



Animal and Plant Health Inspection Service
U.S. DEPARTMENT OF AGRICULTURE

National Aquaculture Health Plan & Standards, 2021-2023



Table of Contents

Abbreviations	2
Definitions	4
Plan Purpose	8
Plan Goal	8
Executive Summary	9
Introduction	10
National Aquaculture Health Standards	12
Pathogen Reporting	12
Laboratory Accreditation for Quality Management	14
Testing Standardization for Determining Aquatic Livestock Health	15
Biosecurity for the Protection of Aquaculture and Aquatic Livestock Health	16
Surveillance for Aquatic Animal Pathogens	18
Response to Threats to Aquaculture and Aquatic Livestock Health	18
Management of Aquatic Livestock Health Data	19
Education and Training to Support Aquaculture and Aquatic Livestock Health	20
Voluntary Aquatic Livestock Health Inspection Options	20
Premises Freedom for Specific Pathogens in Aquaculture Settings	21
Comprehensive Aquaculture Health Plan Standards (CAHPS)	22
Cohort Test Negative Status	26
Aquatic Livestock Health in the Exclusive Economic Zone	28
Federal Oversight and Partnerships for Aquaculture and Aquatic Animal Health	30
United States Department of Agriculture (USDA)	30
Other Federal Agencies	31
Implementation Roadmap	34
Summary	36

Abbreviations

AAVLD: American Association of Veterinary Laboratory Diagnosticians

AFS: American Fisheries Society

AFS/FHS: American Fisheries Society, Fish Health Section

AHPA: Animal Health Protection Act

APHIS: Animal and Plant Health Inspection Service

APPL: Assumed pathogen prevalence level

BB: Blue Book

BMBL: Biosafety in Microbiological and Biomedical Laboratories

CAHPS: Comprehensive Aquaculture Health Program Standards

CDC: Center for Disease Control and Prevention

CFR: Code of Federal Regulations

CI: Confidence interval

CVO: Chief Veterinary Officer

DOC: Department of Commerce

DOI: Department of the Interior

EDS: Early detection system

EEZ: Exclusive economic zone

EO: Executive Order

EPA: Environmental Protection Agency

FACA: Federal Advisory Committee Act

FDA: U.S. Food and Drug Administration

FWS: Fish and Wildlife Service

ISO: International Organization for Standardization

NAA: National Aquaculture Association

NAAHP: National Aquatic Animal Health Plan

NAHLN: National Animal Health Laboratory Network

NAHRS: National Animal Health Reporting System

NIST: National Institute of Standards and Technology

NLRAD: National List of Reportable Animal Diseases

NMFS: National Marine Fisheries Service

NOAA: National Oceanic and Atmospheric Administration

NSTC: National Science and Technology Council

NVSL: National Veterinary Services Laboratories

OIE: World Organization for Animal Health

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

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

OS: Official surveillance

QA/QC: Quality assurance/quality control

RAS: Recirculating aquaculture systems

SAHO: State animal health official

SOP: Standard operating procedure

TWG: Technical Working Group

USDA: Department of Agriculture

VCPR: Veterinarian-client-patient relationship

Definitions

Agent: Biological materials that can spread infectious diseases in livestock.

Approved laboratory: A laboratory with oversight from APHIS for conducting pathogen testing for the purposes of official surveillance, testing and export requirements.

Aquaculture: The breeding, rearing, and harvesting of fish, shellfish, algae, and other organisms in all types of water environments to produce food and other products, enhance wild stocks, restore declining wild populations or species, or recover wild threatened and endangered species.

Biosecurity: The practices and measures taken to prevent the introduction or spread of harmful organisms onto an aquaculture facility or system.

Blue Book: Refers to the “Suggested Procedures for the Detection and Identification of Certain Finfish and Shellfish Pathogens” published by the Fish Health Section of the American Fisheries Society.

Disease: A disorder of structure or function, especially one that produces specific signs or symptoms not simply a direct result of physical injury.

Early detection system: A system for ensuring the rapid recognition of clinical signs in an animal or population that are consistent with disease, specifically infectious diseases.

Emerging disease: A disease, infection, or infestation that is a threat to animals or humans and meets one of the following criteria:

- a. An unknown agent that is causing disease on a premises and has the potential to result in a significant animal or public health impact, and applied diagnostic tests have yielded negative or non-negative results: OR
- b. A newly identified agent that is causing disease in a premises and has the potential to cause significant animal or public health impact, or is occurring in multiple premises; OR
- c. A previously identified or known pathogenic agent that has a change in epidemiology, such as: unexpected production impacts or morbidity/mortality over a previously defined range for the agent, expanded host range, or change in geography of an agent with the potential to cause a significant animal or public health impact.

Endemic disease: A disease that is known to be present in the U.S.

Exclusive economic zone: The zone where the U.S. and other coastal nations have jurisdiction over natural resources and extends no more than 200 nautical miles from the territorial sea baseline and is adjacent to the 12 nautical mile territorial sea of the U.S., including the Commonwealth of Puerto Rico, Guam, American Samoa, the U.S. Virgin Islands, the

Commonwealth of the Northern Mariana Islands, and any other territory or possession over which the United States exercises sovereignty.

Farm-raised: Aquatic animals reared in controlled environments with intentional interventions to enhance animal production through feeding, husbandry, and protection from predators with an implied ownership throughout the rearing period. Farm-raised animals may include animals reared for the purposes of enhancing wild stocks, restoring declining wild species or populations, or recovering wild threatened and endangered species and those animals are privately owned until purchased and legally released by public or private entities.

Feral: A feral animal is one that has escaped from a domestic or captive status and is living as a wild animal, or one that is descended from such animals.

Inshore: Rearing of aquatic organisms in State waters.

Inspection: All activities related to the determination of a health designation conferred to a population of animals or the premises on/in which the animals are raised.

Laboratory: A laboratory engaged in conducting testing for the purpose of aquatic animal health inspection and diagnostics in support of aquatic animal health and aquaculture commerce.

Land-based: Occurring on land.

Livestock: Animals reared as an asset and/or commodity in an agricultural setting. Livestock may include animals reared for the purposes of enhancing wild stocks, restoring declining wild populations or species, or recovering wild threatened and endangered species and those animals are privately owned until purchased and legally released by public or private entities.

Monitored disease: A disease that is endemic (present) in the United States and is required to be reported in 6-month and annual reports to the World Organization for Animal Health (OIE).

Net pen: An aquaculture production system that confines aquatic animals to a specific location, typically in open water settings. Synonymous with sea cages.

Notifiable disease: A disease or condition that requires notification to Federal and State veterinary authorities. In addition to the listed notifiable diseases, these animal disease conditions are notifiable and must be immediately reported to the appropriate authorities:

- a. Suspicion or detection of any animal disease or infection not known to exist in the United States
- b. Exotic vectors
- c. Emerging disease

Official surveillance: Describes the APHIS reviewed surveillance plan for aquatic animal sample

identification, collection, pooling and testing for pathogens of concern to establish or maintain a health status for the aquaculture premises or aquatic livestock.

Official testing: Pathogen testing procedures, including animal collection, sample handling and pooling, conducted at an approved laboratory for the purpose of establishing or maintaining a health status for an aquaculture premises or aquatic livestock population.

Offshore: Rearing of aquatic organisms in controlled environments (e.g., sea cages or net pens) in federally managed areas of the ocean. Federally managed areas begin where State jurisdiction ends and extend 200 miles offshore, to the outer limit of the U.S. Exclusive Economic Zone (EEZ).

Partners: Private and public stakeholders, including Federal departments, Tribal entities, State governments, farmers, laboratories and other persons, associations or groups who contribute to the betterment of aquatic animal health and aquaculture development and support these standards.

Pathogen: An infectious organism that causes disease.

Pathogen of concern: Any infectious pathogen that causes significant impact to aquaculture, aquatic animal production and/or trade/movement. Includes, but not limited to pathogens listed by the OIE, NLRAD and emerging pathogens.

