described in the following sections.

9.3.1 Aquaculturists

Some of the most important tasks at an aquaculture facility include observing the general health and behavior of the cultured animals, removing mortalities while noting clinical signs, and recording this information on a regular basis. These tasks are especially critical during epidemiological investigations and may be the key to diagnosing a problem. The aquaculturist is instrumental in implementing the primary element of a surveillance program and must be well trained on how to observe the health of the animals, effectively remove and accurately count the mortalities and record them, and know when the situation requires the services of an aquatic animal health specialist with more advanced knowledge and tools for disease identification.

Extension services are currently provided by both NOAA (through Sea Grant universities) and by USDA (through some Land Grant universities). These programs fund at least one extension agent. Most extension agents work very closely with aquaculture producers and often provide educational materials to these groups as well as to the general public. In addition, many extension agents often augment their funding by applying for grants in order to conduct basic and applied research. If funding is available, workshops may be organized on request of the local industry to cover specific concerns as needs arise. Extension agents often cooperate with other entities or act as facilitators and communicators such as with Federal and State agencies to address industry needs.

In the context of the NAAHP, extension courses could be organized by a Federal interagency technical team for producers and taught by extension staff from both USDA and NOAA. Extension services should expand training programs, not only for the producer but for all others involved in aquatic animal health services. Education in aquaculture and aquatic animal health can be taught as early as the high school level. Again, many of these programs, such as raising fish in the classroom, are or could be coordinated out of an extension office or a local hatchery.

9.3.2 Aquatic animal health specialist

The aquatic animal health specialist (AAHS) is an individual with specialized training in evaluating the health of aquatic animals. This individual must have knowledge of the biology and life history of the animal, husbandry practices, disease diagnosis, sample collection, disease treatments, and the aquatic ecosystems inhabited by both wild and cultured animals. There are two types of licensed/certified professionals who currently fill the role of AAHS: the veterinarian licensed by States to practice veterinary medicine and the professional certified by the American Fisheries Society, Fish Health Section (AFS/FHS) as a Certified Fish Pathologist. Additionally, States may recognize their own aquatic animal health professionals outside of these certification paradigms.

In certifying an individual as a fish pathologist, the AFS/FHS provides a peer review system to identify professionals possessing the competence, training, and ethics required to effectively serve the aquatic animal health needs of fisheries programs and aquaculture. The AFS/FHS has a minimum set of standards for certification as a fish pathologist, including a bachelor's or advanced degree in a biological science from an accredited college or university. Specific courses and specialized training in fish health is also required. In addition, applicants must have

3 years of full-time fish health work experience within the 5 years preceding application and must submit four letters of recommendation, including one from the applicant's immediate supervisor. Once the above requirements are fulfilled, the applicant must pass (with a minimum score of 70 percent) a written examination covering topics such as fish disease etiology, diagnostic procedures, pathology of fish diseases, fish disease therapy, fish pond management, fish disease control, general fisheries, fish culture, and other items essential to a thorough knowledge of the care and health of fish.

Licensing for veterinarians is regulated by each State and Territory. The State also determines the definition of the practice of veterinary medicine and defines what types of animals fall under the licensing laws. The AHPA of 2002 defines "animal" to include all species except humans. Therefore, finfish, amphibians, reptiles, mollusks, crustaceans, corals, sponges, zooplankton, and all other invertebrates fall under the USDA definition for "animal." All of these species groups are being reared in aquaculture ventures.

Not all States recognize the USDA definition for animal. All States recognize aquatic animals in their veterinary practice acts; however, some States also provide for other professionals to work with certain species, such as individuals certified by AFS/FHS or recognized by the State outside of these certification paradigms. It would be beneficial for national consistency to harmonize these definitions among States. It is not the role of this Plan or the Federal competent authorities to dictate to States how they regulate their industries, resources, and professionals. It is the role of the Task Force, however, to suggest models that might be adopted both locally and nationally in the near term and long term. Regardless of the health professional approved by the States or recommended in the NAAHP, it is important that the health professional and aquaculturist develop and maintain a cooperative relationship so as to best serve the health and productivity of the cultured animals.

