CHAPTER 5. SURVEILLANCE

5.1. Introduction

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

For the purposes of this plan, surveillance is a systematic series of investigations of defined populations of aquatic animals, conducted to detect the occurrence, prevalence, or incidence of a pathogen which causes a PAAD, RAAD, or other disease determined to be of national importance.

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

To implement an effective surveillance program, consideration should be given to other existing Federal and State animal disease control programs as models. Some attributes to consider are voluntary participation; cooperation among all major entities, starting at the producer/resource manager level; and flexibility of disease lists.

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

5.2. Surveillance Objectives

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

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

  A surveillance program provides a process to rapidly detect a new occurrence or change in prevalence or incidence of specified aquatic animal diseases, or potentially previously unknown emerging diseases, within the United States. It also allows farmers and producers to quickly respond, as appropriate, to manage, control, or eradicate disease, and prevent the spread of infected animals.

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

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

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

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

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

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

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

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

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

5.3. Guiding principles

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

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

5.4. General surveillance procedures

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

There are three components to a surveillance plan:

- Collecting and testing samples
- Reporting occurrences and communicating results to stakeholders
- Analyzing and storing surveillance data

5.4.1 Collecting and testing samples

The sampling process should be driven by the objective of the surveillance program and the species being sampled. Consider the following elements when developing sampling protocols for surveillance:

- Consistency with methods prescribed by the OIE Manual of Diagnostic Tests for Aquatic Animals or the AFS Blue Book (Suggested Procedures for the Detection and Identification of Certain Fish and Shellfish Pathogens)

- Confidentiality of information
- A statistically and epidemiologically justifiable approach
- Adequate training for personnel

The NAAHP Task Force, via Uniform Standards or regulations, will standardize sampling protocols in order to assure consistency and transparency. Recognizing the success and applicability of the NPIP program to many aspects of aquatic animal health management, the Task Force may use the NPIP program as a model for sampling and testing for surveillance**.**

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

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

The Task Force may use the NPIP laboratory model for establishing approved laboratories to collect surveillance information, recognizing that laboratories conducting testing for export health certificates must be approved by the Federal competent authorities.

5.4.2 Reporting occurrences and communicating results to stakeholders

<u>Reporting occurrences</u>

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

The Task Force will develop policy to require, or at least encourage, reporting of NAAHP-listed diseases. Partnerships need to be established between the Federal competent authorities and all entities conducting testing for PAADs or RAADs to facilitate the reporting of suspect findings. Upon notification, the competent authorities would cooperate with the laboratory and producer or resource manager to further investigate and verify the suspect isolation.

Reporting of a RAAD or suspicion of a RAAD is required within 24 hours if <u>any</u> of the following conditions occur:

A. A new detection in the United States in a specified geographic zone (see Chapter 7, Zonation), or a recurrence in the United States or zone previously considered to be free of that disease;
B. Occurrence in a new host species;
C. New pathogen strain or disease manifestation;
D. Potential for international spread; or
E. Potential for zoonotic spread.

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

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

The following information should be provided to the AVIC upon preliminary findings or suspicion of a RAAD. Whenever possible, details of the finding should remain confidential.

A. Name, phone number, and address of person reporting the finding or suspicion of a RAAD.
B. The location of the finding (address and GPS, if known), and name and phone number of person in charge of facility/resource area.
C. The disease suspected or diagnosed

D. The species of aquatic animal affected
E. Approximate number of animals affected
F. Measures being taken to prevent the spread of the disease
G. Restrictions or quarantines, if any, placed on the facility or zone

Communicating results to stakeholders

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

5.4.3 Analyzing and storing surveillance data

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

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

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

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

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

The NAAHP places a high priority on the development of a single, centrally located and managed Federal data system. As APHIS' Center for Epidemiology and Animal Health (CEAH) has existing infrastructure to support such a system, such as the NAHSS and NAHRS systems, the Task Force will work with CEAH in developing a primary location for storing information on reportable aquatic pathogens. The FWS, NOAA Fisheries, other Federal, State, and tribal

agencies, and private industry could support this effort by developing, in conjunction with the NAAHP, a common format to submit data to this centrally located and managed system to make the process consistent and effective.