Premises Freedom: A designation assigned by APHIS to premises following the requirements for premises freedom from specific pathogens.

Private operation: A business or industry that is owned by private person(s) or independent companies/managers or jointly owned by individuals. Not owned by State, Tribal or Federal entities.

Public operation: An enterprise wholly or partly owned by a State, Tribal or Federal organization and controlled through public authority.

Shellfish: Animals that dwell in water and have a shell, shells or exoskeleton. Examples include mollusks and crustaceans.

Veterinary-Client-Patient Relationship: according to *21 CFR 530*, is one in which:

(1) A veterinarian has assumed the responsibility for making medical judgments regarding the health of (an) animal(s) and the need for medical treatment, and the client (the owner of the animal or animals or other caretaker) has agreed to follow the instructions of the veterinarian;

(2) There is sufficient knowledge of the animal(s) by the veterinarian to initiate at least a general or preliminary diagnosis of the medical condition of the animal(s); and

(3) The practicing veterinarian is readily available for follow-up in case of adverse reactions or failure of the regimen of therapy. Such a relationship can exist only when the veterinarian has recently seen and is personally acquainted with the keeping and care of the animal(s) by virtue of examination of the animal(s), and/or by medically appropriate and timely visits to the premises where the animal(s) are kept.

Wild: An animal that lives in the wild. This includes feral animals, and those animals released into the wild or held by public operations for the purposes of enhancing wild stocks, restoring declining wild populations or species, or recovering wild threatened and endangered species.

Plan Purpose

The purpose of this document is to describe the plan that replaces the 2008 National Aquatic Health Animal Plan (NAAHP). This new National Aquaculture Health Plan & Standards (NAHP&S) presents the USDA vision for a strong domestic infrastructure for supporting and determining aquatic livestock health. Further, this plan establishes USDA as the Federal lead agency for the oversight of the health and promotion of farm-raised aquatic livestock. This new plan does not apply to wild animals or public operations supporting wild animals. The domestic aquaculture industry has changed significantly in the past decade and is poised to expand even more in the decades to come. This expansion and growth are crucial for domestic food security and safety. The elements presented in this new national plan are deemed essential to support the needs and growth of U.S. aquaculture such that farm-raised aquatic livestock are produced in a manner which provides health and management oversight as well as addresses the integrity and consistency of services used to determine and evaluate aquatic animal health.

Plan Goal

The overarching goal of this new 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. This goal is achieved by establishing oversight and implementing risk-based approaches for sound health assessment and development of management practices to protect and support the health of farm-raised aquatic animals and to prevent the introduction, spread, or release of pathogens of concern.

USDA is committed to working toward seeing these standards initiated in the first 2 years of this plan's inception by working collaboratively with all partners, including industry, Federal departments, State agencies, Tribal entities, and allied enterprises. Activities that support the plan goal are addressed in this plan and include the following:

- Reporting of notifiable pathogens of concern,
- Accreditation of laboratories conducting official surveillance and/or export testing,
- Standardization of diagnostic assays and procedures used for official surveillance and/or export testing,
- Implementation of national biosecurity controls,
- Strategies for national surveillance of aquatic animal pathogens,
- Planning for responses to a pathogen outbreak event,
- Management of data collected to support decisions and determinations on aquatic animal health to define premises freedom, zones or regions of pathogen presence or absence,
- Supporting the education of aquatic animal and aquaculture health professionals, and
- Implementing voluntary aquatic livestock health inspections.

Executive Summary

In 2008 USDA APHIS, NOAA NMFS and USFWS released the National Aquatic Animal Health Plan (NAAHP) which created a Federal co-competency task force between these agencies to implement the recommendations in the NAAHP. These recommendations were designed to facilitate aquatic animal movement, both interstate and international, protect the health of farm-raised and wild aquatic animals, ensure the availability of diagnostic and certification services as well as minimize the impacts of disease events when they occur. Between 2008 and 2020, APHIS' achievements under the NAAHP included coordination between the task force agencies for export certification services, the development of 4 aquatic animal health modules for the National Veterinary Accreditation Program (NVAP), incorporation of aquatic animal pathogens into the National Animal Health Reporting System (NAHRS) and 3 aquatic animal pathogens added to the National Animal Health Laboratory Network (NAHLN), as well as several surveillance projects, including multi-partner surveillance efforts on infectious salmon anemia (ISA) and viral hemorrhagic septicemia (VHS). These achievements were important for the advancement of aquatic animal health in the U.S., but further implementation efforts of the 2008 NAAHP were not successful. Implementation was limited by lack of resources and challenged by the vast diversity of species, production methods, end uses of aquatic animals reared in the U.S. and the diverging views of acceptable levels of risk and approaches to risk mitigation.

In 2020, the signing of Executive Order 13921, *Promoting American Seafood Competitiveness and Economic Growth*, provided an opportunity to the Secretary of USDA to replace the 2008 NAAHP with a new national plan for aquaculture health. This development of this National Aquaculture Health Plan & Standards: 2021-2023 positions USDA as the lead Federal authority for the protection and health of aquatic livestock. USDA is the natural Federal entity for the oversight of aquatic livestock and aquaculture health as it is for other traditional livestock commodities. This leadership role does not preclude or replace the partnership, collaboration or cooperation with other Federal, Tribal and State entities which have roles and responsibilities for other aspects of aquatic animal health. Rather, this leadership role leverages all of USDA's experience and expertise in protecting, promoting, and certifying livestock health, including aquatic livestock.

This document, National Aquaculture Health Plan & Standards: 2021-2023, establishes infrastructure for the consistent implementation of integral activities for the protection of health and improvement for aquatic livestock, such as pathogen reporting, standardized laboratory quality and testing, surveillance, data management and health certification programs. These elements are fundamental for a proactive and robust national aquaculture health system. The integrity of this system is the platform for safeguarding the health of all aquatic animals, farm-raised and wild, as well as supporting health certification of U.S. aquaculture-produced aquatic animals. This system does not apply to public operations or replace their existing aquatic animal health plans, guidance, or policies for their aquatic animal programs.

Introduction

In the U.S., Federal oversight for the health of aquatic animals reared in controlled or selected environments has been vague and dispersed among several Federal agencies as well as varied departments at the State level. This ambiguity has led to confusing and sometimes redundant regulations for the determination of aquatic animal health at the expense of aquaculture farms and entrepreneurs, as well as millions of healthy animals that have been destroyed because of the lack of clear authority, leadership and interpretation of risk. U.S. aquatic animal exporters face significant challenges in meeting health requirements of trading partners because of the void of a comprehensive national plan for the protection, health determination and verification of aquatic livestock produced in the U.S. The U.S. is far behind the rest of the world in its support and promotion of aquaculture despite bountiful aquatic resources, including the world's second largest exclusive economic zone (EEZ) and a seafood demand that has made the U.S. the world's leading importer of seafood and other aquatic animals.

In 2015, APHIS VS, in partnership with representatives from the National Aquaculture Association (NAA), drafted the Comprehensive Aquaculture Health Program Standards (CAHPS), a voluntary program for farm-raised aquatic livestock. CAHPS embraces the uniqueness of aquaculture production through scalability and flexibility of site-specific health plans that capture farm design, species being cultured, production method used, end use of the animals, pathogens of concern and emerging technology. The concept of CAHPS is based on five pillars that work together to establish, ascertain, and protect the health of farm-raised aquatic livestock, as well as provide assurance and confidence that the animals and water (e.g., effluent) leaving a CAHPS site are healthy, free of specific pathogens, and appropriate for the intended end use. CAHPS success depends on a consistent infrastructure for pathogen testing, reporting, analysis, and inspection. Because of shared risks and mutual benefits, all aquaculture facilities should be held to the same standards.

