

# **PROGRESS TOWARDS THE NATIONAL STRATEGIC PLAN TO ENHANCE REGULATORY EFFICIENCY IN AQUACULTURE (2023)**

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*PREPARED BY THE*  
NATIONAL SCIENCE AND TECHNOLOGY COUNCIL SUBCOMMITTEE ON  
AQUACULTURE  
REGULATORY EFFICIENCY TASK FORCE

FEBRUARY 2024

**REGULATORY EFFICIENCY TASK FORCE MEMBERS**

**Kristine Cherry**, DOC-NOAA, Chair

**Brian Fredieu**, DOC-NOAA

**Gabriela McMurtry**, DOC-NOAA

**Marilyn Blair**, DOI-USFWS

**Marcus Zobrist**, EPA

**Kip Tyler**, EPA

**Jennifer Matysczak**, FDA

**Quentin Forrest**, FDA

**Charles Williams**, USDA-FSIS

**Kathleen Hartman**, USDA-APHIS

**Paul Lewis**, USDA-AMS

**Jacob Siegrist**, USACE

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## Abbreviations and Acronyms

<b>AADAP</b>	Aquatic Animal Drug Approval Partnership	<b>NEPA</b>	National Environmental Policy Act
<b>AFWA</b>	Association of Fish & Wildlife Agencies	<b>NMFS</b>	NOAA National Marine Fisheries Service
<b>AIED</b>	Aquaculture and Industry Enhancement Division	<b>NOAA</b>	National Oceanic and Atmospheric Administration
<b>AOA</b>	Aquaculture Opportunity Areas	<b>NOS</b>	NOAA National Ocean Service
<b>APHIS</b>	USDA Animal and Plant Health Inspection Service	<b>NSSP</b>	National Shellfish Sanitation Program
<b>CVM</b>	FDA Center for Veterinary Medicine	<b>NSTC</b>	National Science and Technology Council
<b>DOC</b>	U.S. Department of Commerce	<b>NWP</b>	Nationwide Permit
<b>DOI</b>	U.S. Department of the Interior	<b>OSTP</b>	Office of Science and Technology Policy
<b>EEZ</b>	Exclusive Economic Zone	<b>PEIS</b>	Programmatic Environmental Impact Statement
<b>EFH</b>	Essential Fish Habitat	<b>PGP</b>	Programmatic General Permit
<b>EIS</b>	Environmental Impact Statement	<b>RGP</b>	Regional General Permits
<b>EPA</b>	Environmental Protection Agency	<b>SAV</b>	Submerged aquatic vegetation
<b>ESA</b>	Endangered Species Act	<b>SCA</b>	NSTC Subcommittee on Aquaculture
<b>FDA</b>	U.S. Food and Drug Administration	<b>SG</b>	NOAA National Sea Grant Program
<b>FY</b>	Fiscal year	<b>U.S.</b>	United States
<b>GP</b>	General Permit	<b>USACE</b>	United States Army Corps of Engineers
<b>GRAS</b>	Generally recognized as safe	<b>USCG</b>	United States Coast Guard
<b>INAD</b>	Investigational New Animal Drug	<b>USDA</b>	United States Department of Agriculture
<b>ISSC</b>	Interstate Shellfish Sanitation Conference	<b>USFWS</b>	U.S. Fish and Wildlife Service
<b>MDNR</b>	Maryland Division of Natural Resources	<b>USGS</b>	United States Geological Survey
<b>NAHPS</b>	National Aquaculture Health Plan & Standards	<b>VS</b>	USDA-APHIS Veterinary Services
<b>NCCOS</b>	NOAA-NOS National Centers for Coastal Ocean Sciences		

## Executive Summary

A *Strategic Plan to Enhance Regulatory Efficiency in Aquaculture* (the plan) outlines actions that Federal agencies plan to take within their existing statutory authorities and budgetary resources to improve efficiency, predictability, and timeliness, and reduce the costs of reviewing, approving, monitoring, and enforcing permits and other regulatory requirements for marine commercial aquaculture ventures. The plan describes key interagency and Federal-State issues concerning aquaculture regulation, as well as science and technology needs to facilitate more efficient State and Federal aquaculture management actions. The plan was developed with the intent to annually report agency achievements that support implementation.

The Regulatory Efficiency Task Force of the Subcommittee on Aquaculture (SCA) prepared the annual report. The SCA is a statutory subcommittee of Federal agency representatives that operates under the Committee on Environment of the National Science and Technology Council (NSTC) under the Office of Science and Technology Policy (OSTP) in the Executive Office of the President [National Aquaculture Act of 1980 (Public Law 96-362, 94 Stat. 1198, 16 U.S.C. 2801, et seq.) and National Aquaculture Improvement Act of 1985 (Public Law 99-198, 99 Stat. 1641)]. In February 2019, the SCA established a Regulatory Efficiency Task Force and charged it with developing a new work plan for interagency coordination to improve regulatory efficiency. In February 2022, the Task Force published the plan and began the process of implementation and released the first annual report in February 2023. This report describes the major accomplishments of the Regulatory Efficiency Task Force since publication of the 2023 Report, and only includes updates for objectives with new information.

The SCA also established a Science Planning Task Force—charged with revising and updating the National Strategic Plan for Federal Aquaculture Research (2014–2019)—and the Economic Development Task Force—charged with developing a strategic plan for economic development through aquaculture. The plan from this Task Force supplements the two other Task Forces' plans.