Veterinarians are also employed by the Federal government in positions of aquatic animal health. APHIS is training field veterinary officers to act as aquaculture liaisons to oversee sampling and certification of aquatic animals. This training began in the fall of 2006 with an internal 1-week course and will continue on an annual basis. In addition, APHIS is in the process of developing an aquaculture certification within their Federal veterinary accreditation program.

Most veterinary schools produce general practitioners. Graduates will have gained knowledge and experience that can be applied to all animals and diseases, although the emphasis is on companion animals and common domestic animals. Those veterinarians wishing to specialize in aquatic animals could take additional courses from a variety of sources, such as universities or veterinary schools specializing in aquatic animal health, Federal and State agencies, or professional organizations.

Continuing education is also important for professionals to remain current with the latest diseases, techniques, and issues. Educational programs are often presented in conjunction with professional meetings, such as those of the AFS-FHS and the American Veterinary Medicine Association. In addition, many universities and some veterinary schools may offer short courses on aquatic animal health which can be used as a refresher course or to provide new material for participants. Several university courses are now online or proposed for online training as well.

Veterinary schools could assess and fill needs in educating veterinarians in the aquatic animal health field as the aquaculture industry continues to grow in the United States. Universities could also expand related programs for aquatics. The NAAHP will encourage veterinary schools and universities to expand curricula on aquatic animal health and to increase continuing education opportunities for veterinarians and other fish health professionals.

9.3.3 Fish health inspector/veterinary technician

Fish health inspectors and veterinary technicians play an important role in the implementation of aquatic health strategies. The AFS/FHS recognizes technicians with expertise in sample collection, processing, testing, and reporting results as "AFS/FHS Certified Fish Health Inspectors." The focus of this certification by AFS/FHS is to identify individuals with competence in isolating pathogens from aquatic animal specimens and with the capability to conduct testing as prescribed by the OIE and the AFS/FHS Blue Book. The inspector may function independently or under the oversight of an AAHS.

Through its certification program, the AFS/FHS identifies individuals possessing the technical skills and high ethical standards, which qualify them to conduct health inspections of aquatic animal populations, to perform recognized and acceptable detection and diagnostic procedures, and to issue certificates or other such documents attesting to the presence or absence of specific pathogens in the populations inspected. AFS/FHS requires fish health inspector applicants to have a bachelor's or higher degree with a major or minor in biological science at an accredited university, or a degree in veterinary medicine. Alternatively, an applicant may be considered who has a specified number of hours in college level microbiology and/or at least 5 years experience in an occupation which routinely uses microbiological methods. In addition, the applicant must have been involved in fish health inspection and diagnostic examination work for at least 20 percent of the time during 3 of the 5 years preceding application. The applicant must also have access to equipment and laboratory facilities; at a minimum, laboratories must be available for analysis of inspection samples. Three letters of recommendation, including one from the applicant's immediate supervisor, must also be submitted for the certification of a fish health inspector.

The veterinary technician, on the other hand, is an individual typically licensed by a State who functions under the supervision of a licensed veterinarian. The technician may be authorized to conduct many functions including sample collection, processing, testing, recording, and reporting of results to the veterinarian.

The Federal agencies responsible for aquatic animal health will also work with States to address needs for appropriately trained individuals for aquaculture facility inspections and certifications for transport. This can take place through improved communication and coordination with States in notification of education and training opportunities such as those listed above.

9.3.4 Laboratory personnel

A need exists for laboratories to provide accurate and timely pathogen testing for aquatic

animals. The personnel conducting these pathogen detection assays need to be appropriately trained, understand the science behind the tests, and be knowledgeable in quality assurance and control for the laboratory.

For laboratories involved in international shipments, a team of auditors from each of the three Federal agencies (APHIS, NOAA-Fisheries, and FWS) under the auspices of the NAHLN is one approach for providing oversight for laboratory approvals and audits and for coordinating laboratory proficiency tests, such as ring testing between laboratories.