This document, National Aquaculture Health Plan & Standards: 2021-2023, hereafter referred to as 'Aquaculture Health Plan' or 'NAHP&S', defines USDA's authority and oversight of aquatic animal health for farm-raised aquatic livestock in the United States. USDA's scope of authority spans both nationally and internationally through the oversight of the movement and trade of animals raised in land-based, inshore, and offshore facilities. This breadth of accountability affords equivalent protection and assurance for all aquatic livestock in the U.S. This plan presents proactive, consistent, and uniform health inspection procedures that ascertains and protects the health of farm-raised aquatic animals as well as establishes a solid foundation for consistent and accurate health testing, early disease detection, reporting of pathogens and response.

USDA is the Federal agency with the authority and responsibility for the protection and promotion of animal health including aquatic livestock. As such the oversight and governance of this Aquaculture Health Plan is the responsibility of USDA in consultation with the NSTC subcommittee on aquaculture and the technical working group established under this plan. This

plan details a voluntary infrastructure and guidance that does not include any regulatory elements; participants can include the private finfish and shellfish aquaculture operations as well as any Federal, State, Tribal or local government agencies that wish to participate.

USDA APHIS proposes standing-up a Technical Working Group (TWG) to oversee the drafting of subsequent NAHP&S. The TWG will consist of representative stakeholders, from public and private operations, who are charged with providing information and data to support this plan. Working group members would be appointed by the Secretary of Agriculture and co-chaired by the USDA APHIS VS Aquaculture Senior Staff Veterinarian and a nominated member from the TWG.

Membership seats of the TWG are as follows:

- USDA APHIS VS Aquaculture Senior Staff Veterinarian (1)
- USDA APHIS VS Senior Staff Aquaculture Specialist for trade (1)
- Chair of the NSTC Subcommittee on Aquaculture or their designee (1)
- President of the NAA or their designee (1)
- President of the AFS FHS or their designee (1)
- A member from the National Assembly of State Animal Health Officials (SAHO) (1)
- A member from AFWA (1)
- A representative each from a public or private fish hatchery/production facility (2)
- A representative each from public and private mollusk hatchery/production facility (2)
- A representative from private crustacean production (1)
- A representative from each type of aquaculture production facilities
 - Land-based: Pond, raceway, RAS (3)
 - Marine net pen: Inshore and Offshore (2)
- A representative each from a private and publicly funded aquatic animal health diagnostic laboratory (aquatic animal cases account for at least 10% of annual caseload) (2)
- A private USDA accredited veterinarian (aquaculture accounts for at least 20% of clientele) (1)

This working group will meet quarterly or at the call of the TWG co-chairs. The group will discuss critical issues, priorities, updates and implementation procedures and milestones for this Aquaculture Health Plan 2021-23; the group will also provide aquaculture sector information to the USDA.

In addition to the TWG, during the 2021-2023 interim, the NSTC Subcommittee on Aquaculture will continue to provide collaborative opportunities for Federal partners to explore best practices and lessons learned from the 2008 NAAHP and the current NAHP&S, which will be part of the development of subsequent national plans.

National Aquaculture Health Standards

This section describes the actions and activities of USDA APHIS VS (hereafter referred to as APHIS) solely, or in conjunction with partners and stakeholders, to secure and protect the health of U.S. farm-raised aquatic animal populations. This plan establishes standards and guidance for the following:

- Pathogen reporting,
- Laboratory accreditation standards,
- Testing standardization,
- Biosecurity,
- Surveillance,
- Response,
- Data management, and
- Education and training.

This plan also establishes the following health inspection options:

- Premises freedom,
- Comprehensive aquaculture health program standards,
- Cohort test negative status, and
- Aquaculture health in marine Federal waters.

Pathogen Reporting

Pathogen identification, response, and reporting are critical elements of these Performance Standards. The accurate identification of pathogens allows for effective and rapid response, which minimizes deleterious effects on public and private aquatic animal premises. If there is the suspicion or detection of a listed pathogen reporting is necessary.

The OIE criteria for listing an aquatic animal pathogen are listed here:
https://www.oie.int/en/what-we-do/standards/codes-and-manuals/aquatic-code-online-access/?id=169&L=1&htmfile=chapitre_criteria_diseases.htm

The U.S. is a member country of the World Organization for Animal Health ([OIE](#)), and obligated to report all detections of OIE-listed pathogens. In the U.S., the USDA APHIS houses the Chief Veterinary Officer (CVO), who serves as the designated delegate to the OIE. It is the responsibility of the CVO to report detections of OIE listed pathogens to the OIE. The OIE reporting and alert system provides all countries and producers the opportunity to take necessary precautions to avoid the introduction or spread of these pathogens. Restrictions on international trade in animals and animal products prevents or mitigates economic impact to _____

Information on NLRAD and the list of pathogens on the NLRAD may be found here:

https://www.aphis.usda.gov/aphis/ourfocus/animalhealth/monitoring-and-surveillance/nlrاد/ct_national_list_reportable_animal_diseases

premises and beyond those premises to wild populations, seafood and recreational supply chains and the ultimate consumer.

The APHIS oversees several programs which capture data used to make informed reports to national and global communities, principally the National List of Reportable Animal Diseases

([NLRAD](#)) and the National Animal Health Reporting System ([NAHRS](#)). On passage of the National List of Reportable Animal Diseases (NLRAD) Rule it will be codified in Title 9 of the CFR Part 57. The NLRAD outlines the legal obligation for all animal health professionals to report detections of NLRAD listed pathogens. OIE-listed pathogens and others of specific concern to the U.S. are listed in the NLRAD and categorized as either “notifiable diseases/ conditions” or “monitored diseases.” Pathogens classified as notifiable encompass 1) foreign animal diseases, exotic vectors, and high priority endemic diseases which may cause serious impacts on animals, humans, or trade; 2) emerging diseases; and 3) disease incidents of importance in other regulations. Pathogens classified as monitored are OIE-listed and endemic in the U.S. The NLRAD specifies the process for reporting pathogens in each category.

APHIS reviews and updates the list of diseases in NLRAD annually, in collaboration with State Animal Health Officials (SAHOs), industry partners, Tribes, and other Federal agencies. All changes to the NLRAD are published in the Federal Register.

Each pathogen listed in the NLRAD has a case definition, and includes parameters used to determine when a test that is not negative is considered a suspect, presumed positive, or confirmed positive test result. All non-negative test results of NLRAD listed pathogens must be reported to the USDA

Information on NAHRS may be found here:

https://www.aphis.usda.gov/aphis/ourfocus/animalhealth/monitoring-and-surveillance/SA_Disease_Reporting

and SAHOs. State, Tribal, and Federal officials will determine how to proceed with further epidemiologic investigation (including additional sample collections), as well as additional testing needed to confirm or deny pathogen detection. Response actions will be determined by APHIS, SAHOs, and Tribes, as necessary, depending on the pathogen, its prevalence within the U.S., and circumstances of the affected population.

The National Animal Health Reporting System (NAHRS) was created by the US Animal Health Association (USAHA), American Association of Veterinary Laboratory Diagnosticians (AAVLD) and USDA for the reporting of both OIE and NLRAD listed diseases and other diseases of interest in aquaculture and terrestrial livestock populations in the U.S. APHIS and State authorities use the data from these reports for trade negotiations and to strengthen local surveillance, as well as guide decision-making processes on animal health issues. Individual animal owners and production sites are never identified in the information submitted to

NAHRS.

Laboratory Accreditation for Quality Management

Laboratories conducting services for their clients to support official testing for the purpose(s) of aquatic livestock health inspection (e.g., CAHPS and premises freedom) and/or to support animal trade, these laboratories are expected to operate under similar standards to ensure inter-laboratory consistency and robustness. These laboratory types may include, but are not limited to, private, public, university, or other laboratories. The standards outlined in this section apply to services required by a public or regulatory entity (such as State, Tribal, or Federal Government agencies, or international trading partners), for the purposes of assigning health status or verification to an aquaculture premises and/or group of aquatic livestock population. These standards do not apply to laboratories conducting clinical diagnostic work.

Currently, some diagnostic laboratories may not meet this Performance Standard. The TWG will adopt a phased schedule to provide laboratories a reasonable and constructive period of transition to meet the Standard.