This plan identifies the following goals:

### **Goal 1. Develop Economic Growth through Aquaculture**

- Objective 1.1: Identify market opportunities for U.S. aquaculture products
- Objective 1.2: Enable science-based expansion of domestic aquaculture
- Objective 1.3: Educate and train a skilled aquaculture workforce

### **Goal 2. Improve Aquaculture Production Technologies and Inform Decision-making**

- Objective 2.1: Provide farmers with access to improved genetics
- Objective 2.2: Develop production technologies that minimize environmental impacts
- Objective 2.3: Advance fish nutrition and feed production technologies
- Objective 2.4: Improve engineering systems for aquaculture

### **Goal 3. Uphold Animal Well-Being, Product Safety, and Nutritional Value**

- Objective 3.1: Develop strategies to protect the health and well-being of aquaculture species
- Objective 3.2: Promote the safety and nutritional value of U.S. aquaculture products

These strategic goals will help Federal agencies build an interagency collaborative regulatory framework to meet the Nation's aquaculture priorities through coordination with the OSTP/NSTC. These goals will also ensure aquaculture facilities continue to meet all applicable environmental, public health, and other Federal requirements. This report highlights Federal agencies' actions, using existing resources, to implement the strategic plan's goals in the past year.



## Goal 1. Improve Efficiencies in Aquaculture Permitting and Authorization Programs

Navigating application and review processes for multiple local, State<sup>1</sup>, and Federal requirements can be challenging, given the number and variety of current laws, regulations, and administrative protocols that exist. For example, agencies must evaluate the potential conflicts with uses (fishing, recreation, energy production, shipping, etc.) and potential impacts on a range of environmental and socio-economic concerns (water quality, marine ecosystems, wild fish stocks, protected species, habitats, cultural resources, etc.). For applicants, permitting and authorization processes can be time consuming, difficult to navigate, and expensive. Once a venture is operational, the permittee is responsible for monitoring and reporting requirements concerning discharge, management measures, aquatic animal health, public health, and other requirements.

Federal agencies have taken several actions in recent years to improve interagency coordination and make regulatory processes more efficient. Several of these are noted in the subsections below. Federal agencies intend to work with State and Tribal agencies and others to build on these coordinating efforts and address challenges that affect specific aquaculture sectors and the industry nationwide. Additionally, Federal agencies intend to improve efficiencies in Federal aquaculture permitting and authorization processes, such as expanding the range of aquaculture activities authorized under general permits (discussed below) through programmatic approaches to environmental review and other applicable authorizations.

Efforts to make the permit process and management of permit compliance more efficient (sometimes termed “streamlining”) are not intended to eliminate, circumvent, or reduce conservation, environmental stewardship, and public health requirements. In fact, the NSTC’s *National Strategic Plan for Aquaculture Research* is a companion to this Plan and serves to communicate Federal priorities for research and technology development that will facilitate responsible expansion of domestic aquaculture. The intent of enhanced efficiency is to improve coordination across Federal agencies to reduce redundancies and shorten permitting timelines through concurrent rather than consecutive processes.

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<sup>1</sup> Most aquaculture in the United States is located either on land or in nearshore waters and is subject to both State and Federal laws and regulations.

**Objective 1.1: Expand the range of aquaculture activities authorized under general permits and through programmatic consultations.**

***DOC National Oceanic and Atmospheric Administration***

National Marine Fisheries Service (NMFS)

NMFS has been working closely with subject specific science teams from regional Fisheries Science Centers (including the Northwest, Southwest, Northeast, and Southeast), the NOAA-NOS National Centers for Coastal Ocean Sciences (NCCOS), and the NMFS Office of Protected Resources to develop science for advice products such as technical memoranda, models, and guidance documents to inform Federal decision-making for aquaculture activities, including the Aquaculture Opportunity Areas (AOAs) process. Subject specific areas include social science, economics, genetics, structural engineering, and disease and biosecurity, and risk assessment. Progress has been made in developing informational products. NMFS highlights include the following completed or in-process products by subject:

- Social Science
  - Socioeconomic indicators have been developed for the Gulf of Mexico. A Story Map, along with data and a methods manual for how to use the data, has been published.<sup>2</sup>
  - Literature reviews and stakeholder interviews.
  - Community case study interviews.
- Economics
  - Literature review and synthesis.
  - Market overview guides for the Gulf of Mexico and the Southern California Bight.
  - Financial and price analysis for the Gulf of Mexico and Southern California Bight.
- Genetics
  - Offshore Mariculture Escapes Genetics Assessment (OMEGA) model simulations and scenario-based risk matrix development to inform consequences (i.e. genetic introgression, competition with native species, and predation on natives) of escapes from aquaculture are ongoing.
- Structural Engineering
  - A technical guidance document for aquaculture gear is in preparation with staff with the Protected Resources Division.
  - Two manuscripts are in progress to document aquaculture gear engineering case studies.
- Disease and Biosecurity
  - The technical memorandum *Review of best practices for biosecurity and disease management for marine aquaculture in US waters* is complete.<sup>3</sup>
  - Recommendations for biosecurity and disease management for marine aquaculture in US waters are in the *Scientific support for health management and biosecurity for marine aquaculture in the United States*.<sup>4</sup> This includes a summary of an associated workshop held July 12, 2022.
  - A second technical memorandum titled *Scientific support for biosecurity and disease management in Aquaculture Opportunity Areas in the U.S.* is in preparation.

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<sup>2</sup> NOAA National Centers for Coastal Ocean Science. *The Opportunity of Aquaculture for Coastal Communities, an Indicator-Driven Approach*. <https://storymaps.arcgis.com/stories/38407437723d493e8950ea5c80222931>

<sup>3</sup> NOAA Institutional Repository. *Review of Best Practices for Biosecurity and Disease Management for Marine Aquaculture in U.S. Waters*. <https://repository.library.noaa.gov/view/noaa/49079>

<sup>4</sup> NOAA Institutional Repository. *Scientific Support for Health Management and Biosecurity for Marine Aquaculture in the United States*. <https://repository.library.noaa.gov/view/noaa/55554>

This document includes a summary of the associated workshop titled Aquaculture Disease and Biosecurity Regulatory Frameworks (held October 11, 2022).