9.4 Other Training Opportunities

The FWS also has several courses in aquatic animal husbandry and health offered through their National Conservation Training Center in Shepherdstown, West Virginia. These courses could be applicable to all roles of aquatic animal health providers listed above. Course offerings are updated as the need arises. Several courses are also often provided for laboratory personnel, either by the FWS or in coordination with other groups. Examples of subject areas include introductory and advanced fish health, fish culture, investigating fish kills, fish histopathology, virology, polymerase chain reaction (PCR) techniques, quantitative PCR, amphibians, and mollusks.

An array of education and training opportunities in aquatic animal health is provided by universities (undergraduate, graduate and postgraduate levels), community colleges, veterinary schools, Federal and State agencies, extension services, and professional organizations. According to technical groups, the training opportunities available at universities, especially ones with strong graduate degrees in aquatic animal health, are critical and provide detailed experience in fisheries biology, fisheries management, fish physiology, and aquatic animal health and husbandry. Many of these courses could support those engaged in all types of roles involved in the NAAHP.

9.5 Education and Outreach

Education and outreach are closely related. In addition to educating individuals associated with the aquaculture industry and the NAAHP, a need also exists to conduct outreach to educate the public on general principles of aquatic animal health. Guidelines for outreach are described in chapter 8.

CHAPTER 10 IMPLEMENTATION

10.1 Introduction

Chapters 1 through 9 of this document provide recommendations for how entities involved in aquatic animal health can work together to protect our farmed and wild resources, facilitate safe commerce, make laboratory testing available, and develop training and educational programs. This chapter on implementation discusses prioritized aquatic animal health programs based on stakeholder input.

The next step is for the Federal agencies to take the recommendations and suggested actions in the Plan and make them into policies, guidelines, and if appropriate, regulations. The Task Force recognizes that these steps, like the development of the NAAHP, must be a continuation of a collaborative process which includes input from States, tribes, and industry. It is also recognized that implementation strategies must be supported by our partners; otherwise, the possibilities for successful implementation may be limited.

10.2 National Advisory Committee

Due to limited resources, the NAAHP must be developed based on priorities. However, beyond the NAAHP priorities as outlined throughout this document, continued stakeholder input will be required to ensure that these priorities and recommendations are current. Therefore, of utmost importance to a successful NAAHP is the establishment of a National Advisory Committee for Aquatic Animal Health (NACAAH).

Many different types of advisory groups exist for the purpose of giving scientific and policy direction to Federal regulatory agencies. Some of these advisory groups are convened under the direction of the Federal Advisory Committee Act, also known as "FACA Committees" (5 U.S.C. App.2). The process by which these advisory committees are formed and membership established and the mechanisms by which they function vary greatly. As programs and services under the NAAHP have not yet been established, the Task Force recommends a small advisory group (15-20 individuals) be established to provide the Federal agencies with impartial advice on how best to implement the NAAHP given current funding levels and priorities. This could be accomplished either by establishing a new FACA-chartered advisory committee within one of the three Federal Agencies (APHIS, FWS, or NOAA-Fisheries) or by creating a subcommittee of a currently established FACA committee, such as the Secretary's Advisory Committee on Foreign Animal and Poultry Diseases within the USDA.

Membership of the NACAAH should include individuals with expertise and experience in:

- Commercially producing finfish, mollusks or crustaceans
- Representing groups/organizations responsible for promoting the recreational use of finfish, mollusks or crustaceans
- Holding a leadership role in a national, State or regional organization representing commercial aquaculture interests

- Managing and regulating fishery resources with emphasis on aquatic health issues as a former or current official in national, State, tribal, or regional organization representing the respective government entity
- Conducting research on aquatic animals to include infectious diseases and health management of finfish, mollusks and crustaceans
- Working with international bodies that accredit or provide recommendations for the regulation of aquatic animal diseases, i.e., OIE
- Providing health care services for aquatic animals
- Regulating commercial movements of aquatic animals to include import, export and interstate commerce

10.3 Priority Areas for the NACAAH

The NACAAH will address the priorities outlined by NAAHP technical groups and the implementation of the various programs and services described throughout the NAAHP. The remainder of this chapter on implementation will focus on some of the more broad-based priorities that have been identified.