1. STANDARD: Laboratory Quality Management Accreditation

Before a laboratory engages in official testing of animals or specimens to support aquatic livestock movement, trade and/or health status (including participating in programs such as CAHPS) it must provide documentation of laboratory quality management system accreditation acceptable to APHIS. Accreditation bodies may include, but are not limited to, the International Organization for Standardization (ISO) 17025 for quality management or the American Association of Veterinary Laboratory Diagnosticians (AAVLD).

2. STANDARD: Laboratory Biosafety

Laboratories conducting official aquatic livestock pathogen testing and/or research must meet, or exceed, biosafety level 2 requirements in accordance with the Center for Disease Control and Prevention (CDC) current edition of the [Biosafety in Microbiological and Biomedical Laboratories](#) (BMBL). Compliance with standard assures biocontainment of pathogens.

3. STANDARD: Specimen Handling

Laboratories conducting official testing must have procedures in place to ensure the integrity of specimens throughout their duration in the laboratory's possession. Procedures may include, but are not limited to, documentation of specimen transportation, receipt, handling, protection, retention and/or disposal. Specimen handling identification procedures are also required to avoid confusion between other specimens handled in the laboratory, or sample(s) derived from a given specimen. At a minimum, procedures must identify and document the following information for each specimen or derived sample:

- Submitting client,
- Location of the production facility the sample was derived from,
- When and who collected the sample,
- What sample type was submitted (e.g., species, tissue type), and
- Condition of samples upon arrival (e.g., temperature, integrity of packaging etc.).

Testing Standardization for Determining Aquatic Livestock Health

When available validated assays should be used for official testing performed for national surveillance, commerce, or to demonstrate the health status of an aquatic livestock population or aquaculture premises.

In lieu of a validated test, laboratorians and diagnosticians in the U.S. may look to the current versions of the [OIE Manual of Diagnostic Tests for Aquatic Animals](#), the [“Suggested Procedures for the Detection and Identification of Certain Finfish and Shellfish Pathogen”](#) (hereafter referred to as the Blue Book or BB), or assays published in peer-reviewed literature and are reviewed and accepted by the TWG that fit the intended purpose. If in doubt, laboratory management should consult with APHIS to determine which test(s) should be used for the official purpose(s) needed. For international export testing, the assay should meet trading partner requirements, if specified.

The following standards serve as a guideline to determine the best assay to use when testing for pathogens in aquatic livestock for official testing purposes.

1. STANDARD: Fit for Purpose

For official testing the purpose for the testing must be known and declared ahead of sample collection and analysis. The test method that best suits the intended purpose for testing should be selected based on the known or estimated knowledge on the health or status of the animal population (e.g., assumed pathogen prevalence level (APPL)), test Sensitivity and Specificity, and finally why the test is being performed, i.e., screening, confirmation, or trade. The test selection should consider these factors to ensure that the test and handling, processing of samples are appropriate.

2. STANDARD: Broad Screening Methods

Routine health screening for pathogens of concern should employ SOPs which may detect multiple pathogens if present in the animal or tissue being tested. For example, non-targeted, general screening may include virus isolation using cell lines that are susceptible to multiple viral pathogens, while targeted methods may include more targeted and specific methods such as polymerase chain reaction (PCR). When turnaround time or other factors (e.g., regulatory requirements) prevent the use of non-targeted, general screening

methods, assay selection should meet the specified requirement (e.g., OIE methods, BB etc.).

3. STANDARD: Diagnostic Sensitivity (Se)

Whenever possible select a diagnostic method that has data on diagnostic performance such as diagnostic sensitivity (Se) and specificity (Sp). Sensitivity and specificity are characteristics of a test for a particular pathogen. Sensitivity is the ability of a test to correctly identify animals or samples that *have a* particular disease. Whereas, specificity is the ability of a test to correctly identify animals or samples that *do not* have a particular disease. Knowing these characteristics of a test can help guide thinking on how many samples need to be collected to achieve health targets, such as a 2% assumed pathogen prevalence level, as well as being able to estimate the impact of pooling of tissues or animals on test performance. Additionally, having data on Se and Sp helps with test result interpretation and confidence in test results.

Because most official health testing is being conducted on animals which are not clinical for disease and/or are from populations or premises that are tested or assumed to be free of infection, the desire is to select a test with a high Se which increases the probability that a negative test result is truly negative.

4. STANDARD: Pooling of Animals or Tissues

The impact of pooling animals or tissues is sometimes needed to yield enough material (i.e., early life stages) to run a diagnostic assay. Further, pooling is desirable to minimize high costs associated with testing individual healthy animals to achieve or maintain premises or population health status. It is a concern when animals or tissues are pooled, particularly in populations of low pathogen prevalence, that there is an increase probability of false negative results because of pathogen agent dilution due to pooling. When pooling is necessary, adjustments may be made in diagnostic test Se (which can be assumed to decrease) as well as the number of samples collected and pooled to off-set the impact of pooling of these samples.

Biosecurity for the Protection of Aquaculture and Aquatic Livestock Health

Biosecurity, or risk mitigation, refers to the practices and control measures which are implemented to protect against infection by pathogens or other harmful agents to support a healthy sustainable animal production system. Effective biosecurity measures may reduce the need for antimicrobial and parasiticide therapy to treat or control pathogens and parasites; this in turn reduces the development of antimicrobial and parasite resistance in premises settings. Biosecurity is a collective effort that requires all allied groups, like the APHIS, industry, states, and tribes, to protect the Nation's aquaculture producers, farm-raised animals, and natural resources.

As a delegate to the OIE, the U.S. follows the [OIE guidelines on basic biosecurity conditions](#) which state that the following conditions, at a minimum, are required to protect a country, region or farm from a specific disease:

1. Mandatory reporting of the disease or suspicion of the disease to the competent authority, **AND**
2. An internal early detection system (EDS), **AND**
3. Provisions to prevent the introduction of a specific pathogen into a country, region or farm or the spread of the pathogen within or from an affected country, region, or farm.

To meet these conditions, APHIS established the NLRAD and NAHRS reporting requirements. CAHPS helps to create the framework for an early disease detection system of pathogens at the premises level. Disease and species-specific health requirements are based on knowledge gained from national surveillance and risk assessments.

APHIS evaluates the need for import health controls of OIE-listed pathogens not known to exist in the U.S. (e.g., foreign animal pathogens), through national surveillance efforts, as described in this plan, and risk assessments performed by APHIS. If national surveillance reveals some pathogens exist in domestic wild animal populations, but not in farm-raised animal populations, then APHIS will evaluate the implementation of import controls and support on-farm surveillance to maintain trade. If surveillance reveals that a pathogen exists only in certain regions or certain populations in the U.S., then APHIS will determine, in partnership with industry and State entities, if local controls should be implemented to protect aquatic livestock.

For those pathogens APHIS has import controls for at the national level, State partners are encouraged to align their movement requirements with the national criteria.

Import controls for OIE-listed and emerging pathogens apply to interstate movement and holding of those pathogens by private and public laboratories or research facilities. This authority is afforded to APHIS under Title 9 CFR Part 122. APHIS will issue import or interstate transport permits for material/samples that contain a known OIE-listed aquatic animal pathogen (including pathogens that have been killed/inactivated); were derived from a known OIE-listed aquatic animal pathogen (including DNA/RNA and recombinants); or serve as a vector for a known OIE-listed aquatic animal pathogen. The permit may require certain conditions to be met for laboratories, such as effluent control to prevent unintentional pathogen release from these facilities.

At the premises level biosecurity is ensured through appropriate risk evaluation for each pathway that may exist for the pathogens of concern, species being cultured, and the production method used. The health inspection options of Premises Freedom and CAHPS both incorporate risk mitigation practices.

Surveillance for Aquatic Animal Pathogens

National surveillance of aquatic animal pathogens requires collaboration of APHIS and all partners involved in aquaculture health. Information collection and data analysis will improve decision-making on animal health and response at all levels: farm, region, State, and country. Efforts should prioritize OIE-listed and emerging pathogens that are not known to exist in the U.S. (i.e., foreign animal diseases), and focus on the goal of declaring disease freedom at the regional or country level.