- Geographic Information System (GIS) distribution mapping of wild fisheries and candidate species for marine aquaculture in Southern California to assess potential disease risk was completed and a technical report is being prepared.
- Risk Assessment
  - Literature review and synthesis is ongoing.
  - Guidance for how to apply risk assessments to aquaculture siting is in development.

#### National Ocean Service

National Centers for Coastal Ocean Science published two Atlases that identify options for Aquaculture Opportunity Areas (AOAs) in the federal waters of Gulf of Mexico and the Southern California Bight in 2021. The Atlases were developed collaboratively, using the best available science and broad stakeholder engagement, and identify areas that have the highest potential to support three to five marine aquaculture operations and least amount of conflict with other ocean uses based on the available data. The Atlases provide the most comprehensive marine spatial analyses ever developed for any U.S. ocean space. NCCOS continues to support permitting and NEPA efforts in these regions with subject matter expertise and spatial modeling.

This same process is now underway for Alaska state waters, where NMFS has started the process of AOA identification. This second round of AOA identification seeks to incorporate Traditional Ecological Knowledge from Tribes and other stakeholders to sustainably advance invertebrate (shellfish, sea cucumber), and seaweed farming in Alaska state waters.

#### *U.S. Army Corps of Engineers*

USACE Headquarters (HQ) and respective districts continue to work with other federal agencies (EPA and NOAA primarily) and provide input on aspects of aquaculture that fall under USACE statutory authorities. USACE HQ and districts also participate, as time allows, in other aquaculture efforts:

- NAB (Baltimore district) uses Nationwide Permit 48 (NWP48) for commercial shellfish mariculture projects working cooperatively in a joint permit process with the Maryland Department of Natural Resources (MDNR) Aquaculture and Industry Enhancement Division (AIED), utilizing a programmatic EFH/ESA process with NMFS. A bi-monthly Aquaculture Review Board is convened by MDNR and appropriate federal and state agencies to review and discuss the aquaculture sector. Additionally, district staff attend the bi-monthly meeting of Maryland's Aquaculture Coordinating Council staying informed, and informing as appropriate, attendees of changes and developments associated with the USACE regulatory program as related to commercial shellfish aquaculture.
- NWS (Seattle District) participates in the Washington Seaweed Collaborative meetings hosted by NOAA and the Shellfish Interagency Permitting Team under the Washington Department of Agriculture, with both efforts focused on the state of science, the industry, and permitting efficiency. Also, NWS and Washington Department of Ecology continue to promote interagency efficiency and co-hosted a virtual public workshop in October 2023 on the status of aquaculture permitting in Washington State. The workshop was attended by over 50 participants from tribes, industry, NGOs, and the public.
- SPL (Los Angeles District) participates in the California Offshore Aquaculture Interagency Working Group to facilitate efficient communication with other state and federal agencies about aquaculture permitting.
- NAE (New England District) is working on a revised EFH consultation agreement to apply district-wide to streamline reviews in EFH, including aquaculture.



USACE HQ routinely participates in NSTC SCA meetings, Regulatory Efficiency task force meetings, and Executive Order 13921 implementation meetings with NOAA, EPA and other federal agencies. USACE HQ also routinely participates in stakeholder and interagency outreach.

- NAD (North Atlantic Division) worked with NOAA Fisheries Northeast Fisheries Science Center Laboratory in Milford, Connecticut on aquaculture and submerged aquatic vegetation (SAV) interactions to develop a gap analysis of research in the U.S. pertaining to aquaculture gear and effects. The purpose is to develop science-based analysis of aquaculture effects on SAV that can be used by USACE and NOAA Habitat Conservation Staff to develop best management practices or conservation recommendations specific to aquaculture leading to fewer expanded EFH consultation and/or more opportunities for general concurrence where aquaculture is concerned.

Although there is already a high use of NWP's and other General Permits (GPs) for aquaculture, USACE continues to encourage coastal districts to develop regional General Permits (RGPs) and programmatic General Permits (PGPs) that could further improve the efficiency of the aquaculture permitting process while meeting the needs of their respective regions.

- MVN (New Orleans District) continues to utilize its PGP for aquaculture projects in the Louisiana coastal zones.
- Norfolk District (NAO) utilizes NWP's, RGPs, and PGPs for efficient aquaculture verifications in waters of Virginia.
- In NAE, the district continues to utilize GPs, and the Massachusetts General Permit was re-issued in June 2023, which included an aquaculture GP that further streamlined aquaculture permitting in the state.
- SAJ (Jacksonville District) continues to utilize two PGPs, the SAJ-99 for aquaculture in state waters (administered by the Florida Department of Agriculture and Consumer Services) and the SAJ-17 for live-rock culture in the Florida EEZ (administered by the NOAA Fisheries Southeast Regional Office).

### ***U.S. Fish and Wildlife Service***

Salmonid imports require a U.S. Title 50 Certification Form be completed by a Service-certified aquatic animal health inspector in the country of origin, Under Title 50 – Salmon Imports, USFWS administered and approved 39 import requests totaling in 7 million eggs and 750,000 fry. Imports were from Canada, Iceland, and Norway. USFWS also approved three new certifying Officials representing Australia, New Zealand, and Canada; it now maintains 37 Officials in 13 countries.

### ***U.S. Environmental Protection Agency***

The U.S. Environmental Protection Agency (EPA)'s Office of Water, Office of Research and Development, and Regional Offices continue to work with other federal agencies (NOAA and USACE primarily) and provide input on aspects of aquaculture that fall under its statutory authorities. The EPA's Office of Water routinely participates in NSTC SCA meetings, Regulatory Efficiency task force meetings, and EO 13921 implementation meetings with other federal agencies. US EPA also routinely participates in stakeholder and interagency outreach.

