

U.S. Aquaculture: Regulatory Reform Priorities

The National Aquaculture Association¹ (NAA) requests action by federal agencies to implement regulatory reforms or new regulations, such as an organic aquaculture label, to achieve the intent, purposes and goals of the National Aquaculture Policy Act and benefit the 5,533 farms in the United States that are producing a huge variety of aquatic animals and plants to satisfy consumer demand for nutritious seafood (fish, shellfish, crustaceans and seaweeds), healthy aquarium and water gardening species, great bait, catchable game and sportfish, or fish to control nuisance aquatic plants. Priorities are briefly described for each agency and supported by supplementary information.

Department of Agriculture

Increased funding and staffing to fully implement the Commercial Aquaculture Health Program Standards (CAHPS).

Revise and update the National Aquatic Animal Health Plan to focus on farm-raised aquatic animal health and risk-based health management.

Publish for public comment the proposed organic aquaculture rule.

Confer with the NAA to develop a schedule for listening sessions with growers to find ways to improve the Whole Farm Revenue Protection (WFRP) program to make it workable for aquaculture producers.

Departments of Agriculture and Commerce

Collaboratively organize stakeholder input to inform the next iteration of the *National Strategic Plan for Aquaculture Research*.

Department of Commerce

Lead the organization of a national aquaculture economic development summit.

Complete and make publicly available an analysis of leasing and property law to inform the public debate regarding the best means of securing tenure for marine aquaculture in federal waters.

Environmental Protection Agency

Initiate rulemaking or develop legislation for the Administration that will implement the Clean Water Act, Section 303(d), Total Maximum Daily Loads recommendations described in the 2001 National Research Council and 2013 Government Accountability Office reports.

¹ The National Aquaculture Association (NAA) is a U.S. producer-based, non-profit trade association founded in 1991 that supports the establishment of governmental programs that further the common interest of our membership, both as individual producers and as members of the aquaculture community. For over 27 years NAA has been the united voice of the domestic aquaculture sector committed to the continued growth of our industry, working with state and federal governments to create a business climate conducive to our success, and fostering cost-effective environmental stewardship and sustainability.

Environmental Protection Agency and Army Corps of Engineers

Confirm that shellfish aquaculture is a type of farming activity that may qualify for the CWA section 404(f)(1)(A) exemption and clarify that most commercial shellfish aquaculture activities do not involve the discharge of dredged or fill material.

Army Corps of Engineers and National Marine Fisheries Service

Create expedited Endangered Species Act, Section 7, Consultation guidance for marine shellfish (clams, oysters, mussels or scallops) and seaweed aquaculture permits in state waters.

Recognize and publicly appreciate that submerged aquatic vegetation (e.g., seagrasses) will colonize active shellfish farming leases or permitted locations. Farms should not be penalized, farming activities curtailed, or permits revoked or modified because of damage to colonizing SAV as an outcome of typical farming activities.

Initiate Regional or State Programmatic General Permits for shellfish culture in state waters to achieve three goals: Create regulatory consistency across the coastal ACOE district offices and NMFS regional offices that are involved or may become involved with shellfish farming regulations; efficiently and effectively conduct and complete a review of navigational or environmental effects; and issue as agencies, or facilitate state issuance of shellfish permits or leases, in a timely manner.

Complete National Environmental Policy Act required environmental analysis or programmatic environmental impact statement to support longline production systems for seaweed and mussels for state and federal waters.

Department of the Interior

Eliminate various overtime and specialty fees to accommodate the inspection of import/export products and animals, live or dead, to reduce the costs and meet the needs of the public and businesses engaged in international trade.

Defer to the USDA, the lead US agency for farmed animal health, the health regulations for imported nonnative aquatic animals and recognize that Congress did not provide the authority within the Lacey Act to regulate native or nonnative animal pathogens.

Immediately adopt methodological and scientific revisions and include subject matter expert review to improve the Ecological Risk Screening Summary and Fish Invasive Species Risk Assessment Model reports and remove posted reports from a publicly accessible website until these changes are completed.

Initiate rulemaking to increase the allowable take to 91,175 birds for individual permits and, after accounting for the needs of the USDA Wildlife Services, allocate this allowable take across these states to fish farms as recommended by the USDA Wildlife Services, and re-establish an Aquaculture Depredation Order for 37 states.

Departments of Interior and Commerce

Under the authority provided by the Endangered Species Act, list as distinct population segments at-risk foreign species, which are also commercially cultured in the United States, within their native range and not as a global listing.

Prior to at-risk native, Endangered Species Act listings, complete an in-depth review of state regulatory and non-regulatory efforts, expenditures and funding sources being implemented to conserve and recover at-risk species.

