

3. ROLES, RESPONSIBILITIES, AND AUTHORITIES OF FEDERAL, STATE, AND TRIBAL GOVERNMENTS, AND PRIVATE INDUSTRY FOR AQUATIC ANIMAL HEALTH IN THE UNITED STATES

3.1 Objective

The objective of this chapter is to define the current roles, responsibilities, and legal authorities of Federal, State, tribal governments, and private industry in administering national aquatic animal health programs.

3.2 Current roles, responsibilities, and legal authorities

3.2.1 Federal agencies

Agriculture - Animal and Plant Health Inspection Service

Legal authorities:

The United States Department of Agriculture (USDA), Animal and Plant Health Inspection Service (APHIS), has always been recognized as the lead agency for regulating diseases and providing Federal oversight to health programs for livestock. This agency's authority in the realm of aquaculture was not well defined until the passage of the *Agriculture, Conservation, and Rural Enhancement Act of 2002* (also known as the "Farm Bill of 2002"). The newly defined authority of USDA for aquatic animals is found in Subtitle C - Animal Health Protection Act, Sec. 1021-1038. In this act Congress finds that "(1) the prevention, detection, control, and eradication of diseases and pests of animals are essential to protect:(A) animal health; (B) the health and welfare of the people of the United States; (C) the economic interests of the livestock and related industries of the United States; (D) the environment of the United States; and (E) interstate commerce and foreign commerce of the United States in animals and other articles."

To carry out this Act, the Secretary of USDA may prohibit or restrict the importation or entry of any animal, the export of any animal, or the movement of any animal in interstate commerce if the Secretary determines that the prohibition or restriction is necessary to prevent the introduction, export, or dissemination within the United States of any pest or diseases of livestock. Further, "the Secretary may hold, seize, quarantine, treat, dispose of, or take other remedial action with respect to...any animal that may carry or may have carried...any pest or disease of livestock."

In extraordinary emergencies, the Secretary may "hold, seize, treat...prohibit or restrict the movement...of any animal." These actions may be taken by the Secretary in any State or tribal jurisdiction if it is determined that the actions taken by the tribe or State are inadequate to control or eradicate the pest or disease. The Secretary is also required by the Act to consult with other Federal Agencies: "(1) IN GENERAL - The Secretary (of Agriculture) shall consult with the head of a Federal agency with respect to any activity that is under the jurisdiction of the Federal agency."

The definitions contained within this Act are all encompassing: "(1) ANIMAL - The term 'animal' means any member of the animal kingdom (except a human)" and "(10) LIVESTOCK -

The term ‘livestock’ means all farm-raised animals.” The Act gives the Secretary of Agriculture regulatory authority over all aquatic animal pests and diseases that have the potential to affect livestock (farmed aquatic animals). The Secretary does not appear to have authority to regulate diseases and pests that will not affect livestock nor to protect or manage aquatic animals that are not farmed. As the word “farmed-raised” is not defined in Subtitle - C, it is not clear if this authority of USDA extends to aquatic animals held in captivity or cultured by other Federal, tribal, State, or non-private, public entities. However, the traditional meaning of “farmed animals” and the intent of previous farming legislation is directed at private, commercial industry.

The Secretary is directed to “consult” with other Federal agencies with jurisdiction in regard to administering Subtitle C. However, there is no language in the Act that removes existing authority over aquatic animals held by the Department of Commerce’s National Oceanic and Atmospheric Administration (NOAA) Fisheries or the Department of the Interior’s Fish and Wildlife Service (FWS). In regard to private commercial aquaculture, the 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 Secretary of Agriculture’s new authority over aquatic animals, obtained from the Animal Health Protection Act of 2002, appears to overlap with authorities of the Secretaries of Commerce and Interior in regard to commercial aquaculture in the Exclusive Economic Zone (EEZ), the culture of wildlife by private companies in near-shore and upland fresh water facilities, and the import of live salmonids from foreign countries as noted in Title 50.

The Federal agency responsible for licensing domestic manufacturers of veterinary biological materials (biologics), such as vaccines, is USDA-APHIS. The Agency’s role is to ensure biologics are pure, safe, potent, and effective. APHIS 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.