10.3.1 Preventing the introduction of PAAPs

The U.S. currently has three Federal regulations to prevent PAAPs from being imported: FWS Title 50 requires certification of freedom from *Oncorhynchus masou* virus disease, VHS, infectious hematopoietic necrosis, and infectious pancreatic necrosis; APHIS has import regulations to protect against the importation of VHS; and APHIS has import regulations to protect against the importation of SVC. In addition, APHIS is in the process of developing import regulations for ISA.

However, these import regulations cover only a limited number of listed PAAPs. To prevent or lower the risk for importing other PAAPs, new import regulations are needed. As a signatory to the WTO and SPS agreements, the U.S. would need evidence that it is free of a pathogen for which it proposes import restrictions or has a Federal domestic control program to justify such protections.

Future import regulations against PAAPs should be promulgated by APHIS. APHIS, through the AHPA, has the regulatory authority to develop and implement interstate regulations, and has had experience developing domestic control programs for terrestrial animals as well as for aquatic animals, such as the ISA program.

10.3.2 Response to PAAPs

The response to PAAPs in culture establishments should be collaboration among Federal, State regulatory agencies, tribal authorities, industry, and other stakeholders. There are no prescribed Federal responses for PAAPs, and initially all such responses are State responses. Multiple factors must be considered in choosing a response, and will likely differ on a case-by-case basis. The appropriate response may range from taking no action to eradication. General approaches to PAAPs should be formalized in contingency plans developed in concert with stakeholders.

Eradication of PAAPs in the wild is more complex than in culture situations, due to the open environment and ecological considerations. Unless the pathogen is detected very rapidly in a geographically distinct area, eradication is likely neither practical nor possible.

10.3.3 Health certification

Whether under a Federal regulation or not, the State competent authority for aquatic animal health determines who is authorized to sign interstate health certificates. Currently, the permit and certification requirements are not streamlined between States and various agencies. Additionally, unlike certificates for other animals, there are no electronic certificates available.

To the degree possible, there needs to be national consistency to harmonize the definition of 'animals' between States with respect to veterinary practice acts. The NACAAH should review the current health certification paradigm for aquatic animals and recommend further changes to streamline and clarify health certification for aquatic animals.

10.3.4 Surveillance scheme for PAAPs and RAAPs

A primary component of this national animal health program is the identification of economically and biologically important diseases and their causative agents. A list of pathogens and diseases (see chapter 3.4) was developed as the starting point for establishing surveillance and monitoring efforts, developing management regions or zones, and creating the infrastructure necessary for implementing a health management program.

Although surveillance for aquatic pathogens occurs at some level within all the Federal agencies and with States, tribes, and industry, there currently are no standard methodologies for all testing and all reporting. Additionally, this surveillance occurs in many locations for many reasons. This patchwork approach to surveillance was a noted deficiency in the 2007 European Union audit of the United States' oversight of aquatic animal health (final audit report pending). It is essential that surveillance for aquatic animal pathogens become transparent, standardized, streamlined, and cost-effective.

10.3.5 Laboratories, standardized testing, quality testing, and approved personnel

Protocols used by the various laboratories conducting pathogen testing that supports Federal regulatory actions should be standardized. Additionally, there is a need for a nationwide laboratory network that utilizes existing Federal, State, tribal and private laboratories to conduct testing for PAAPs, RAAPs, export health certificates, and any other activities with NAAHP involvement. This network should incorporate the skills and assets already in place including those in the FWS Fish Health Centers and university, State, Tribal, and private laboratories. The NACAAH should consider the NAHLN as an existing network that may accommodate the needs expressed during technical group meetings.

10.3.6 Education and training

According to input from NAAHP technical groups, the NAAHP highlights the following needs for education:

- Increase in core and elective education in health management of aquatic animals in veterinary schools.
- Improve training for Federal and State regulators.
- Expand extension services to offer training to everyone involved in aquatic animal health services.
- Improve laboratory personnel training in standard methods and procedures for pathogen testing, quality control, and quality assurance.