Food and Drug Administration

Review and modify drug approval policies and procedures for farm-raised aquatic animals privately or publicly produced as requested in joint letters to the agency by the Association of Fish and Wildlife Agencies and NAA dated December 7, 2017 and December 20, 2018, respectively.

Supplementary Information

Department of Agriculture

Animal and Plant Health Inspection Service
Aquatic Animal Health Program

We request that the funding and staffing be increased to fully implement Commercial Aquaculture Health Program Standards (CAHPS) to respond to emerging and existing pathogen threats, conduct a Western regional conference to test the utility of CAHPS by farms and natural resource agency fishery and hatchery managers, revise and update the National Aquatic Animal Health Plan (NAAHP) and associated agency MOU to recognize USDA as the lead agency for farm-raised aquatic animals and structure the NAAHP to focus on farm-raised aquatic animal health management, and reduce a nationwide shortage of private practice veterinarians that assist fish and shellfish farmers.

Farmers and USDA Veterinary Services are working to respond to three emerging foreign pathogens: Tilapia Lake Virus, Ostreid herpesvirus microvar 1 (oysters) and the recent introduction to the United States of a special strain of virulent *Vibrio parahaemolyticus* (acute hepatopancreatic necrosis disease) found on a Texas shrimp farm, and two endemic pathogens: *Aeromonas hydrophilia* (catfish) and three species of flavobacterium (trout).

CAHPS provides an integrated and continuous program to prevent or manage identified pathogen risks to a farm or the market where the farm may sell its production. Across the United States, aquatic animal health is shared between multiple state agencies and to achieve adoption by these agencies requires state specific training and demonstration of the program's utility to achieve adoption by the private and public sectors.

The National Aquatic Animal Health Plan is 11 years old and must be revised and updated. We request that the revision focus on farm-raised aquatic animals and the specific needs of the farming community, a risk-based approach, and risk analysis for specific pathogens to inform the farming community of where, when and how they should manage for those pathogens.

Nationwide there is a shortage of trained and experienced aquatic animal veterinarians to advise, diagnose, treat and write prescriptions to treat aquatic animals for the 5,533 farms that raise aquatic animals. Recent Food and Drug Administration rules require all antimicrobial medicines to be provided via addition to feed and veterinarian prescription, termed Veterinary Feed Directive, to allow the purchase and feeding of these specialty, medicated feeds.

Agricultural Marketing Service
National Organic Program

The NAA requests publication for public comment, as soon as possible, the proposed organic aquaculture rule that required five years to develop and has been held in limbo by the agency for the last three years. The proposed rule should be released for these specific reasons:

- Farm grown fish and shellfish are the only major foods not certified under the Organic Food Production Act of 1990. In every respect aquaculture qualifies for inclusion and by doing so satisfies a Congressional intent within the National Aquaculture Policy Act to reduce the seafood deficit and encourage the development of aquaculture in the United States.
- American consumers want organically produced farmed fish and shellfish. As reported in the study we provided to the agency, 70% of the seafood consumers surveyed indicated an interest in purchasing organic seafood and 59% believed that organic seafood would be pesticide and antibiotic free which indicates that false consumer concerns about farm-raised seafood are overcome by a USDA organic label.² The study was funded by the USDA Agriculture Marketing Service.
- In the United States., approximately 90% of all seafood is imported from foreign countries that often are subsidized and have significantly lower production costs due to lower regulatory burdens and compliance. American aquatic farmers must be allowed to utilize a wide variety of tools to compete against these imports and organic labeling is one of these tools that is currently not available to domestic growers.
- Organic labeled seafood products are imported in large amounts and currently certified by programs significantly less strict than proposed USDA standards. Organic shrimp from South America bearing a private organic label; organic salmon from Scotland and Ireland bearing the EU organic label; and organic mussels from Canada that are grown to Canadian standards all compete with U.S. produced products that cannot be certified as organic due to the lack of domestic standards. There are even some products sold in the U.S. under an organic claim that are grown to no recognized standards whatsoever, particularly from China. In each case producers and retailers are able to charge premium prices. The sale of all these products rightfully belongs to American farmers who, with organic premiums will be able to compete with foreign imports.
- The lack of USDA organic standards currently allows import of products that would not be allowed because the non-USDA standards these products are being certified to are significantly less stringent than the proposed USDA standards. If USDA standards are implemented these imports would have to comply with the USDA standard or at least be certified under a standard that is deemed equivalent. Thus, US and overseas aquatic farmers would be held to equivalent standards and the playing field for domestic and foreign producers would become equitable to everyone and benefit the US consumer.
- Consumers are seeking healthy and nutritious fish and shellfish, and the USDA and Department of Human Health Services recommend that Americans consume two portions of seafood a week. New consumption will develop once the USDA organic label is available for U.S. farmed fish. According to the Organic Trade Association, overall organic food production now accounts for approximately 5% of all food consumed in the

² O'Dierno, L.J., R. Govindasamy, V. Puduri, J.J. Myers and S. Islam. 2006. Consumer perceptions and preferences for organic aquatic products: Results of a telephone survey. New Jersey Agriculture Experiment Station. P-02275-2-06 (<http://www.dafre.rutgers.edu/documents/ramu/organicaquaculturesurvey.pdf> accessed February 28, 2019).