Roles and responsibilities:

The Secretary of Agriculture, via his/her designee, is the leader of the Joint Subcommittee on Aquaculture (JSA) - the interagency Federal committee organized under the Executive’s National Science and Technology Council, Committee on Science. The National Aquatic Animal Health Task Force (NAAHTF), which is responsible for the development of the National Aquatic Animal Health Plan (NAAHP) and organized under the auspices of the JSA, is also chaired by a representative of the Secretary of Agriculture.

The National Veterinary Service Laboratories (NVSL) is operated by APHIS. These laboratories provide diagnostic services for domestic and foreign animal diseases, provide support for disease control and eradication programs and training, approve diagnostic tests, and participate in the approval of laboratories to conduct inspections for certain pathogens.

The Animal and Plant Health Inspection Service, 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 Office International of Epizootics (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, or CVO. The CVO is the official voting representative of the United States at meetings of the OIE.

The Animal and Plant Health Inspection Service entered into an export memorandum of understanding (MOU) with the FWS and NOAA Fisheries in 2004. The purpose of the export MOU was to define responsibilities of Federal agencies for the issuance of official health certificates for live aquatic animals shipped from the United States. In that MOU, APHIS is responsible for export health certificates for all commercially farmed aquatic animals including aquatic livestock reared in academic institutions, research facilities, and public aquaria, with the exception of aquatic animals farmed in the EEZ, which are the responsibility of NOAA Fisheries.

Commerce - National Marine Fisheries Service (NOAA Fisheries)

Legal authorities:

A variety of laws give NOAA Fisheries responsibility and authority over activities affecting aquatic animal health. The Magnuson-Steveson Fishery Conservation and Management (Magnuson-Stevens Act, 16 U.S.C. Sec. 1801), requires the agency to “take immediate action to conserve and manage the fishery resources found off the coasts of the United States, and the anadromous species and Continental Shelf fishery resources of the United States by exercising (A) sovereign rights for the purpose of exploring, exploiting, conserving, and managing all fish, within the exclusive economic zone established by Presidential Proclamation 5030, dated March 10, 1983, and (B) exclusive fishery management authority beyond the exclusive economic zone over such anadromous species and Continental Shelf fishery resources.” The term “fishery resources” and the act of harvesting these resources, i.e. “fishing,” has been determined by NOAA’s General Council to include aquaculture activities (Rieser, 1997). Therefore, under this interpretation, NOAA Fisheries has the responsibility of protecting and managing the health of wild and cultured aquatic animals in the EEZ.

Under the Endangered Species Act, 16 U.S.C. 1531 (ESA), NOAA Fisheries and FWS are identified as the lead agencies with the responsibility of protecting and conserving endangered or threatened species. In marine waters, including the EEZ, this legal mandate is primarily the responsibility of NOAA Fisheries. Aquaculture programs in the EEZ could occur in the vicinity where listed species reside or could actually be part of an aquaculture activity, the purpose of which is to conserve and re-establish an endangered marine species. NOAA Fisheries, therefore, has a significant responsibility for managing aquatic animal health in the EEZ in those situations when the health of ESA-listed species may be impacted.

In addition the Atlantic Coastal Fisheries Management Act of 1993, 16 U.S.C., requires that the Secretary of Commerce, in cooperation with the Secretary of the Interior, develop and implement a program to support the Atlantic States Marine Fisheries Commission in interstate fishery management consistent with the Magnuson-Stevens Act. The Atlantic Tunas Convention Act of 1975, 16 U.S.C. 971-971i, applies to management of stocks of Atlantic tunas, swordfish, and