To declare disease freedom at a national or regional level, the following elements are part of the process:

1. Design and launch national/regional surveillance for a specific pathogen,
2. Collect data from data streams,
3. Analyze data,
4. Report findings, and
5. Implement measures to secure the national or regional health status, based on findings.

Surveillance project design may include passive and active surveillance strategies. Data streams may include laboratory test results, observational surveillance, risk-based surveillance (e.g., testing most susceptible species or highly likely infected individuals), disease ecology or epidemiology studies, and expert elicitation.

Surveillance data will be used to support national, regional, and premises-level health claims that are then used to support trade, secure movement of aquatic animals domestically, as well as guide protections for natural resources. Additionally, an integrated national surveillance system affords early detection system (EDS), triggering a response that prevents unintentional spread of pathogens. National surveillance is conducted to support and guide on-premises surveillance plans, such as those required as part of the Comprehensive Aquaculture Health Program Standards (CAHPS), premises freedom or other health policies.

Response to Threats to Aquaculture and Aquatic Livestock Health

Inevitably there will be threats to the health aquatic livestock in the U.S. In order to protect animal life and well-being, as well as trade and marketability, APHIS will lead the investigation and response to these events. When a detection of a NLRAD pathogen is found, reporting efforts should be in accordance with the “National Reporting of Aquatic Animal Pathogens” section of this plan. Information may be reportable only for monitoring and characterization of disease threat, before any action is taken in response to this detection. In most cases, the inclusion of a given pathogen on the NLRAD list implies some action may be necessary to control the disease.

If a NLRAD pathogen is found in wild aquatic animals, the agency responsible for the health of those animals will immediately notify APHIS, as well as the SAHOs. Additionally, notifications or

alerts may be communicated to other public and private aquaculture facilities deemed at risk because of the detection.

Upon notification of a suspicion or detection of a NLRAD listed or emerging pathogen, APHIS will immediately initiate a plan that may include some or all the actions describe below.

- Work with local/regional authorities to appropriately quarantine or stop movement of affected populations.
- Determine if pathogen confirmation is needed.
- Determine if additional sampling and testing is needed.
- Initiate a premises epidemiological investigation, include the tracing of sources and animal movements.
- Make additional notifications as needed.
- Develop a response plan in agreement, as necessary, with industry, State, Tribes, and other Federal agencies and involved parties.
 - a. Develop and sign a premises plan agreement for the release of quarantine or hold order.
 - b. Develop secure movement plans for unaffected animals to leave the affected premises, or for affected animals to move to a terminal market.
- Launch the response plan including provisions for animal disposition, cleaning, and disinfection.
- Assist the affected facility or region in regaining health status.
- Conduct an after-action review.

Indemnification and [other financial assistance](#) to eligible impacted private aquaculture facilities will be determined by APHIS. Privately held aquaculture operations that participate in CAHPS may influence eligibility and receive priority over facilities not participating in CAHPS.

Management of Aquatic Livestock Health Data

For APHIS to make claims about the status, prevalence, and absence of aquatic animal pathogens in the U.S., data must be collected, stored, and analyzed. APHIS conducts data management and analysis in compliance with the Foundations for Evidence-Based Policymaking Act (Evidence Act; P.L. 115-435), and the laws and guidance established by the National information collected by a Federal Government agency. Together, the Evidence Act and NIST [RMF](#) form a risk management framework that outlines the controls, processes, systems, and operating plans used to protect the integrity and source of data collected.

When APHIS reports analyses of collected data, it will be aggregated to the highest level such that no premises or personal identifying information will be revealed.

Education and Training to Support Aquaculture and Aquatic Livestock Health

Protection of U.S. aquaculture and aquatic livestock depends on educated aquatic animal health professionals working in partnership with private operations. APHIS supports partnership and collaboration of all professionals working in the field of aquatic animal health. These professionals include veterinarians, geneticists, researchers, extension agents, laboratorians, diagnosticians, and others who have training and knowledge on aquaculture production and aquatic animal health.

APHIS manages the National Veterinary Accreditation Program ([NVAP](#)). Veterinarians issuing health certificates must be APHIS accredited. The NVAP establishes [standards for accreditation](#) and offers categories of accreditation based on target species. Veterinarians issuing international health certificates, assisting with disease outbreak response, and practicing medicine in offshore facilities must comply with the requirements for category II accreditation status. Veterinarians must establish a valid veterinarian-client-patient relationship ([VCPR](#)) with aquaculture clients as directed by States and Federal government agencies. A VCPR establishes that the veterinarian assumes the responsibility for making medical diagnoses and prescribing treatment.

APHIS, like the American Veterinary Medicine Association (AVMA), recognizes veterinary telemedicine as a tool that uses electronic/digital communications for the exchange and assessment of health information and status. The opportunities and application of telemedicine in aquaculture is yet to be fully appreciated. A veterinarian may employ telemedicine technology in aquaculture if a VCPR exists and is conducted in accordance with existing State and Federal laws.

APHIS recognizes the importance and role of non-veterinary professionals in the field of aquatic animal health. While veterinarians must conduct, supervise, or oversee certain activities to fulfil Federal or other requirements or expectations (e.g., those written or implied by a trading partner), non-veterinarians are critical to the overall health and expansion of U.S. aquaculture. These non-veterinary professionals include, but are not limited to [Fish Health Pathologists](#) and [Fish Health Inspectors](#) certified by the [American Fisheries Society Fish Health Section](#) (AFS FHS), those employed by State or Tribal entities to carry out aquatic animal health work, as well as extension personnel working in the field of aquaculture.

Voluntary Aquatic Livestock Health Inspection Options

Aquatic animal health inspections are performed to support culture, movement, marketability, and trade of healthy animals. A health inspection, for the purposes of this plan, includes all activities related to the determination of a health designation conferred to a population of animals or the premises on/in which the animals are raised.

Activities conducted under a health inspection include, but are not limited to:

- Routine observation of animal populations for signs of disease,
- Routine testing for pathogens of concern,
- Implementation of biosecurity practices and control measures to protect animal health, and
- Record-keeping/documentation of treatments, morbidity and mortality rates.

Health inspections must be conducted in a manner that demonstrates a health status that can be verified.

APHIS is the Competent Authority for aquatic livestock health and provides certification based on inspections conducted to establish, manage, and maintain a health status for an aquaculture premises and aquatic livestock populations. APHIS offers four voluntary options for aquatic livestock health inspections and recognition of aquaculture premises. Regulatory requirements set forth by another entity or trading partner may be satisfied by participating in a health inspection program with Federal oversight.

The APHIS aquaculture health inspection options are:

1. Premises Freedom for Specific Pathogens in Aquaculture Settings,
2. Comprehensive Aquaculture Health Program Standards (CAHPS),
3. Cohort Test Negative Status for Specific Pathogens in Aquaculture Settings, and
4. Aquaculture Health in the Exclusive Economic Zone.

These programs are voluntary; but once enrolled, adherence to the requirements under each is mandatory. If a participating entity is not able to maintain compliance with the requirements, the status of that premises or animal population will be suspended or revoked by APHIS until compliance and status is regained, as determined appropriate by APHIS.

1. OPTION: Premises Freedom for Specific Pathogens in Aquaculture Settings

This option is for private aquaculture operations that need oversight and approval by APHIS to meet commerce requirements for specific pathogens, and do not participate in CAHPS. This standard is also a pathway to enrollment and participation in CAHPS.

The following criteria for surveillance and risk mitigations must be met to demonstrate premises freedom for specific pathogens.

a. Specific Pathogen Surveillance – sampling

At a minimum, the premises must maintain at least two years of historical test negative status for the pathogen(s) of concern established by the sampling and testing requirements below. In addition, populations are routinely monitored for health abnormalities. Any suspicions or detections of disease, pathogens or agents of concern are reported to APHIS.