United States. We expect that farmed seafood consumption will do as well, if not better once the US farmer has access to USDA organic certification.

Risk Management Agency

The NAA requests the opportunity to recommend to the Risk Management Agencies feasible dates and locations to complete the listening sessions directed by Congress in the 2019 Farm Bill to inform changes to the Whole Farm Revenue Protection policy.

Approximately 60 percent of U.S. aquaculture farms reported a farm-gate income of \$100,000 or less.³ The majority of aquaculture farms are family-operated and each aquaculture segment and regional production practices (foodfish, shellfish (molluscs and crustaceans), baitfish, ornamental fish and invertebrates, aquatic plants, game and sportfish, reptiles, and others) vary in their availability away from the farm to best provide informed guidance to the agency.

Departments of Agriculture and Commerce

We request that the departments collaboratively organize stakeholder input to inform the next iteration of the *National Strategic Plan for Aquaculture Research*. We request that the Plan incorporate sufficient detail and direction that the agencies and subcomponents of those agencies refrain from conducting separate, disconnected exercises to inform their research priorities.

Department of Commerce

We request that the Department of Commerce (DOC) assume a leadership role in organizing a national aquaculture economic development summit. We further request the summit include the Secretaries for Agriculture, Transportation, and Interior, the Deputy Assistant Secretary for the Army (Civil Works), the U.S. Environmental Protection Administrator, Governors and state executives from the state economic development agencies.

Based upon our experience and knowledge of aquaculture economic development programs by Japan, Norway, and Ireland, a similar economic development effort by the DOC could significantly decrease our country's seafood trade deficit and create new businesses and jobs. We believe that in order to achieve these goals and stimulate aquaculture investment and growth in the United States, the DOC must also support permit process streamlining, applied research targeting industry bottlenecks, technology transfers designed to capture innovation and technologies being used in other countries, training focused on workforce and entrepreneurial development, improved financing programs, investment incentives including tax credits, development of risk management tools, and incentives to the states that wish to step up and support the initiative.

The development of the initiative should include private sector representatives who understand what is required to build aquaculture businesses. The initiative should create a DOC led task

³ U.S. Department of Agriculture. 2013. Census of Aquaculture. U.S. Department of Agriculture, National Agricultural Statistics Service. Washington DC. (https://www.nass.usda.gov/Surveys/Guide_to_NASS_Surveys/Census_of_Aquaculture/ accessed March 5, 2019).

force to create specific recommendations for actions that federal and state governments should take, a time table for those actions and a series of metrics designed to measure program efficacy. We suggest that the initiative include an investment of federal resources equivalent to 5% of the annual seafood trade deficit. As the initiative succeeds and the seafood trade deficit is reduced the need for government investment would decline.

The National Aquaculture Association and U.S. Aquaculture Society are currently working together to organize a national meeting of aquaculture scientists and producers in Washington, D.C. We suggest merging this effort with the national aquaculture economic development summit to bring together agency, farmer and science representatives. We are also prepared to help identify seafood market chain executives to contribute to the summit and to work through state and species aquaculture associations to encourage state participation.

National Oceanic and Atmospheric Administration
National Sea Grant Program
National Sea Grant Law Center

We request that the National Sea Grant Law Center, in partnership with the National Agriculture Law Center, complete and make publicly available an analysis of leasing and property law to inform the public debate regarding the best means of securing tenure for marine aquaculture in federal waters. This analysis should address the following questions:

- Are there any statutory or regulatory restrictions in existing federal law which would prevent Congress from providing a federal agency the authority to issue and manage leases in the Territorial Sea and EEZ? Provide detailed citations and descriptions.
- Are there any restrictions in United Nations Convention on the Law of the Sea (UNCLOS) as it is being interpreted and applied (Customary Law) by the United States to manage the EEZ that would prevent Congress and the Federal government from establishing a leasing program for commercial aquaculture?
- In the standard practice of land management by governments and the private sector today, what are the important legal differences as commonly understood between providing access to and managing a site with a permit system and a leasing system? Provide real-world examples of each.
- Research the history of amending the Outer Continental Shelf Lands Act (OCSLA) to allow leasing for wind farms (circa 2007). Our understanding is, the siting process was going to rely upon the ACOE Section 10 Permit, but that was abandoned because of issues like the ACOE permit provided no security of tenure and no exclusive use controls. Congress acted so these very expensive projects could go forward. Report the results.
- What are the limits to Congress concerning the authority to create and grant leases within the Territorial Sea and/or the Exclusive Economic Zone?