billfish. The Fish and Wildlife Conservation Act of 1980, 16 U.S.C. § 2908 et seq. provides technical and financial assistance to States, in order to assist them in the development of conservation plans and programs that protect non-game species and “encourages” all Federal departments to use their statutory and administrative authority to conserve and promote conservation of non-game fish and wildlife, and authorizes all Federal agencies to provide assistance to states which seek to develop or revise conservation plans (i.e., loaning personnel or equipment, sharing scientific or other types of information). The Lacey Act Amendments of 1981, 16 U.S.C. §§ 3371-3378, prohibit the trafficking and possession of any wildlife, fish, or plant taken in violation of domestic, foreign, State, or Indian tribal law, and prohibits the import, export, or transport of fish or wildlife unless the container or package is appropriately marked. Under the Act, the Secretaries of Commerce and Interior must jointly promulgate regulations for the marking and labeling of containers or packages containing fish or wildlife. The Secretaries of Commerce, Interior, Transportation, and Treasury must enforce the Act and have discretionary authority to enter agreements with government agencies or Indian tribes to further these efforts. The Fish and Wildlife Improvement Act of 1978, 16 U.S.C. 7421, 753a authorizes cooperative training and enforcement with State personnel; cooperative research. Secretaries of Interior and Commerce are authorized to use, by agreement, personnel, equipment, and facilities of other Federal agencies or States for enforcement of any Federal or State law concerning fish and wildlife.

In addition, NOAA Fisheries has certain responsibilities and authorities relating directly to facilitation of utilization of seafood products. The Agricultural Marketing Act of 1946, 7 U.S.C. §§ 1621-1627 directs NOAA Fisheries to conduct, assist, and foster research, investigation, and experimentation to determine the best methods of handling, and marketing seafood products, determine costs, foster more efficient marketing; develop and improve standards of quality, condition, grade, etc.; increase consumer education; and conduct a voluntary inspection and certification program; conduct other research and activities to facilitate utilization of seafood products. Legislation regarding Cooperative Fisheries Associations, 15 U.S.C. §§ 521-522, requires the Secretary of Commerce to address monopolies and restraints of trade by fisheries associations in interstate or foreign commerce to such an extent that the price of any aquatic product is thereby unduly enhanced. The Fish and Seafood Promotion Act, 16 U.S.C. 4003-4017 requires the Secretary of Commerce to participate on a National Fish and Seafood Promotional Council. The Secretary has numerous responsibilities relative to the Council, including reviewing an annual marketing and promotion plan and budget, promulgating regulations to carry out the Act, administering the Fisheries Promotional Fund, and making appointments to the Council within a certain timeframe. The Secretary is also required to review and approve or, if requested by a council, to develop, quality standards for a fish or fish product. The Secretary also is required to promulgate regulatory procedures for the use of an official label/identification to indicate that a fish or fish product meets the quality standard. The Fish and Wildlife Act of 1956 and associated provisions, 16 U.S.C. 742a-753d, 742e-742j, 742k, 744-748, 750-753, 753a-753b, 754, 758-758d, 760a-760g declares that the fishing industry can fulfill its proper function only if certain needs are met, including better health standards and sanitation. The Act authorizes NOAA Fisheries to conduct investigations and prepare and disseminate information and reports regarding fish and their habitats in order to provide for the proposed development of fish resources. The Fish and Wildlife Coordination Act 16 U.S.C. 661-666c provides authority for Commerce and DOI to conduct cooperative programs with NMFS and other agencies. The

National Aquaculture Act, 16 U.S.C. 2801-2810 directs Secretaries of Commerce, Interior, and Agriculture to develop, periodically review and revise, and implement an Aquaculture plan/program. It also directs the Secretaries to undertake a continuing assessment of aquaculture in the U.S. It requires the Secretaries to provide educational and technical assistance to interested persons. It requires submission of a biennial report to Congress. 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. If the grants made under this section are inadequate, the Secretary shall carry out a national program of research and development addressed to the aspects of United States fisheries that are not covered by projects receiving grants. The Secretary is obligated to make an annual report with respect to projects receiving grants.