The EPA highlights include the following completed products:

- The EPA released a video that describes how National Pollutant Discharge Elimination System (NPDES) permits apply to discharges from aquaculture operations.
- The EPA issued an NPDES permit for a marine aquaculture facility in federal waters of the Gulf of Mexico. The permittee will operate a "net-pen" aquatic animal production facility and is anticipated to be the first time that cultured fish are grown for harvest in the Gulf's federal waters

**Objective 1.3: Establish regional interagency coordinating groups and processes for implementation of permits and authorizations for aquaculture in Federal waters.**

***USDA Animal and Plant Health Inspection Service***

**Veterinary Services (VS)**

The VS Strategy and Policy/Aquaculture Commodity Health Center is partnering with NOAA and coastal states to ensure the development of science and risk-based animal health requirements for stocking into federal waters.

***DOC National Oceanic and Atmospheric Administration***

NOAA is continuing the process to identify AOAs in southern California and the Gulf of Mexico. The West Coast and Southeast Regional Offices each published a Notice of Intent to prepare a Programmatic Environmental Impact Statement (PEIS) and conducted 60 day formal public scoping periods in 2022. NOAA Fisheries expects the draft PEISs will be available for public comment in 2024. NOAA has started the process to identify AOAs in Alaska state waters and collected public comment to help identify study areas and data to inform the identification process in Fall 2023.

***U.S. Army Corps of Engineers***

USACE districts along the Gulf Coast, Southern California and Alaskan waters are all regularly participating in coordination calls, meetings, and workshops for the identification of AOAs and their associated PEIS. SWG (Galveston District), MVN, SPL, and Alaska District (POA) participate in AOAs Interagency Team web-based meetings and workshops and as a cooperating agency on the PEIS with NOAA Fisheries as lead agency.

To continue collaboration on evaluating and permitting aquaculture proposals in waters offshore of the U.S., USACE continues to coordinate with EPA and NOAA Fisheries in accordance with Executive Order 13921. SAJ, NAE, SPL, and New York District (NAN) continue to participate in interagency collaboration to inform finfish, shellfish, and macroalgae aquaculture proposals.<sup>5</sup>

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<sup>5</sup> SAJ (Velella Epsilon, Manna Fish Farms), NAE (Blue Water Fisheries), and SPL (Pacific Ocean Aquafarms) have all worked with, and continue to work with NOAA, EPA, and all other applicable agencies to process the NEPA documents as needed.

**Objective 1.5: Establish a clear and transparent Federal Process for ensuring the safety of molluscan shellfish grown in Federal waters.**

***DOC National Oceanic and Atmospheric Administration***

In March, the full Interstate Shellfish Sanitation Conference (ISSC) Biennial Conference<sup>6</sup> voted to adopt a new guidance document developed by NOAA Seafood Inspection Program and FDA for federal waters bivalve molluscan harvest and aquaculture that specifically addresses this action item. A NOAA Seafood Inspection Program and FDA Memorandum of Understanding (MOU) for shellfish in federal waters is under review. The ISSC Biennial conference also adopted language corrections and sunsets based on the 2019 ISSC NSSP Model Ordinance Revision approved by the ISSC Executive Board.

***U.S. Food & Drug Administration***

FDA is working directly with NOS-NCCOS to incorporate the NSSP shellfish growing area pollution assessment sanitary survey criteria into the NCCOS initial shellfish aquaculture site screening process for federal waters.

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<sup>6</sup> Interstate Shellfish Sanitation Conference. 2023 ISSC Biennial Meeting. <https://www.issc.org/2023-issc-biennial-meeting>



## **Goal 2. Implement a National Approach to Aquatic Animal Health Management of Aquaculture**

Aquatic animal health is paramount for the success of the aquaculture industry. Both infectious and noninfectious diseases affect animal productivity and well-being. The inevitable bridges between natural resources and aquaculture farms create an opportunity for the introduction and transmission of pathogens throughout and between facilities and jurisdictions. Therefore, aquatic animal health, whether in farm-raised or wild animals, must be addressed with a uniform approach on a national level. This approach must assess animal health using a risk-based approach based upon best available science. It must protect animal health, safeguard wild stocks and environmental quality, and instill confidence in animal production practices. Also, Federal and State agencies must develop a unified road map and collaborative framework to implement a national approach to managing aquatic animal health.

Effective aquatic animal health management depends on a unified approach to how health is determined, reported, maintained, and protected on aquatic animal farms. This approach must involve all Federal and State agencies with authority for aquatic animal health and aquaculture. These authorities have oversight of pathogen surveillance and testing in aquaculture farms and wild aquatic animal populations. They also oversee drug approval and licensing of vaccines, which can minimize the use of drugs on a farm and help keep farmed animals healthy.

**Objective 2.1: Review, evaluate, and update the National Aquatic Animal Health Plan.**

***USDA Animal and Plant Health Inspection Services***

The National Aquaculture Health Plan & Standards (NAHP&S) presents the USDA vision for a strong domestic infrastructure for supporting and determining aquatic livestock health. The overarching goal of the National Aquaculture Health Plan & Standards is to protect and support the health of farm-raised aquatic livestock reared in any private aquaculture operation setting for any end use. USDA is committed to working collaboratively with all partners, including industry, Federal departments, State agencies, tribal entities, and allied enterprises on this deliverable. USDA is leveraging the NSTC special project committee which includes key contacts from USFWS and NOAA to represent the perspectives of each agency. Currently the 2021-2023 is undergoing revisions for the 2024-2026 NAHP&S. This is a national farmed aquatic animal health plan that involves agencies with specific animal health statutory authority for aquatic health. The revised 2024-2026 NAHP&S is targeting to be published by the end of CY 2024.

USFWS and NOAA are currently engaged with USDA APHIS to determine the best way forward to ensure the health of aquatic animals, both captive reared and in the wild.