- How is a lease for oil and gas platforms and wind farms defined in terms of the space occupied in the OCSLA and what property rights and exclusive use controls are conferred to the leaseholder?
- OCSLA encompasses all federal waters from state waters seaward to the boundary of the EEZ. Are the lease conditions the same throughout this area?
- Given oil/gas and wind energy facilities are stationary, occupy a space from the bottom to surface, and are supported by extensive land-based facilities, very similar to offshore farms, what are the law enforcement provisions inherent to OCSLA as conferred to the Bureau of Ocean and Energy Management?
- Will a permit provide rights of restitution and rescission similar to that of a lease?
- Include an assessment of investor/entrepreneur opinions from those with aquafarm experience regarding the distinction between use of a federal lease versus permit for purposes of securing legal access to a site in the EEZ, maintaining exclusive use controls, and obtaining insurance. One approach could be for the National Aquaculture Association and the NOAA Office of Aquaculture to provide lists of aquafarm investors and entrepreneurs to be interviewed by the NGSL research team.

U.S. Environmental Protection Agency

Clean Water Act
Section 303(d)
Total Maximum Daily Load (TMDL)

We request that the agency begin rulemaking or develop legislation for the Administration that will be submitted to Congress to implement the recommendations contained in 2001 National Research Council⁴ and 2013 Government Accountability Office⁵ reports. Specifically:

- Develop and issue new regulations requiring that TMDLs include *additional elements*—and consider requiring the elements that are now optional—specifically, elements reflecting key features identified by National Research Council (i.e., other pollutants beyond those defined in the Act and stressors such as habitat degradation, flow alteration, channelization, and loss of riparian areas) as necessary for attaining water quality standards, such as *comprehensive* identification of impairment (i.e., point and nonpoint sources), reasonable assurances that nonpoint source pollution projects are implemented and are working, actions to monitor water bodies to verify that water quality is

⁴ National Research Council. 2001. Assessing the TMDL Approach to Water Quality Management. National Academy Press, Washington DC (<https://www.nap.edu/catalog/10146/assessing-the-tmdl-approach-to-water-quality-management> accessed February 27, 2019).

⁵ U.S. Government Accountability Office. 2013. Clean Water Act: Changes Needed if Key EPA Program is to Help Fulfill the Nation’s Water Quality Goals. Washington, DC. (<https://www.gao.gov/products/GAO-14-80> accessed February 27, 2019).

improving, and adaptive management provisions (i.e., active monitoring and data analysis) that are implemented to achieve continuous TMDL improvement.

- To ensure more consistent application of *existing TMDL elements* and to provide greater assurance that TMDLs, if implemented, can achieve tangible water quality results, identify regional offices with criteria for interpreting and applying such elements in reviewing and approving state-developed TMDLs and issue guidance with more specificity, directing all regional offices to follow the same criteria, including requesting that states provide more-detailed information about pollution causes and abatement actions.
- Place conditions on states' annual use of nonpoint source management and water pollution control grants to ensure that the funds meet the purposes for which they are awarded and achieve greater reductions in nonpoint source pollution associated with TMDL implementation, such as by targeting funds to states and projects that incorporate factors needed for effective TMDL implementation (e.g., targeting grant funds to projects where implementation plans have been developed and where external agency assistance is available).
- Obtain missing data that currently impede EPA's efforts to determine whether and to what extent TMDLs have been implemented or to what extent implemented TMDLs have helped impaired waters attain water quality standards by:
 - directing states to use and report specific GIS data when implementing projects to which TMDLs apply; and,
 - requesting that USDA ask landowners who participate in conservation programs funded by the department in areas subject to a TMDL to disclose information on the location, type, and number of projects implemented under these programs.

U.S. Environmental Protection Agency and U.S. Army Corps of Engineers

U.S. Environmental Protection Agency (EPA)
U.S. Army Corps of Engineers (ACOE)
Clean Water Act
Section 404

Permitting Discharges of Dredge and Fill Materials

The NAA requests that EPA confirm that shellfish aquaculture is a type of farming activity that may qualify for the CWA section 404(f)(1)(A) exemption and clarify that most commercial shellfish aquaculture activities including placing clean shell (i.e., cultch) or shell that has live settled oyster spat on a marine oyster aquaculture lease or permitted location for the purpose of oyster culture or oyster reef restoration do not involve the discharge of dredged or fill material. The placement of cultch or spat-on-shell cultch is an established and long practiced shellfish aquaculture production method that is already recognized by state lease or permit requirements. The Section 404 permit and enforcement by federal agencies is costly and redundant to the farmer and federal agencies because of state regulations and should be eliminated.