Testing of representative samples to provide 95% confidence that

disease(s)/pathogen(s) of concern will be detected in the population given a prevalence of 2% or less. Sample selection criteria should be based on susceptible species, life stage, and season which offer the best opportunity to detect the pathogen with the appropriate diagnostic test. If moribund animals are available, they should be sampled.

b. Risk Mitigations

Risk mitigations must be outlined in a written biosecurity plan, with associated activity logs and SOPs, addressing pathogens of concern in all the following areas.

1) Animals

- a) Only animals of known, equal or higher health status are allowed onto the premises, **AND**
- b) Animals must be housed separately by life stage and year class on the premises and/or adhere to all-in all-out management practices.

2) Water

- a) Influent water originates from a secure water source free from pathogens of concern, such as well or ground water, **OR**
- b) Influent water is treated and/or managed in a manner to prevent the introduction of pathogens of concern.

3) Feed

- a) Feed ingredients DO NOT contain pathogen(s) of concern for susceptible or vector species

4) Vectors/Fomites

- a) Cleaning and disinfection protocols are appropriate for pathogens of concern, **AND**
- b) Fallowing is instituted for “hard breaks” between year classes/life stages, as appropriate for pathogens of concern, **AND**
- c) Parasite, pest, and predator management as appropriate for pathogens of concern.

2. OPTION: Comprehensive Aquaculture Health Program Standards (CAHPS)

This option requires that all five pillars of CAHPS are implemented for the management of aquatic livestock health. APHIS oversees participation and compliance in CAHPS. CAHPS is a series of premises specific best practices that protect aquatic animal health, enhance individual premises biosecurity, and, most critically, describe methods for aquaculture production facilities to observe to facilitate commerce, movement, standards of international equivalence for trade purposes, and marketability of aquatic animals. Participation in CAHPS, allows risk and pathogen-based reductions in testing over time without compromising the integrity of the health status of the animal population or site.

APHIS supervises CAHPS through premises inspections to verify compliance with all pillars as described in the CAHPS site-specific health plan. Third party verifiers may be used for the auditing of compliance with CAHPS.

PILLAR 1: *Aquatic Animal Health Team* – A CAHPS participant must identify the aquatic animal health and aquaculture professionals that will assist with the site-specific health plan that is required. This team of experts may be composed of the premises animal health manager, APHIS accredited (category II) veterinarians, American Fisheries Society (AFS) certified professionals, diagnostic laboratory representatives, and other knowledgeable subject matter experts including, but not limited to, extension personnel and consultants. The premises' management will designate a leader of this aquatic animal health team (AAHT). The leader is responsible for a developing and maintaining a communication plan with the rest of the AAHT and APHIS inspectors.

This team will determine pathogens of concern (e.g., pathogens of regulatory or production concern); risk mitigation strategies; and disease detection and reporting strategies, which must be outlined in a surveillance plan. An APHIS accredited veterinarian must be identified to lead disease investigations, treatment, reporting, and other responses, as needed. This team is responsible for site-specific training protocols for personnel on aquatic animal health and specific diseases of concern. Management and the accredited veterinarian share responsibility for reporting and maintaining open communication with APHIS and other appropriate entities. It is the responsibility of the CAHPS participant to ensure that the professionals working on their AAHT communicate with each other, and that all team members are knowledgeable of the animal health status of the premises.

Veterinarians participating on the team must be able to demonstrate a valid veterinary-client patient relationship (VCPR) as described by the American Veterinary Medical Association (AVMA) and State veterinary boards, as well as maintain APHIS accreditation under NVAP.

PILLAR 2: *Premises Specific Risk Evaluation* - CAHPS participants must have a written biosecurity or risk mitigation plan that details the practices on the premises, including SOPs and means of record-keeping that facilitates periodic auditing.

A premises specific risk evaluation should be conducted annually. A risk evaluation consists of four steps which lead to the development of appropriate management practices to minimize disease risks. It includes strategies to prevent the introduction, spread, and/or release of pathogens of concern. A written site-specific biosecurity plan describes the risk mitigations needed for biosecurity and surveillance specific to the pathogens and pathways identified.

The CAHPS risk evaluations are comprised of four steps.



1. Risk identification – is a systematic premises-specific assessment performed by the AAHT. In this step, pathogens of concern are identified based on the susceptibility of the species being cultured and health requirements needed to meet end use purpose(s).
2. Risk Characterization – The AAHT examines the pathways or critical control points (CCP), by which specific pathogens could enter, spread through, or be released from the premises. This step may also identify factors that affect population vulnerability to a pathogen, as well as husbandry or management practices that might increase premises exposure to risk (e.g., water source, feed, cleaning and disinfection).
3. Risk mitigation – AAHT implementation of biosecurity practices appropriate for the pathogens and pathways identified in previous risk steps. At a minimum the site-specific biosecurity plan should address these biosecurity factors:
 - a. Animal introductions, management (e.g., separation of life stages and year class) and movement on premises, including the use of quarantine facilities,
 - b. Water source, water quality and treatment,
 - c. Feed type, storage, and source,
 - d. Vector control and mitigations by management for both mechanical and biological vectors, and
 - e. Fomite management, including cleaning and disinfection.
4. Risk communication – AAHT method(s) used to communicate the premises' biosecurity risk management practices to workers, visitors, and service personnel. Elements of this step include, but are not limited to, signs, SOPs, and other forms of information sharing.

PILLAR 3: Surveillance and sampling – Premises specific surveillance plans are driven by the needs and goals of the premises, and by the national surveillance standards. The AAHT will develop a surveillance strategy for the submission of diagnostic specimens to a laboratory that meets their animal health, movement and/or trade needs. The surveillance and sampling strategies for pathogens of concern will depend on the disease risks and susceptibility of the species being cultured, and the business objectives, such as stocking into public or private open waters, interstate movement, or international export of live animals. CAHPS uses risk-based surveillance strategies to determine the sampling numbers and frequency. Risk-based methods require knowledge of site and/or regional factors which impact the vulnerability and animal susceptibility to pathogen introduction. Risk-based surveillance also provides a mechanism for reductions in sampling over time for pathogens that are repeatedly demonstrated as absent. Participation in CAHPS does not supersede or negate any health requirements established by trading partners, domestic or international.

Routine active and passive premises surveillance will establish acceptable premises specific morbidity and mortality rates, which may vary by life stage, environmental factors, or production activities. Identifying these thresholds is important to determine when unusual or unexpected changes in health occur. Routine observational surveillance, as well as knowledge of animal production and disease, are fundamental factors for detection of early signs of infectious and non-infectious disease.

Factors that impact surveillance validity and scope are the sampling strategy, and the diagnostic tools used to detect pathogens of concern in the samples collected. A well-developed surveillance plan must account for changing risk factors and adjust the frequency or number of samples collected for testing.

PILLAR 4: *Disease Investigation* – When morbidity and/or mortality rates exceed AAHT determined acceptable premises-specific thresholds, the CAHPS participant must initiate a disease investigation to determine the cause of the problem. Disease investigations will vary depending on the scope, pathogenicity, and specific pathogen suspected. A CAHPS disease investigation has four steps:

1. Realization of a problem,
2. Internal communication of the problem,
3. Targeted sample collection, and
4. Diagnostics and identification of cause.

If a foreign animal disease, or a disease that is otherwise required to be reported is suspected, the event should be reported by the AAHT. An investigation by State/ Federal authorities will aid in diagnosis.

If diagnostic evaluation indicates that treatment is warranted using an antimicrobial product, the usage of these compounds must be recorded, and the product label or veterinarian prescribed treatment implemented.

PILLAR 5: *Response, Reporting and Recovery* – CAHPS participants must establish aquatic animal health management infrastructure (i.e., technical expertise, risk management) capable of identifying and responding to pathogen findings as well as pathogen response contingency plans. Responses to disease outbreaks are conducted by the AAHT.