**Objective 2.2: Work with partners and stakeholders to update and establish proficient, efficient, and equivalent standards or guidelines for diagnostics and inspections of aquatic animals.**

***USDA Animal and Plant Health Inspection Service***

Veterinary Services

- VS published *Notice of Request for Approval of an Information Collection; Comprehensive Aquaculture Health Program; Use of MI-CO Application* in the Federal Register on October 24, 2023, for a 90-day comment period. Comment period closed on December 26, 2023, and no comments were submitted. Request is now with OMB for approval.
- VS continues to prioritize the Comprehensive Aquaculture Program Standards (CAHPS) and the program is in the process of rulemaking.
- VS has updated the National List of Reportable Animal Diseases (NLRAD) that will be posted early in 2024.
- In early 2024, VS will post country level declarations of freedom for 3 salmonid pathogens listed by the WOA. These 3 pathogens are epizootic hematopoietic necrosis virus, salmonid alphavirus, and *Gyrodactylus salaris*. The declaration packets follow WOA guidance for determining freedom on a historical basis and accrued anonymized data from USFWS Fish Health Centers, state hatchery facilities and private and academic laboratories conducting testing of salmonid species both wild and farmed. These declarations will reduce the requirement for pre-export or movement testing of these pathogens in susceptible species. VS continues to work with these partners to create a routine process to collect on-going testing data at 6-month intervals to support the maintenance of this freedom status. VS will next develop freedom packages for other foreign animal diseases of aquatic animal species which will include pathogens such as Taura Syndrome, Yellowhead, Infectious myonecrosis virus, decapod iridescent virus, red sea bream iridovirus, and *Perkinsus olseni*.
- Cooperative agreement with the Virginia Institute for Marine Science (VIMS) for veterinary education and training for the molluscan shellfish industry to enhance veterinary expertise in critical aspects of shellfish aquaculture production systems, and, more broadly, improve shellfish aquaculture health management in the context of national and international commerce.
- Cooperative agreement with Texas A&M for web-based education and training modules targeting aquaculture veterinarians and farmers on topics such as sampling healthy populations of aquatic livestock to demonstrate health status, conducting on-farm risk evaluations for pathways of risk introduction for aquatic animal pathogens of concern, evaluate biosecurity practices and diagnostic test interpretations.
- **Maine infectious salmon anemia (ISA) control program 20 YR Program Review.** Partnership with Maine NOAA Sea Grant to conduct (1) a historical review of ISA Program activities, (2) examine trends in pathogen detection and disease occurrence through time, (3) explore stakeholder input on program objectives and function, and (4) identify Program elements considered key to achieving evolving definitions of Program success.
- **Early Disease Detection Needs Assessment & Mortality Reporting for Shellfish Producers.** Agreement with the Pacific Shellfish Institute to improve the understanding of the industry's needs for early disease detection and shellfish mortality events on the U.S. west coast. This project will help characterize needs and ways forward for enhancing early disease detection systems to protect the health of shellfish and the shellfish aquaculture industry on the Pacific Coast. To do this the Pacific Shellfish Institute (PSI) will work with shellfish producers, diagnostic laboratories, monitoring programs, and agencies on the west coast to 1) support health and disease monitoring, 2) characterize shellfish mortalities, 3) identify shellfish farm health plan needs and assist with plan development, 4) identify producer concerns about geographical

mortality reporting, and 5) identify shellfish seed biosecurity and mitigation protocols and needs to prevent introduction and dissemination of pathogens and invasive organisms.

- **Establishment of quality control parameters for antimicrobial susceptibility testing of *Flavobacterium psychrophilum* and *Flavobacterium columnare* by disk diffusion.** Project goal is to improve options and capacity for antimicrobial susceptibility testing (AST) of important bacterial pathogens of aquatic animals and support development of standards for AST for monitoring antimicrobial resistance in aquaculture. The major objectives of this project will be to develop testing protocols and define quality control ranges for AST using *E. coli* and *A. salmonicida*, common reference strains, for a Tier 2 quality control study appropriate for *F. psychrophilum* and *F. columnare*.
- **Risk Assessment of Fish Movements from Great Lakes Region Fish Farms and Hatcheries to Natural Waters or Other Premises During a Viral Hemorrhagic Septicemia Outbreak.** Assessment conducted via agreement with the University of Minnesota (MN03.21).
- **Development of Environmental Models to Advance Aquaculture Disease and Surveillance.** Agreement with University of Kansas.
- **Interagency agreement with USDA ARS National Cold Water Marine Aquaculture Center (NCMA)** to collaboratively investigate and mitigate ISAV HPR0 persistence or entry points at NCMA by surveying all life stages of Atlantic salmon at the hatchery and environmental samples to identify critical control points.
- **Cooperative agreement with University of Arizona, Aquaculture Pathology Laboratory** to identify a real-time assay for the detection of infectious hypodermal and hematopoietic necrosis virus (IHHNV) including test performance characteristics.<sup>7</sup>
- **Cooperative agreement with University of Florida, Wildlife and Aquatic Veterinary Disease Laboratory** to generate a standardized protocol for a network of testing laboratories to conduct a ring trial to evaluate inter-laboratory performance.
- **Cooperative agreement with University of Maryland/Baltimore County** to enhance the ability to detect OSHV-1 which included evaluation of real-time PCR assay, establishing SOPS for use in export testing laboratories, evaluate archived known infected tissue to increase the number of publicly available OSHV-1 whole genome sequences.
- **Cooperative agreement with Virginia Institute of Marine Science of the College of William Mary** to identify genus and species-specific real-time PCR assays.
- **Cooperative agreement with University of Illinois** to evaluate the efficiency of utilizing oligo baiting to identify pathogens in a primary sample. Case studies will be pathogens causing neurologic disease in horses, and pathogens causing morbidity in fish, crustaceans, and mollusks. Objective is to compare this method to the single plex PCR and determine sensitivity parameters.
- **Grant awarded through the National Animal Health Laboratory Network (NAHLN) to Washington Animal Disease Diagnostic Laboratory at Washington State University.** Grant to develop rapid pathogen detection by unbiased deep sequencing as a diagnostic tool for multiple agent specific assays on single tissue sample.
- **Grant awarded through the National Animal Health Laboratory Network (NAHLN) to Bronson Animal Disease Diagnostic Laboratory in Florida.** Grant to conduct a comparison of published real-time spring viremia of carp virus (SVCV) assays.