U.S. Army Corps of Engineers and National Marine Fisheries Service

U.S. Army Corps of Engineers (ACOE)
National Marine Fisheries Service, Protected Resource Division (NMFS PRD)
Endangered Species Act

Section 7 Consultation

The NAA requests that the ACOE and NMFS PRD create expedited Endangered Species Act Section 7 Consultation guidance for marine shellfish (clams, oysters, mussels or scallops) and seaweed aquaculture permits in state waters. Aquaculture production gear and practices are not all that different, fundamentally, across the several coasts and clearly there could be specific conclusions reached on the various gear types and distribution of those gear types such that NMFS PRD and the ACOE should be able to make permit decisions much faster. The NAA recommends farm tours for the agency staff to observe production gear in action, information sharing across the regional offices relative to Section 7 Consultations, interaction with Land Grant or Sea Grant Aquaculture Extension Specialists concerning at-risk species protections or potential interactions, and consultation with the farming community regarding at-risk species interactions.

U.S. Army Corps of Engineers (ACOE)
CFR Title 33, Section 320
National Marine Fisheries Service, Protected Resource Division (NMFS PRD)

Shellfish Farming and Submerged Aquatic Vegetation

The NAA requests that the ACOE and NMFS PRD recognize that submerged aquatic vegetation (SAV) will colonize active shellfish farming leases or permitted locations. Published research and farmer observations indicate shellfish farming activities are beneficial for SAV colonization and growth. The potential outcome that SAV will colonize shellfish farms should be recognized with agency regulatory guidance. Farms should not be penalized, farming activities curtailed, or permits revoked or modified because of damage to colonizing SAV as an outcome of normal farming activities.

U.S. Army Corps of Engineers (ACOE)
National Marine Fisheries Service, Office of Aquaculture
National Marine Fisheries Service, Protected Resource Division (NMFS PRD)
National Aquaculture Policy Act
River and Harbors Act
Section 404 Clean Water Act
Endangered Species Act

Regional or State Programmatic General Permits

The NAA requests that the ACOE continue to work with the shellfish farming community, Office of Aquaculture and NMFS PRD to build upon the beneficial outcomes of such efforts as

recently described in the Government Accountability Office report.⁶ The ACOE, Office of Aquaculture and NMFRS RPD should continue to develop NWP48, Regional or State Programmatic General Permits for shellfish culture in state waters to achieve three goals: Create regulatory consistency across the coastal ACOE district offices and NMFS regional offices that are involved or may become involved with shellfish farming regulations; efficiently and effectively conduct and complete a review navigational or environmental effects; issue as an agency, or facilitate state issuance of shellfish permits or leases, in a timely manner; and, achieve the intent, purposes and goals of the National Aquaculture Policy Act. The similarity of shellfish production gear, practices and objectives across the country facilitates the development of general permits and given the growth in shellfish production by small producers that can lease or permit small acreages allocated by states, these regional or programmatic general permits should reduce time, effort and expense for the agencies.

National Marine Fisheries Service, Office of Aquaculture
U.S. Army Corps of Engineers (ACOE)
National Marine Fisheries Service, Protected Resource Division (NMFS PRD)
National Aquaculture Policy Act
River and Harbors Act
Section 404 Clean Water Act
Endangered Species Act

Programmatic NEPA Analysis: Seaweed and Mussel Longline Culture
The NAA requests that the Office of Aquaculture complete a programmatic National Environmental Policy Act (NEPA) analysis focused on longline production systems for seaweed and mussels for state and federal waters. Production gear, and practices. Such an analysis will facilitate permit review by the federal agencies to reduce the time and resources required to review and approve permits and achieve the intent, purposes and goals of the National Aquaculture Policy Act.

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

U.S. Fish and Wildlife Service
Office of Law Enforcement

Import/Export Inspection Fees – Title 50 CFR 14

The NAA requests elimination of the various fees to recognize that inspecting import/export products and animals, live or dead, is the service that has to be performed and that employee working hours and shifts should be scheduled to coincide with the needs of the public and businesses that are engaged in international trade. Examples of the variety of current fees can be found here: <https://www.fws.gov/le/pdf/SampleFeeAssessments.pdf>.

⁶ GAO. 2019. Army Corps of Engineers: Information on Shellfish Aquaculture Permitting Activities. U.S. Government Accountability Office. Washington, DC. GAO-19-145. (<https://www.gao.gov/assets/700/697024.pdf> accessed March 5, 2019).