Finally, NOAA Fisheries is vested with certain responsibilities in the realm of seafood safety that relate to the health of aquatic animals. Pursuant to Executive Order 13100, the President's Council on Food Safety, NOAA Fisheries participates on an interagency council to develop a food safety strategy, develop a comprehensive Federal food safety plan, advise agencies of priority areas, coordinate Federal budgets, and guide Federal research efforts. The Public Health, Security and Bioterrorism Act of 2002, Pub. Law 107-188, Title III, Subtitle A, Protection of Food Supply, requires participants on the President's Council on Food Safety, including NOAA Fisheries, to develop a crisis communications and education strategy. NOAA Fisheries also participates on the White House Interagency Working Group on Mercury, May 2002, (via the National Science and Technology Council, EO 12881). The work group will examine and coordinate efforts to advance our understanding of methylmercury in the environment, the potential for human and possibly aquatic animal exposure, health effects, and technological solutions to these problems.

Roles and responsibilities:

The National Oceanic and Atmospheric Administration Fisheries is represented on the JSA and on the NAAHTF. A NOAA representative serves as vice co-chair of the NAAHTF.

The National Oceanic and Atmospheric Administration Fisheries entered into an export MOU with the FWS and APHIS in 2004. The purpose of the export MOU is to define responsibilities of Federal agencies for the issuance of official health certificates for live aquatic animals shipped from the United States. In that MOU, NOAA Fisheries is responsible for issuing export health certificates for all wild marine animals and aquatic animals farmed in the EEZ. NOAA Fisheries is also identified as responsible for issuing health certificates for exports from marine research laboratories, aquariums, and academic institutions.

A variety of services for the international commerce of aquatic animals is provided by NOAA Fisheries. Marine aquatic animals harvested in the wild are shipped to many countries, primarily as processed bait or seafood. Some countries require animal health inspections on these exported products. These inspections are provided by the NOAA Seafood Inspection Program. This is a voluntary, fee-for-service operation that provides for sanitary inspection programs, process and product inspection, product grading, laboratory analysis, training and consultation. The

emphasis of these services is on human health issues. However, as mentioned above, inspections are provided in connection with animal health issues.

Four science centers are operated by NOAA Fisheries. These centers have associated laboratories where research is conducted on management, culture, and health of anadromous and marine aquatic animals.

Interior - Fish and Wildlife Service

The U.S. Fish and Wildlife Service (FWS) has regulatory authority over two areas of aquatic animal health- 50 CFR Part 16.13 ("Title 50"), Injurious Wildlife, and 16 U.S.C 1531 *et seq* - (Endangered Species Act). Title 50 states: "Live or dead unviscerated salmonid fish (family Salmonidae), live fertilized eggs, or gametes of salmonid fish are prohibited entry into the United States for any purpose except by direct shipment accompanied by a certification that: as defined in paragraph (e) (1) of this section, the fish lots, from which the fish originated, have been sampled; virus assays have been conducted according to methods described in paragraphs (e) (2) through (4); of this section; and *Oncorhynchus masou* virus and the viruses causing viral hemorrhagic septicemia, infectious hematopoietic necrosis, and infectious pancreatic necrosis have not been detected in the fish stocks from which the samples were taken. In addition, live salmonid fish can be imported into the United States only upon written approval from the Director of the U.S. Fish and Wildlife Service." This section goes on to prescribe how eggs must be sanitized before entry into the United States, the format for the health certificate, and the manner in which the samples will be tested for viruses. An exemption from these requirements is allowed if the fish in question are "caught in the wild in North America under a valid sport or commercial fishing license." This exemption appears to allow the capture, transport, and landing of live, wild fish--including salmonids--from marine or fresh waters. Current FWS "policy" allows for salmonids destined for (and remaining in) scientific or medical research, education or zoological purposes to be imported without a "Title 50 Health Inspection Certificate." Such importation, however, can only be undertaken with a valid FWS Injurious Wildlife Permit.

The primary purpose of Title 50 is to protect wild and cultured fish in the United States from viruses that may be imported with live or dead salmonids or their products. This authority of the FWS appears to overlap the authority of the Secretary of USDA, who has the authority to restrict the import of any animal with the potential to introduce pests or diseases that could negatively affect livestock.

The FWS also has shared authority with NOAA Fisheries under the ESA to protect, conserve, and manage listed species. The authority of FWS under ESA is primarily exercised in upland and fresh waters of the United States.