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<sup>7</sup> Dhar, Arun, K, Cruz-Flores, Roberto, Mai, Hung N., Warg, Janet. 2024. Comparison of Polymerase Chain Reaction (PCR) assay performance in detecting *Decapod penstylhamaparvovirus* 1 in penaeid shrimp. Journal of Virological Methods, 323. <https://doi.org/10.1016/j.jviromet.2023.114840>

***U.S. Fish & Wildlife Service***

USFWS published its Aquatic Animal Health Policy<sup>8</sup> that defines how the Service conducts aquatic animal health work, including criteria and methods for detecting aquatic animal pathogens.

USFWS remains involved in the initiatives listed in the section directly above.

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<sup>8</sup> U.S Fish & Wildlife. *Aquatic Animal Health Policy*. <https://www.fws.gov/policy-library/713fw1>



### **Objective 2.3: Improve efficiencies obtaining legal marketing status for drugs, food additives for animal feed, and biologics.**

#### ***Food & Drug Administration***

Center for Veterinary Medicine (CVM)

In January 2023, FDA-CVM facilitated several educational sessions in the “Comprehensive Animal Feed Ingredient Submission Course,”<sup>9</sup> held in conjunction with the Association of Animal Feed Control Officials' (AAFCO'S) 2023 mid-year meeting. This offered an opportunity to continue to educate stakeholders on pre-market requirements for substances intended for use in animal food and the available pathways.

In March 2023, the FDA finalized Guidance for Industry #106 on *The Use of Published Literature in Support of New Animal Drug Applications*.<sup>10</sup> The purpose of this document is to provide guidance to animal drug sponsors on specific areas of the approval process where the available scientific literature may be useful to support the approval of a new animal drug application, an abbreviated new animal drug application, or a conditionally approved new animal drug application, as well as methodologies to ensure the validity of conclusions drawn by animal drug sponsors from the scientific literature to support an approval.

In September 2023, FDA released its Animal and Veterinary Innovation Agenda detailing CVM actions to foster product development and implement smart, risk-based approaches to regulating modern animal and veterinary products. The innovation agenda will facilitate development of technologies ranging from novel food ingredients to animal biotechnology products and aims to encourage the development of products for unmet human and animal needs, including aquaculture.

In December 2023, the FDA finalized Guidance for Industry #61, *Special Considerations, Incentives, and Programs to Support the Approval of New Animal Drugs for Minor Uses and for Minor Species*. This guidance is intended to assist those interested in pursuing FDA approval of new animal drugs for minor species, including finfish and shellfish. The Guidance outlines the basic requirements and special considerations for approvals of minor species drugs and describes the incentives available to encourage their development.

Guidance for Industry #210, entitled *The Index of Legally Marketed Unapproved New Animal Drugs for Minor Species* is currently being revised. FDA reviewed all comments submitted and is taking the feedback provided into account when revising the guidance.

FDA-CVM continues to encourage stakeholders to take advantage of the pre-submission consultation opportunity described in Guidance for Industry #262, *Pre-submission Consultation Process for Animal Food Additive Petitions for Generally Recognized as Safe (GRAS) Notices*. Under this process, FDA has engaged with several individual firms on specific projects throughout 2023. FDA-CVM also continues to encourage stakeholders to submit Generally Recognized as Safe (GRAS) Notices for substances identified as GRAS, as well as encourage stakeholders to meet with FDA prior to submitting their food additive petition (FAP) or GRAS Notice for evaluation.

#### ***U.S. Fish & Wildlife Service***

USFWS Aquatic Animal Drug Approval Partnership (AADAP) continues to work with partners to obtain FDA approval of safe and effective new drugs for use in aquaculture and fisheries

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<sup>9</sup> Association of American Feed Control Officials. *Comprehensive Animal Feed Ingredient Submission Course*. <https://www.aafco.org/resources/online-courses/comprehensive-animal-feed-ingredient-submission-course/>

<sup>10</sup> Food and Drug Administration. *GFI #106: The Use of Published Literature in Support of New Animal Drug Applications*. <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/cvm-gfi-106-use-published-literature-support-new-animal-drug-approvals>

management. In FY23, AADAP's National Investigational New Animal Drug (INAD) Program reactivated its Benzoak (benzocaine) INAD to pursue approval of this drug for sedation to handleable and began work to study Aqui-S20E (eugenol) for extended light sedation. The INAD team has established new mini workshops for INAD participants consisting of 1-2 hour-long webinars that are held with a specific organization or company to discuss the INAD process and answer any questions specific to the needs of the participants. In addition, AADAP's research program continues to conduct or assist partners with Effectiveness and Target Animal Safety studies that fulfill data needs required for the drug approvals through the FDA. In 2023, the Research Team worked with the drug sponsor of a spawning aid to develop a target animal safety study protocol for establishing a margin of safety for this product when used to induce spawning in female catfish. Work was also conducted to develop an analytical methods for measuring hydrogen peroxide (H<sub>2</sub>O<sub>2</sub>) concentration in open ocean net pens to remove external parasites. AADAP met with NOAA at their Southeast Science Center located in Galveston, TX in May 2023 and the Northwest Science Center in Manchester, WA in September 2023 to explore collaborations in specific saltwater drug approval projects that may be appropriate to these locations. In addition, AADAP worked with the Office of Minor Use and Minor Species within FDA to develop an Indexing Guide for both internal use and to assist sponsors in navigating FDA's Indexing process.

In July 2023, USFWS, USGS, and NOAA renewed the memorandum of agreement with AFWA to continue to establish and describe responsibilities and facilitate cooperation among these agencies in coordinating and collaborating on research and data submittals to the FDA-CVM for approval of priority drugs for use in public aquaculture in the United States.