International trade of regulated live animals or their parts occurs primarily through international airports via air cargo. Authority to regulate this trade rests upon the Endangered Species Act and its authorization for the United States to participate in the Convention on International Trade in Endangered Species of Wild Fauna and Flora and the Lacey Act. Shipments may consist of regulated or non-regulated animals and live or dead animal parts. Inexplicable, the work of inspecting shipments whether they include live or dead or regulated or non-regulated animals requires the payment of different fees in addition to the salary and compensation received by FWS employees. Freight and passenger airline arrival and departure occurs on a 24-hour, seven day a week basis but FWS Port Inspector workday is typically 8 to 5. As a result, importers/exporters are required to pay overtime fees for inspections prior to the work day or after the work day, during weekends, and higher fees during federal holidays.

U.S. Fish and Wildlife Service
Fish and Aquatic Conservation

Lacey Act and Listing Injurious Wildlife

The NAA requests that the U.S. Fish and Wildlife Service collaborate with the USDA to regulate the importation of nonnative salamanders that might be carriers of a fungus lethal to those species. Congress did not intend or authorize the listing of native species as Injurious Wildlife under the authority granted by the Lacey Act. The U.S. Fish and Wildlife Service listed 201 nonnative and native salamanders during January 2016 by using an interim rule to regulate a pathogen. The U.S. Code pertinent to this authority is found in Title 18 – Crimes and Criminal Procedures, Part I – Crimes, Chapter 3 – Animals, Birds, Fish and Plants, Sec. 42. Importation or shipment of injurious mammals, birds, fish (including mollusks and crustacea), amphibia, and reptiles; permits, specimens for museums; regulations. Granted the plain reading of Section 42 does not include adjectives, like “foreign,” that appeared in the original Act which would limit animals subject to the law to those from outside the United States. The removal of this key adjective, foreign, occurred in 1948.

A bill entitled, Prohibiting the Transportation of Wild Animals and Birds under Inhumane or Unhealthy Conditions (S. 1447), was introduced to the Senate to amend the Lacey Act. The purpose of the bill was to prevent future horrific events involving animals shipped on open cages by ship and described to Senate Committee on Interstate and Foreign Commerce where the bill was first heard on June 16, 1947. The Committee acted favorably to amendments proposed to achieve that objective. However, in the course of making those changes the Department of Interior was consulted and a sentence that included the word “foreign” was deleted from the law. This sentence concerned a required permit that the Department deemed of “...little beneficial effect in connection with the enforcement of the general purposes of the section.” This sentence read, “No person shall import into the United States or into any Territory or District thereof any foreign wild animal or birds, except under special permit from the Secretary of Interior.”

Subsequent references by the Senate and House of the 80th Congress, Second Session, to S. 1447 identified the bill as being “An act to prohibit the importation of foreign wild animals and birds

under conditions other than humane, and for other purposes.” The legislative history of the bill included:

- The Senate, June 10, 1948 considered S. 1447. The Congressional Record for that date includes the original language and the proposed language. The changes were agreed and passed.
- The House debated the bill, agreed, passed and then tabled it. Subsequently it was passed by the House without changes.
- The President signed the bill into law on June 29, 1948.
- Public Law 818 codified the changes noting in both the title and marginal note that the objective was to prohibit importation of foreign wild animals and birds under conditions other than humane, and other purposes.

The consistency in language between the original Act and the statutes of today is remarkable. It is clear that the purpose and intent of the Lacey Act, as expressed in 1900 and throughout subsequent amendments, is to focus federal agency regulatory action upon the importation of foreign animal species. At no time has the Lacey Act been further modified to authorize listing of native animals as injurious wildlife. In no instance have knowledgeable citizens, or Congressional offices that have analyzed the Lacey Act, interpreted the Act to authorize the inclusion of native animals as injurious wildlife. The Service exceeded its authority, ignored an opportunity to collaborate with the USDA, and disregarded the intent of Congress by implementing this interim rule.

U.S. Fish and Wildlife Service (FWS)
Fish and Aquatic Conservation

Ecological Risk Screening Summaries (ERSS)

Fish Invasive Species Risk Assessment Model (FISRAM)

We appreciate the effort the FWS has made in proposing species additions to the list of injurious wildlife authorized by the Lacey Act and to inform the public that certain native and foreign species may pose a risk to the environment, economic activities or human health. Within several letters to the FWS over the last five years the NAA has expressed reservations with the Ecological Risk Screening Summary methodology and disagreed with the science contained in the publicly published reports derived from the methodology. We have recommended methodological and scientific revisions, provided peer-reviewed literature to support corrections based upon peer-reviewed science, and identified subject matter experts to peer-review the methodology and draft reports.

A second quick screen, Fish Invasive Species Risk Assessment Model, has been developed by the FWS for similar purposes. Recently, a peer-reviewed paper reported the use of FISRAM to assess the risk posed to the Michigan by the nonnative African longfin eel (*Anguilla mossambica*).⁷ The authors used two different climate matching programs. The second program resulted in a lower climate match of the species. The authors reported:

⁷Wyman-Grothem, K. E., N. Popoff, M. Hoff and S. Herbst. 2018. Evaluating risk of African longfin eel (*Anguilla mossambica*) aquaculture in Michigan, USA, using a Bayesian belief network of freshwater fish invasion. *Management of Biological Invasions*. 9: 395-403.