Roles and responsibilities:

The FWS is represented on the JSA and on the NAAHTF. A FWS representative serves as vice co-chair of the Task Force.

The FWS entered into an export MOU with APHIS and NOAA Fisheries in 2004. The purpose of the export MOU was to define responsibilities of Federal agencies for the issuance of official

health certificates for live aquatic animals shipped from the United States. In that MOU, FWS is responsible for export health certificates for all wild, freshwater aquatic animals, and fresh water aquatic animals cultured in public-sector hatcheries (i.e., Federal, State, tribal and other municipal jurisdictions), aquariums, research laboratories, and academic institutions.

The FWS operates nine Fish Health Centers distributed throughout the United States. These centers are integral to the health management of wild and cultured fish stocks in the United States. These centers are responsible for conducting the National Wild Fish Health Survey and providing diagnostic and research services for FWS, some tribal, and some State-operated fish management programs. The Fish Health Centers provide additionally, on a case-by-case basis, certification services and diagnostic services for private aquatic farmers.

Environmental Protection Agency

Legal authority:

The authority of the Environmental Protection Agency (EPA) is found in 33 USC 1251, also known as the *Clean Water Act*. This law gives EPA the authority to require a *National Pollutant Discharge Elimination System* (NPDES) permit for aquaculture operations in the United States. EPA is in the process of updating its rules for discharge permits for aquaculture operations. Areas that the new rules (and some existing NPDES permits for near-shore aquaculture operations) impact include the discharge of drugs and chemicals used to treat aquatic animals, the disposal of mortality, and potentially the discharge of pathogens from an aquaculture site. EPA also regulates the administration of some pesticides. The NAAHP will make no recommendations for changing the current authorities of EPA.

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 USC 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. “Drugs” do not include biologics under the authority of USDA. The NAAHP will make no recommendations for changing the current authorities of FDA.

State Department and U.S. Trade Representative

The State Department and the U.S. Trade Representative (USTR) negotiate treaties and agreements with foreign countries. The NAAHP will make no recommendations for changing the current authorities of the State Department or the USTR.

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 NAAHTF is one of the many working groups under the JSA and is charged with developing a national aquatic animal health management plan.

3.2.2 States and territories

Legal authorities:

The fifty States and U.S. territories have authority over aquatic animal health issues within their borders and within their coastal zones to the boundary of the EEZ. Animal health regulations are administered by one or more agency in each State. Typically, the regulating State agencies are the departments of agriculture, fish and wildlife, and/or natural resources. While States have regulatory authority over controlling introduction of animals across their borders from other States or countries, these existing regulations may not be in harmony with existing Federal regulations or new regulations proposed in the NAAHP. It is critical that States participate in the development 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.

3.2.3 Federally-recognized Native American Treaty Tribes

Legal authorities:

Federally-recognized Native American treaty tribes (Tribes) have legal authority within their respective tribal treaty 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 may not be in harmony with existing Federal regulations or new regulations proposed in the NAAHP. It is critical that Tribes participate in the development of this plan to ensure harmony between Federal, State, and tribal regulations.

Roles and responsibilities:

Animal health programs vary from tribe to tribe 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.

3.2.4 Industries

Roles and responsibilities:

The NAAHP is a plan that recommends how aquatic animal health may be managed in the United States. The primary role of industries should be to actively participate in the development and review of the NAAHP. Stakeholder meetings have been held in the past and will continue in the future. The commercial aquaculture industries will continue to be invited and expected to attend.

It is the responsibility of the industries, once the NAAHP has been developed, to be an active team member in the implementation of the plan. More detail on how industries will assist in plan implementation can be found in Elements 10 and 11.

3.2.5 National and International Advisory Bodies

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. The OIE is notified by the Chief Veterinary Officer of the United States when an OIE notifiable pathogen is isolated in U.S. State or territory. Pathogen and disease data from 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 procedures manual known as the “Bluebook” for the diagnosis and testing of certain aquatic animal diseases and pathogens which includes a segment specific for inspections. Its newest version 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 for consideration of issues of 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. It develops solutions of animal health-related issues 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.