***USDA Animal and Plant Health Inspection Service***

Veterinary Services, Center for Veterinary Biologics

In May 2023, the Center for Veterinary Biologics (CVB) provided guidance regarding regulation of biologics used in Aquatic Animals as part of the training provided at the Veterinary Biologics Training Program hosted by the Institute for International Cooperation in Animal Biologics, in Ames, Iowa.

## **Objective 2.4: Review and clarify guidance for domestic movement of live aquatic animals across State lines**

Recent examples of contaminated commodities (e.g. crayfish found in shipments of feeder goldfish) suggest that additional mitigation work is needed within supply chains of wildlife, fish, and plants at the producer, supplier, and retail levels. To help mitigate such risks, the Aquatic Nuisance Species Task Force formed the Organisms in Trade Hitchhikers Work group under the Prevention Subcommittee to engage with the aquaculture and pet industry to explore opportunities to manage risks within aquaculture producer supply chains and trail settings to reduce invasions risks of hitchhiking organisms within pet commodities. Work conducted in FY23 included development of outreach materials and training that guide staff on biosecurity practices suppliers can follow to reduce the probability of unintentionally shipping contaminated product and what mitigation measures pet retail staff can take when a contaminant is received with wildlife, fish, or plant commodities.

### ***U.S. Fish & Wildlife Service***

USFWS awarded a grant to Oregon State University to produce an after-action report of the action taken to respond to the importation of zebra mussel contaminated moss ball products into the United States. The report will compile and catalog existing statutes, regulations, and policies related to the response. A detailed case study will be developed of invasive species legal framework, how that framework supported the response, the interplay of the state's response with the federal response, and the role (if any) local governments played in the response. The report will also identify gaps in federal authorities and regulations and identify opportunities for states to better align their responses to national-scale incidents. Anticipated completion of the report is Spring 2024.

Using appropriations from the Bipartisan Infrastructure Law to the Department of Interior (DOI), the USFWS, in collaboration with other DOI bureaus, awarded a grant to Conservation Collaborations LLC to develop an action plan to mitigate the risks of aquatic invasive species trade and transport through commerce. A component of the action plan will identify regulatory gaps nationally and regionally and provide specific regulatory language to federal agencies and the states to implement laws that address aquatic invasive species sold through commerce. The project will also develop an online toolkit for industry sellers to ensure accessible information about restricted species in each state, as well as information about best management practices and responsibilities associated with buying aquatic species. Anticipated completion for the project is Spring 2024.

At the annual Aquaculture America Conference in 2023, USFWS presented operational processes and benefits of the 50 CFR 16.13 (regulations under the Lacey Act) for the national aquaculture industry.

### ***DOC National Oceanic and Atmospheric Administration***

#### **National Marine Fisheries Service**

NOAA continues to provide financial support for the Regional Shellfish Seed Biosecurity Program (RSSBP) being led out of Rutgers University in New Jersey. The RSSBP is coordinated under the guidance of the Shellfish Health Advisory Council. The Council serves to support state regulators by providing science-based advice on shellfish transfers as well as overseeing the hatchery certification/compliance process and best management practices. In 2023, NOAA funded the RSSBP via an Advanced Aquaculture Collaborative Programs award to expand the effort from the Atlantic into the Gulf of Mexico. NOAA also recommended 2023 Saltonstall-Kennedy Grant funding for the RSSBP to expand the Regional Shellfish Seed Biosecurity Program from the hatchery to the nursery setting.

The Calendar Year 2022 pilot project grant program was discontinued in FY23. An IMTA project was funded in FY23 for the third year in a row. Congress directed funding to the NMFS Aquaculture Office, in partnership with the Gulf States Marine Fisheries Commission, to partner with a university or consortium of universities to establish a multi-year demonstration pilot of an Integrated Multi-Trophic Aquaculture (IMTA) system in State waters of the Gulf of Mexico, which shall culture native species of finfish, bivalve mollusks, and macroalgae. The pilot is to be for research, training, and educational purposes only and should involve students, fishermen, and farmers, and shall endeavor to inform how to adapt IMTA methods and systems, in an environmentally and ecologically balanced manner, for deployment in warm water environments.

#### National Sea Grant Program

Recent examples of support provided for Extension Services, workforce development, test beds, and demonstration and production assistance include:

- Funding five pertinent projects: (1) Southern New England Aquaculture Hub, (2) Establishing a Hawai'i-Pacific Aquaculture Consortium: A Revitalization and Expansion of the Aquaculture Development Program, (3) Catalyzing a Cross-Pacific Regional Collaborative Hub to Advance Indigenous Aquaculture Practices and Enhance Marine Food Production for Cultural-Ecological Benefits, (4) Maine Aquaculture Hub: Building capacity for industry-driven innovation, diversification, and workforce development, (5) Great Lakes Sea Grant Aquaculture Collaborative
- Provide supplemental funding for several 2020 and 2022/2023 projects that increase extension capacity and workforce training
- Provide 2020 COVID-19 Rapid Response funding for projects that increase extension capacity
- Administer the 2021 "Food From the Sea" Careers Program that includes projects focused on seafood resources (fisheries) and aquaculture training and workforce development
- Fund six Aquaculture Workforce Development Support Projects and fund six projects: (1) Enhancing and Promoting Aquaculture Workforce Development in Hawaii and the Pacific; (2) Connecticut Aquaculture Workforce Development Strategy; (3) Extending and Integrating Aquaculture Workforce Development Between Communities in MA; (4) Developing a Commercial Seafood Workforce Training Program in South Carolina; (5) Tide's Out: WA Shellfish Crew and Manager Training; (6) Designing and launching a community college aquaculture workforce development program to help ready Southern California for a growing aquaculture industry
- Fund three Young Fishermen's Career Development Projects: (1) AK On-Board: Young Fisherman Training and Apprentice Program; (2) From the Dock to the Deck to the Wheelhouse: Developing Skilled Fishermen in New England through Three Early Career Stages; (3) A Next-Gen Seafood Industry: Implementing Career-Development Programming in the Southeast Region Through Public-Private Partnerships
- Fund two projects with FY23 Aquaculture Workforce Technologies and Education Travel Grants: (1) Expansion of the Pier to Peer program for oyster (*Crassostrea virginica*) aquaculture farmers in the southeastern U.S.; (2) Training and educating auditors, extension agents and regulators on the Regional Shellfish Seed Biosecurity Program