“Changing the input Climate 6 Score from ‘medium’ to ‘low’ resulted in a lower predicted probability that *A. mossambica* would be invasive, as would be expected with a climate less suitable to establishment. There was also a tripling of the predicted probability that further evaluation was necessary.”

Water temperature is a critical determinate for poikilothermic fish is a very significant determinate of survivability and it appears FISRAM is inherently biased by discounting the physiological significance of water temperature data.

We request that draft reports be reviewed by subject matter experts for scientific accuracy and FISRAM be reevaluated as a quick screen to correctly weigh the importance of water temperature as a determinate for species survivability.

We also request that an introductory language be added to each report to inform the reader that:

- There are significant scientific uncertainties associated with quick ecological screens because they are performed quickly.
- Quick ecological risk screens do not reflect the complexity of science associated with the animal biology, ecology, and novel environments.
- State regulations that may restrict or prohibit species were not considered during the assessment and may significantly reduce risk.
- Readily available air temperature data was utilized to predict climate match for aquatic animals which may inaccurately predict species range.
- A “high risk” finding may not apply to the entire United States.
- Quick ecological risk screens do not produce results that are actionable in a regulatory setting.

U.S. Fish and Wildlife Service
Migratory Bird Program

Aquaculture Depredation Order

The NAA requests the that FWS being rulemaking to re-establish an Aquaculture Depredation Order for 37 states and increase the allowable take to 91,175 birds for individual depredation permits, after accounting for the needs of the USDA Wildlife Services, and distribute an allowable take across the several regions to fish farms as recommended by the USDA Wildlife Services.

An Aquaculture Depredation Order was created in 1998 under the authority granted by the Migratory Bird Treaty Act to the US Fish and Wildlife Service (FWS) that allows the USDA Wildlife Services to work with fish farmers in 13 states to implement non-lethal and lethal techniques to deter double-crested cormorants from eating fish grown in ponds (e.g., catfish, hybrid striped bass, redbird, baitfish and ornamental fish). In October 2014 a non-governmental organization, Public Employees for Environmental Responsibility (PEER), filed suit against the FWS that challenged the 2014 extension of two depredation orders that authorize fish farmers and states and tribes, respectively, to manage double-crested cormorants. The challenge was

predicated, in part, on an inadequately prepared Environmental Assessment (EA). An EA is required by the National Environmental Policy Act. In March 2016, the Court granted PEER's motion for summary judgement and in May 2016 wrote a Memorandum of Opinion noting that Individual Permits for the double-crested cormorant could be granted to fish farmers and that the FWS had proposed to prepare an EA in seven months. The Court vacated with Order predicated upon Individual Permits that would mitigate the bird's detrimental impacts.

Following the Court's decision, the FWS and Department of Justice attorneys contacted PEER and found that PEER was not opposed to Individual Permits, but the FWS determined the EA also supported issuance of Individual Permits. The FWS perceived a litigation risk to issuing Individual Permits under an EA found to be inadequate by the Court. The FWS informed fish farmers in September of 2016 of their decision not to issue Individual Permits.

On November 15, 2017, the FWS expedited the release of an EA to support Individual Permits for the double-crested cormorant across 37 central and eastern States and the District of Columbia. The EA utilized a Population Take Limit (PTL) model based upon nest counts, did not account for the vacatur of the Public Depredation Order that was used to control double-crested cormorants in the Great Lake region since 1998, and adopted a very conservative approach by constraining allowable take to 51,571 cormorants per year, which is well below the lower limit the PTL model estimated. The PTL model estimated a biologically sustainable range of 73,396 to 108,954 birds that could be killed annually. In implementing this allowance, the FWS regional offices further limited take on farm permits and the total take was also split with USDA Wildlife Services for their control work.⁸

The double-crested cormorant is a resident of the southern states but that population expands with the migration of a large number of birds from the Great Lakes and Canada during the winter (October through April). The double-crested cormorant is a large water bird that feeds mainly on fish. Commercial fish ponds are stocked at high densities ranging from 2,000 to 60,000 catfish per acre and 50,000 to almost 200,000 bait fish per acre. These efficient production practices make fish farms highly susceptible to bird predation, particularly by cormorants. Studies conducted prior to the 1998 Order estimated cormorant related production losses on catfish farms in the Mississippi delta region at 18 to 20 million fingerlings per winter or for 37% of catfish production losses. Cormorants cause additional economic damage by spreading fish parasites.