10.4 Harmonization of Federal Import Regulations

APHIS currently has import requirements in place for SVC and VHS and is developing import regulations for ISA. These regulations are being promulgated under APHIS' authority under the AHPA and are in compliance with WTO and OIE standards. Prior to the AHPA of 2002, FWS developed import requirements for certain salmonid diseases of concern as part of Title 50. These regulations are not entirely in compliance with OIE or WTO standards and are part of a regulation that is written primarily for wildlife.

Now that the AHPA is in place, stakeholders have expressed a desire for harmonization of Federal import requirements related to aquatic animal health. From a Federal perspective, it is important that the United States, as a signatory to the OIE and WTO, be in harmonization with the trade principles of these organizations while protecting the health of our nation's aquatic species and habitats. Therefore, FWS and APHIS should explore opportunities for harmonizing the aquatic animal health requirements found under Title 50 and the AHPA.

10.5 Estimated Costs for Immediate Programs

The JSA recognizes that implementation of the NAAHP will not occur without some cost to the taxpayer. Section 10.3 describes some of the broad-based priority areas in aquatic animal health as identified through stakeholder meetings and information obtained from technical groups. Some of these activities are continuations or expansions of existing aquatic animal health programs, while others are new initiatives. Stakeholder input and recommendations from the NACAAH will be necessary to prioritize the activities for which funding should be sought.

Due to the conservative funding environment for Federal animal health programs, we expect that any funding for the NAAHP and the ability to implement any aspects of the NAAHP will be limited in the foreseeable future. However, in order to continue existing or inactive programs (which provide the basic framework for implementation of the NAAHP) and to address deficiencies in Federal aquatic animal health activities (as identified in part by the European Union audit of 2007), we have estimated the costs for some core NAAHP activities. These figures represent estimated costs for the first year of implementation only:

NAAHP Existing or Inactive Programs	Approximate Annual Cost
ISA control program for salmon farming industry in Maine	$450,000*
SVC certification program	$200,000*
VHS control and surveillance program	$5,750,000**

In addition to these established programs, funding for laboratory infrastructure improvements was also identified as a key priority in NAAHP implementation. The table below lists estimated costs associated with these activities:

NAAHP Infrastructure Improvement	Approximate Cost
Support of the National Veterinary Services Laboratories	$600,000
Development and support of an aquatic animal health laboratory network such as the National Animal Health Laboratory Network (first year cost)	$1,000,000*

Finally, new activities that were identified as critical early priorities in NAAHP implementation include oversight of surveillance for molluskan diseases in areas approved for export and establishment of an indemnity fund should eradication be required for a disease occurrence. Additionally, funding for NACAAH meetings would be required should this group become established as an official advisory committee, to support travel and meeting attendance. The approximate costs for these activities are provided in the table below.

New NAAHP Activity	Approximate Annual Cost
NACAAH meeting fund	$150,000*
Molluskan disease surveillance support	$500,000**

10.6 Conclusions and Next Steps

This chapter concludes the draft NAAHP. The next step is to move forward in establishing a NACAAH that can advise and formalize recommendations to the Federal agencies regarding the NAAHP. The Federal agencies must prepare to implement the recommendations received by the NACAAH. This includes ensuring that Federal budget proposals account for implementing these recommendations in a timely fashion.

As the individual Federal agencies begin to act on the recommendations of the NACAAH, it is necessary that outreach activities continue in order for the public to be aware of Federal agency activity relating to aquatic animal health. Therefore, as part of implementation, the Federal interagency team that serves on the Task Force should continue to remain engaged in the following activities:

- Attend national meetings of stakeholders
- Maintain an informational Web site on aquatic animal health activities.

* Costs are estimated and based on 2008 dollars. Requests for Congressional appropriations have not been made through any of the responsible Federal Agencies; therefore, these figures are not part of any specific budget proposal.

** President's budget for fiscal year 2009 funds a portion of this amount.

- Publish an informational newsletter two to three times a year
- Maintain a list of contacts in the three Federal agencies to serve as informational resources on NAAHP and Federal agency activity in aquatic animal health

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