#### ***USDA Animal and Plant Health Inspection Service Veterinary Services***

In 2023, VS released the interactive map of State Regulations for the Domestic Movement of Live Aquatic Animals.<sup>11</sup> This tool was developed at the request of the farming community to better

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<sup>11</sup> USDA Animal and Plant Health Inspection Service. *State Regulations for the Domestic Movement of Live Aquatic Animals*. <https://www.aphis.usda.gov/aphis/maps/aphis/state-regs-live-aquatic-animals>

understand what the current aquatic animal health requirements are for each state and identify a point of contact for any issues with domestic aquatic animal movement.

**Objective 2.5: Develop surveillance strategies and emergency response plans for priority aquatic animal pathogens.**

***USDA Animal and Plant Health Inspection Service***

**Veterinary Services**

VS supports surveillance testing of over 35 mollusk farms in the Northeast for about eight (8) select pathogens of concern. This surveillance assists producers to make animal management and marketing decisions. Additionally, Maine sampled 5 sites of wild mollusks.

VS partnered with the state of California on the planting of sentinel susceptible oysters in at-risk areas in California for ostreid herpesvirus-1 in effort to determine the presence of this pathogen in these areas.

VS developed field investigation documents to support VS field epidemiologists and veterinary medical officers on aquaculture incident investigation and response.

VS has drafted new hazard identification factsheets for the following pathogens – epizootic hematopoietic necrosis virus (EHNV), *Gyrodactylus salaris*, infectious hematopoietic necrosis virus (IHNV), viral hemorrhagic septicemia virus (VHS), salmonid alphavirus (SAV), and infectious anemia virus (ISAV) which will all be posted in early 2024 on the APHIS Aquaculture Aquatic Animal Pathogen webpages.

**Objective 2.6: Clarify and define Federal agency roles in aquatic animal health attestations/certification and import/export of aquatic animals.**

***USDA Animal and Plant Health Inspection Service***

Veterinary Services

**Exports:** Effective September 18, 2023, VS updated its Registered Aquaculture Export Facility (RAEF) inspection program to support live aquatic animal exports from the United States. RAEF participation is required when an importing country requires official APHIS oversight of a U.S. exporting facility, or premises freedom for any pathogens. In conjunction with this update, APHIS developed a new aquatic animal export website, which includes disease testing and sampling information as well as various other guidance and reference materials related to the aquaculture exports: [USDA APHIS | Live Animal Export Resources – Aquatic Animals](#).

**Imports:** APHIS aims to regulate additional aquatic animal pathogens in the coming years, pending the draft proposed rule which will be published for public comment in the Federal Register. Information about import requirements for certain aquatic species has been published at: [USDA APHIS | Fish, Fertilized Eggs, and Gametes](#).

**Objective 2.7: Establish standard operating procedures for agency communication and points of contact for Federal and State agencies involved in the movement (import/export) of aquatic animals.**

***USDA Animal and Plant Health Inspection Service***

Veterinary Services

VS updated their federal aquaculture regulatory fact sheet in 2023 and is posted on the SCA website.<sup>12</sup>

USDA APHIS continues to communicate monthly with its partners in USFWS and NOAA on the import and export of healthy aquatic animals.

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<sup>12</sup> USDA Animal and Plant Health Inspection Service. *Aquatic Animal Health Overview*.  
<https://www.ars.usda.gov/SCA/Fact%20Sheets/USDA%20APHIS%20VS%20AAH%20Factsheet%20v2.pdf>





### Goal 3. Refine and Disseminate Tools for Aquaculture Regulatory Management

Regulatory processes require objective, efficient, and timely decisions based upon the best available science, so science has a key role in improving regulatory decision-making. Science-based tools are needed, for example, to site and manage aquaculture facilities, identify strategies to minimize, and avoid negative impacts to protected species and habitats, reduce the risk of invasive species introductions, minimize use conflicts, and evaluate risks associated with disease and genetic risk interactions between farmed and wild populations. Decision-support tools grounded in sound science can greatly improve the quality, consistency, and efficacy of regulatory decision-making for the benefit of industry, society, and the environment. Realizing the goals of economic performance, legal compliance, improved trade, and environmental compatibility will require such critical science-based management tools.

Translating scientific information garnered from robust science programs into operational decision support tools is critical to regulatory efficiency, fulfilling environmental requirements, and supporting industry development. Science information provides the foundation for evidence-based tools that inform decision-making at multiple levels of government. Industry uses this information to help understand and meet regulatory requirements, and it is critical to increase public understanding of the benefits and risks of aquaculture.

Optimizing the development of science-based management tools for aquaculture is complex. Multiple programs and institutes play a role in creating, funding, directing, transferring, and ultimately using science and technology for meaningful aquaculture development. The process of creating new ideas often occurs when a diverse mix of basic and applied research projects interact. The development of Federal science tools for aquaculture management occurs through a combination of work at Federal research laboratories; Federal funding of university, nonprofit, and industry scientists through competitive grants or contracts; cooperative extension work by USDA, the National Sea Grant College Program, and State extension agents; and other public-private research partnerships.

Specific science needs for aquaculture regulatory management and industry development are featured in the companion *National Strategic Plan for Aquaculture Research*. Updates are highlighted in the 2023 Progress Report for this plan, found on the [Science Planning Task Force website](#).