If the AAHT suspect or know a NLRAD listed pathogen (including [OIE-listed pathogens](#)) is the cause of disease or present on the site, they must notify the appropriate State and/or Federal Government authorities. Reporting the presence of pathogen(s) will not necessarily lead to Federal or State regulatory actions. Disease events or detection of pathogens of concern will not impact a premise CAHPS status but may affect marketability due to concerns with disease spread.

3. OPTION: Cohort Test Negative Status for Specific Pathogens in Aquaculture Premises
This option is for private aquaculture operations that need oversight and approval by APHIS to meet requirements for commerce and do not participate in CAHPS.

To demonstrate cohort test negative status from specific pathogens, biosecurity must be maintained around the tested population as described by criteria established by APHIS.

For status as cohort test negative for specific pathogens of concern in aquaculture premises, a premises must meet all the following criteria listed below

- a. A representative sample, appropriate for the purpose of testing and pathogen(s) of concern, must be collected and tested within 45 days prior to movement, and test negative for the pathogen(s) of concern.
- b. Samples must be collected by or the under supervision of an accredited veterinarian.
- c. At the time of sample collection, the cohort was visually examined and found to be free of signs of infection and disease. If moribund animals are present, they must be included in the sample.
- d. Biosecurity practices must be in place for the tested cohort population at the time of sample collection through to time of movement or shipment.
 - 1) Once samples have been collected, no animals may be introduced into the sampled population.
 - 2) Cohorts must remain isolated OR in the same system in which they were tested with no change in risk of exposure to pathogen(s) of concern.
 - 3) During the time of segregation there is no unexplained or unusual morbidity or mortality.
 - 4) Only water from this site of the same health status as shipment is used in this shipment.



Table 1. Comparison of different inspection options for the establishment of premises or population health status.

	AFS BB	CAHPS	Premises Freedom	Cohort Freedom
Lot* Based	Yes	As needed	No	Yes
Farm* Based	Yes, if every lot tested	Yes	Yes	No
Inspection Frequency	Annual	Bi-annual	Bi-annual	As needed
Eligible Collectors	AV, SAHO, AFS	AV, SAHO, AFS	AV	AV
Selection of Moribund	Yes, if present	Yes, if present	Yes, if present	Yes, if present
APPL/CI	5%/95% (max =60 for lot or 60/lot for farm)	2%/95% or as needed	2%/95%	2%/95% or as needed
Pathogen-based Reductions	No	Yes, may able to justify a different pathogen prevalence given pathogen/host/environment/management practices	No	No
Risk-based Reductions	No	Yes, after 2 yrs. or history	No	No
Sample Handling Guidance	Yes	Yes	Yes	Yes
Laboratory Quality Management Standard	No requirement	AAVLD/ISO/NAHLN	AAVLD/ISO/NAHLN	AAVLD/ISO/NAHLN
Risk mitigation	Minimal	Yes, acknowledges varying degrees	No	Yes – around lot
Oversight	None	APHIS	APHIS	APHIS
Detection Assay SOPs	BB/OIE (assume 100% Sn/Sp)	OIE/BB/Other (at least >85% Sn; assume 100% Sp per confirmatory testing)	OIE/BB/Other (>85% Sn; assume 100% Sp per confirmatory testing)	OIE/BB/Other (>85% Sn; assume 100% Sp per confirmatory testing)
CAHPS Eligible	No	Yes	Possible	No

	AFS BB	CAHPS	Premises Freedom	Cohort Freedom
Routine Monitoring (EDS)	No	Yes	Yes	Yes
Reporting of listed pathogens	Yes	Yes	Yes	Yes
Disease Response Plans	No	Yes	No	No

*The definition of “lot” varies. For the purposes of this table “lot” as defined by the BB is lots of different species on the farm. APHIS defines a lot of animals as susceptible species that share, by direct or indirect contact, water, feed, vector and/or fomites.

4. OPTION: Aquatic Livestock Health in the Exclusive Economic Zone

This standard applies to private aquaculture operations operating in permitted sites in the exclusive economic zone. This standard does not supersede or replace requirements by other Federal Government agencies, but rather outlines how aquatic animal health will be managed for the protection of the cultured animals, as well as all wild animals interfacing with captive populations.

APHIS supports the American Veterinary Medical Association (AVMA) policy on veterinary practice in offshore aquaculture facilities operating in Federal waters. The AVMA policy establishes that veterinarians who practice in these waters, outside State jurisdiction, must:

- Hold a valid State, territory, or Federal license to practice veterinary medicine,
- Hold a category II accreditation with APHIS, and
- Have a valid veterinarian-client-patient relationship with the facility.

APHIS establishes these criteria for the health inspection of animals being stocked in marine Federal waters:

Stocking of aquatic animals in Federal marine waters

U.S. marine aquaculture operates within one of the most comprehensive regulatory environments in the world. For operations in Federal waters (i.e., offshore aquaculture), existing regulations govern a multitude of environmental concerns including disease management, water discharge, siting of gear, seafood safety, use of medication, feed ingredients, consistency with State laws, and the protection of marine mammals, fish habitat, and threatened and endangered species.

Only aquatic livestock of known health status will be permitted to be stocked in marine Federal waters. Animals stocked into marine offshore aquaculture operations must test negative for pathogen(s) of concern as directed by regulation or determined by species susceptibility and the region into which they are being stocked. Land-based source hatcheries must participate in one of the health inspection standards, such as CAHPS or the guidelines established for premises freedom or cohort test negative status.

Aquatic livestock feed in Federal marine waters

Only feeds and feed ingredients that do not contain pathogen(s) of concern for susceptible or vector species may be feeds used in these environments.

Federal Oversight and Partnerships for Aquaculture and Aquatic Animal Health

United States Department of Agriculture (USDA)

USDA APHIS VS

USDA APHIS VS is the competent authority for the protection, inspection, and certification for aquatic animal health. The Deputy Administrator of VS is the Chief Veterinary Officer for the United States and is the delegate to the World Organization of Animal Health (OIE).

This authority is provided by the following codes and regulations:

U.S. Code (USC) and Code of Federal Regulations (CFR)

VS authority and aquatic animal health activities covered in the USC and CFR include:

7 USC - Animal Health Protection Act (AHPA): The AHPA grants the Secretary of Agriculture authority over the prevention, detection, control, and eradication of animal diseases, including aquaculture, with animal defined as any member of the animal kingdom (excluding humans). Section 8322, National aquatic animal health plan, grants the Secretary of Agriculture authority to enter into cooperative agreements for the purpose of detecting, controlling, or eradicating diseases of aquaculture species and promoting species-specific best management practices. Section 10401 provides authority for the Secretary to regulate aquaculture. This includes health certification for export, negotiations of sanitary regulations, regulation of biologics, OIE representation, regulation of imported aquatic animals and products, diagnostic services, and disease control and eradication.

16 USC – National Aquaculture Act of 1980: This Act promotes and supports the development of private aquaculture and strives to ensure the coordination among various Federal agencies that have aquaculture programs and policies. USDA is the lead agency for interagency coordination.

CFR References:

- Title 7 CFR 371.4: Describes the role of APHIS Veterinary Services
- Title 9 CFR Part 161: Describes the activities of an Accredited Veterinarian
- Title 9 CFR Part 130: User Fees
- Title 9 CFR Part 93.900 et. seq.: Importation of aquatic animal species

- Title 9 CFR Part 53: Foot and mouth disease, pleuropneumonia and certain other communicable diseases of livestock or poultry

Executive Order (EO) 13921: This EO titled *Promoting American Seafood Competitiveness and Economic Growth* was signed into effect on May 7, 2020; it seeks to realign Federal authorities and promote industry growth and opportunity for investment by removing regulatory barriers. Section 10 of the EO, calls on the Secretary of USDA to consider updating or replacing the 2008 National Aquatic Animal Health Plan (NAAHP). This new plan presents a national roadmap to protect the health of all aquatic livestock in the U.S. and provides general guidelines to industry sectors, States, Tribes, Federal agencies and other stakeholders, which outlines infrastructure for consistent and reliable detection and reporting of pathogens as well as describes procedures to conduct health inspections of aquatic livestock. As directed in the EO, the Performance Standards are to be update biennially.