A two-year study published in 2012 of double-crested cormorant feeding on farm-raised catfish in Mississippi during the winter months (October 1 to April 30) found that cormorant depredation represents an annual estimated economic loss of \$34.3 million to \$73.4 million. A Government Accountability Office report noted:

“Fish-eating birds (e.g., cormorants, herons, egrets, and pelicans) can cause severe damage at aquaculture farms, eating catfish, crawfish, salmon, bass, trout, and ornamental fish. According to a USDA National Agricultural Statistics Service (NASS) survey of catfish producers from 15 states, 69 percent reported some

⁸ U.S. Fish and Wildlife Service. 2017. Environmental Assessment for Issuing Depredation Permits for Double-crested Cormorant Management. U.S. Fish and Wildlife Service. Division of Migratory Bird Management.

wildlife-caused losses, with a financial loss of \$12.5 million to wildlife predation in 1996.”⁹

Double-crested cormorant populations in the Southeast are not at-risk and have been increasing in numbers for the last 30 years.

U.S. Fish and Wildlife Service and National Marine Fisheries Service

U.S. Fish and Wildlife Service
Endangered Species
National Marine Fisheries Services
Protected Resources Division

Distinct Population Segment Listings for Cultured Species

The NAA requests that within the constraints of the ESA that at-risk, wild species, which are also commercially cultured, be listed as a distinct population segment for their native range. Given that these circumstances are few and unusual when a commercially produced species is also at-risk in its native range, then a distinct population segment will be used “sparingly” in keeping with Congressional guidance to the agencies.

Species are assessed and listed under the authority granted in the Endangered Species Act (ESA) based upon whether they are at-risk within native ranges; however, when a species is listed federal protection is extended to wherever that species may occur. Species in commercial production or established outside a native range are not considered during the risk assessment but are impacted when a species is listed. The automatic inclusion of commercially valuable and actively farmed and marketed species eliminates jobs and income and does not improve or contribute to species recovery. However, the listing decision prohibits commercial production and sale, negatively impacts jobs and economic activity and terminates the opportunity for farmer knowledge sharing with state and federal at-risk species programs, public education both on and off-farm, participation in or support of species research, or farms as sources of genetic material or live animals for research or stock restoration.

U.S. Fish and Wildlife Service
Endangered Species
National Marine Fisheries Services
Protected Resources Division

Endangered Species Act, Section 4, Determination of Endangered Species and Threatened Species

We recommend that the agencies seek state assistance to complete an in-depth review of state regulatory and non-regulatory efforts, expenditures and funding sources being implemented to conserve and recover at-risk species. Justification for this requirement is provided by Endangered Species Act Section 4 that requires the Secretary to determine the efforts by the states to protect species such as their regulatory mechanisms or conservation practices.

⁹ GAO. 2001. Wildlife Services Program: Information on Activities to Manage Wildlife Damage. Government Accountability Office. Washington, DC. (<http://www.gao.gov/products/GAO-02-138> accessed March 5, 2019).

Critical to species protection, and required by the ESA, is a constructive partnership with the states and, by implication, their citizens (Section 6 Cooperation with the States). The states have adopted at-risk species regulations and species recovery offices and programs can be readily identified through simple web searches. A variety of non-governmental organizations are engaged in listed or at-risk species protection and recovery and operate under state permitting and may be receiving state, federal or private funding. The agencies should not be inconvenienced and will, through publication of this information, inform a petitioner or the public and further the goals of the ESA to encourage means other than species listings to support species conservation and recovery.

U.S. Food and Drug Administration

U.S. Food and Drug Administration (FDA)
Center for Veterinary Medicine

Aquaculture Drug Approval

The NAA requests that the FDA's drug approval policies and procedures for farm-raised aquatic animals be reviewed and modified as recommended in joint letters to the agency the Association of Fish and Wildlife Agencies and NAA dated December 7, 2017 and December 20, 2018, respectively.

There are very few drugs or chemicals approved for aquatic animals which in turn provide limited choices for aquaculture producers. This situation restricts what the producer can use when trying to match FDA-approved drugs with the species they raise and the production systems they use and creates an opportunity for antimicrobial drug resistance to develop. The drug approval process for fish is conducted under the human health paradigm which requires time-consuming and costly studies that do not reflect the common-sense scenario that the subject animals are fish. Under this complex paradigm, FDA does not consider data in studies published in peer-reviewed journals, requires quality assurance oversight such as described for Good Clinical Practice and Good Laboratory Practice studies that are not practices of academic researchers, and requires effectiveness studies which for the aquaculture marketplace are redundant and unnecessary given the expertise of the public and private users. Due to the arduous nature of the FDA regulatory process, few in public or private aquaculture are willing to become directly involved. This dilemma exacerbates an already over-burdensome process.