Other USDA Agencies

USDA Agricultural Research Service (ARS) and National Institute of Food and Agriculture (NIFA) conduct or support research on aquatic pests and pathogens and strategies to reduce on-farm losses to disease. APHIS, ARS, NIFA and aquaculture stakeholders must maintain effective communication for identifying research priorities and bringing Federal resources to bear in response to emerging diseases.

Other Federal Agencies

APHIS VS welcomes interaction and partnership with other Federal agencies to help streamline regulatory authority and ensure the health of all aquatic animals. This interaction may occur at meetings of the NSTC Subcommittee on Aquaculture.

Food and Drug Administration (FDA)

The FDA protects public health by regulating aquaculture drugs and feeds and helping to ensure the safety of our Nation's seafood supply. The FDA is responsible for assuring that animal drugs and medicated feeds are safe, effective, quality manufactured, and properly labeled, and that food from treated animals is safe to eat. The FDA also reviews the safety of new ingredients for use in aquaculture feeds. The FDA operates a mandatory food safety compliance program for all domestic and imported fish and fishery products under the provisions of the Federal Food, Drug, and Cosmetic Act, and pertinent regulations. FDA partners with other Federal, State, and local agencies in a cooperative effort to manage food

safety risks and provide consistent standards and regulations for seafood products in various industry sectors.

U.S. Fish and Wildlife Service (USFWS)

18 U.S.C. 42; 50 CFR 16.13

Authority provided in Title 50 of the Lacey Act the USFWS regulates the importation of all live salmonid fish and their eggs as well as dead whole, uneviscerated salmonids imports into the United States.

National Oceanic and Atmospheric Administration (NOAA)

NOAA has regulatory and stewardship authority for fisheries, marine sanctuaries, marine mammals, threatened and endangered species, and habitat conservation. NOAA also engages in consultations with other agencies.

Statutes that apply to aquaculture projects in which NOAA has a role include:

- Magnuson-Stevens Fishery Conservation and Management Act (1976)
- Endangered Species Act (1973)
- Marine Mammal Protection Act (1972)
- National Marine Sanctuary Act (1972)
- Coastal Zone Management Act (1972)
- National Environmental Policy Act (1969)
- Fish and Wildlife Coordination Act (1934)

Under these laws, NOAA is responsible for considering, preventing and/or mitigating the potential adverse environmental impacts of planned and existing marine aquaculture facilities through the development of fishery management plans, sanctuary management plans, permit actions, proper siting, and consultations with other regulatory agencies at the Federal, State, and local level. NOAA also considers all relevant Federal, State and local animal health regulations and laws in their planning and support of marine aquaculture.

NOAA has the Federal lead for Section 6.0 of the Executive Order titled Promoting American Seafood Competitiveness and Economic Growth to undertake environmental review of Aquaculture Opportunity Areas. This analysis will include aquatic animal health and disease prevention and mitigation.

The Commerce Certification Division of NOAA Fisheries' [Office of International Affairs and Seafood Inspection](#) operates the Seafood Inspection Program under the authority of the 1946 Agricultural Marketing Act. Participants in our program include vessels, processing plants, and retail facilities. All edible product forms ranging from whole fish to formulated

products, as well as fishmeal products used for animal foods, are eligible for inspection and certification. U.S. participants in the program may use official marks on their products indicating they have been federally inspected. The program offers a variety of professional inspection services on a voluntary, fee-for-service basis which ensures compliance with all applicable food regulations.

Implementation Roadmap

This section describes how APHIS will work towards implementing the components of this plan. Executive Order 13921 mandates that the plan will be updated every 2 years by USDA and allied partners.

As noted in the introduction, for the period of 2021-2023 the TWG will meet quarterly or at the call of the TWG co-chairs. The group will meet to discuss critical issues, priorities, updates and implementation procedures and milestones for this Aquaculture Health Plan 2021-23; the group will also provide aquaculture sector information feedback to the USDA on the biennial revision, as directed by Executive Order 13921. Additionally, the NSTC Subcommittee on Aquaculture will continue to provide collaborative opportunities for Federal partners for a dialogue to explore best practices and lessons learned from the 2008 NAAHP and the current NAHP&S, which will be part of the development of subsequent national plans. The long-term vision is to transition the TWG to a formal Federal Advisory Committee compliant with FACA.

For the 2021-2023 period, and commensurate with available resources, APHIS will pursue priority activities to support the plan.

Pathogen reporting

- Develop an algorithm for the listing and delisting of aquatic animal pathogens in the NLRAD.
- Complete case definitions for pathogens listed in the NLRAD.
- Coordinate the drafting of best professional practices for aquatic animal health professionals and laboratories.
 - Partner with AVMA, AFS, AAFV and others to draft.

Laboratory accreditation

- Participate in the drafting of agricultural biorisk management guidelines for aquatic animal pathogens.
- Assist laboratories not currently accredited to become accredited.
- Assist AFS FHS with the development of Tier 3 of the AFS FHS Lab QA/QC.
- Review and strengthen permitting process for the importation and movement OIE-listed, emerging and other important pathogens of concern for in vivo or in vitro laboratory work or research.

Testing Standardization

- Develop a fit for purpose reference manual of acceptable diagnostic test methods for OIE-listed, emerging and important endemic or other pathogens of concern.
- Support or develop ring test (proficiency test panels) for OIE-listed, emerging and important endemic or other pathogens of concern.
- Develop pooling guidance.

Biosecurity

- Prioritize pathogens for import controls (OIE-listed or emerging pathogens).
- Conduct risk assessment to support for national import controls.
- Develop post-entry quarantine standards for animals.
- Draft list of acceptable fomite disinfectants for use in aquaculture settings and the efficacies of each.

Data Management

- Determine resources for the fair market value (FMV) of farm raised aquatic animals in cases of indemnity.
- Develop software platform for aquaculture health data collected from multiple data streams.

Surveillance

- Develop process for the prioritization of pathogens for national surveillance (OIE-listed or emerging pathogens).
- Establish clear “communication pathways” and Federal agencies roles and responsibilities for national surveillance.
- Develop criteria for zones and regions for specific pathogens.

Response

- Develop secure overlays for the farmed aquaculture sector to ensure timely recovery and continuity of business in the event of significant aquatic animal disease events.

Education and Training

- Update NVAP aquatic animal health modules.
- Develop Qualified Accredited Veterinarian (QAV) program for aquaculture.
- Establish guidelines for the use of telemedicine in aquaculture settings.
- Create aquaculture food safety training for veterinarians and industry.

Health Inspections

- Develop informational materials on the different health options available to private operations.
- Enroll participants in CAHPS.

Summary

Executive Order 13921, *Promoting American Seafood Competitiveness and Economic Growth* provided an opportunity to the Secretary of USDA to replace the 2008 NAAHP with a new national plan for aquatic livestock health. To protect and support the growth of the domestic aquaculture industry sectors critical infrastructure issues need to be address including the following:

- The comprehensive and consistent reporting of pathogens of concern,
- Laboratory accreditation for quality management,
- Diagnostic testing standardization and fit for purpose,
- National biosecurity controls, National surveillance for pathogens of concern,
- Response planning for pathogen outbreak events,
- Data collection, management, and protection,
- Education and outreach for aquatic animal health professionals, and
- Health inspection options to support the business and marketing needs of U.S. aquaculture producers.

This document, *National Aquaculture Health Plan and Standards: 2021-2023*, establishes the start of addressing these issues. As per Executive Order 13921, this plan will be updated every 2 years with the input from the established Technical Working Group and other allied Federal, State, and Tribal partners. This plan details a strictly voluntary program that does not include any regulatory elements; participants can include the private aquaculture operations and any Federal, State, Tribal or local government agencies that wish to participate.



Fish health inspector. Photo: Kennebec River Biosciences.