

Draft Plan for the implementation of a national aquatic animal pathogen testing network (NAAPTN)

*USAHA/AAVLD
Committee on Aquaculture*

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Outline

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1) Purpose of the Network

Purpose of the Laboratory Network: To protect the health of wild and cultured fish and shellfish, to provide quality testing in support of interstate and international trade, and to meet challenges associated with implementation of the National Aquatic Animal Health Plan.

2) Principles of the Network

- a) All State, Federal, academic, extension and private laboratories that meet the qualifications detailed in section 4 will be eligible to participate in the Network.
- b) Participating laboratories will all use standardized protocols for the detection of pathogens important in interstate and international trade and to the natural aquatic resources of the nation, or included in the NAAHP. These protocols will include pathogen detection, calibration and operation of all relevant equipment, and the collection, handling, transport, storage, and preparation of samples for testing.
- c) Participating laboratories are free to choose which NAAPTN tests they will offer. There is no requirement for laboratories to offer all NAAPTN tests.
- d) Laboratories must have an established Quality Assurance (QA) system, a quality manager and document control system, must provide written documentation that the system is followed, and provide this documentation for annual review by APHIS, USFWS, or NOAA.
- e) Participating laboratories will have qualified personnel to conduct or supervise the specific assays for the detection of aquatic animal pathogens and are able to recognize new or emerging pathogens that may be of importance for aquatic animal health, public health or trade purposes.
- f) Results from the NAAPTN laboratories will be recognized by the co-competent US authorities for aquatic animal health (APHIS, NOAA, and USFWS).
- g) Participating laboratories must be appropriately equipped to conduct those assays.

- h) Network laboratories will have adequate biosafety and biosecurity in place to ensure employee safety and pathogen security.
- i) There will be a reporting system in place to provide the information necessary for implementation of a comprehensive NAAHP, but that will also appropriately protect the confidentiality of those that submit samples to a network laboratory.
- j) To maintain competency and to reduce inter-laboratory variability, laboratories will participate in an annual training event for new lab personnel, and training events scheduled to support the implementation of new NAAPTn assays.
- k) That standardized reagents will be made available to Network Laboratories as appropriate.
- l) Participating laboratories must pass NAAPTn proficiency testing to remain in the network.
- m) When suspect positive test results are obtained, participating laboratories will forward samples to other Network Laboratories or NAAHP approved reference laboratories for confirmation of the positive test result.

3) The Trial Period

Rather than attempt to establish a NAAPTn in a single step, the Program will begin with a trial period. The goals of this period will be...

- a) to establish a collaborative structure to develop standardized protocols
- b) to gain experience in the communicating those protocols
- c) to develop methods to insure laboratory compliance
- d) to develop standardized reference materials for lab use
- e) to develop proficiency testing samples for labs
- f) to develop mechanisms for collecting lab results
- g) to determine test accuracy and sensitivity among laboratories
- h) to determine the need for formal centralized training of laboratory personnel
- i) to establish a mechanism to validate future pathogen screening methodology

4) Qualified Laboratories for the Trial Period

- a) For the trial period, a minimum of 10 labs will be included, but more laboratories would be desirable if sufficient funding is available. A mix of private, state, University, and federal laboratories will be selected by the NAAPT N Committee based on the following criteria.
 - i) experience in aquatic animal pathogen testing and a demonstrated interest in regulatory aquatic animal testing.
 - ii) a written letter from the appropriate State official or co-competent authority (APHIS AVIC, USFWS, or NOAA) supporting the laboratory's participation in the pilot and full NAAPT N
 - iii) a Quality Assurance (QA) system that includes a quality manager appointed member of staff who, regardless of other duties and responsibilities, shall have defined responsibility and authority for ensuring that the quality system is implemented and followed at all times
 - iv) a document control system that will ensure that only the current version of a correct document is in use in the laboratory, and that the documents needed for staff to perform their work are available at the work location.
 - v) equipment needed to do cell culture and PCR procedures required by NAAPT N protocols
 - vi) laboratory space with appropriate biosafety for sample handling, processing and testing capacity for network purposes (as required by APHIS)

- b) After the trial period, laboratories that meet the following criteria will be eligible for full NAAPT N
 - i) Nomination by their official State agency for aquatic animal health, APHIS, NOAA, or USFWS
 - ii) A letter of support from their APHIS AVIC, NOAA, or USFWS
 - iii) Implementation of an appropriate formal MOU with APHIS that will describe acceptable use of any funds or materials provided by APHIS and provide a formal agreement by the NAAPT N lab to fully comply with the requirements of the NAAPT N.
 - iv) Review and approval by the NAAPT N Committee

- c) NAAPTN laboratory participation is reviewed on an annual basis, and continued participation is granted based on...
 - i) Full reporting of all required data to the NAAPTN office
 - ii) A passing performance on NAAPTN proficiency tests (if proficiency is below standards, approval may continue based on the development and implementation of a plan for corrective action).
 - iii) Continued compliance with NAAPTN eligibility requirements

5) Laboratory responsibilities

- a) During the trial period, participating NAAPTN laboratories must
 - i) Send at least one laboratory employee to an initial training session organized by the NAAPTN that will include both assay performance and record keeping requirements.
 - ii) Perform all proficiency tests required by the NAAPTN
 - iii) Perform assays on other samples provide by the NAAPTN
 - iv) Follow the approved NAAPTN protocols for all NAAPTN testing
 - v) Report all results to the NAAPTN office in a timely manner
- b) For the full NAAPTN, laboratories must
 - i) Participate in NAAPTN mandated training
 - ii) Follow the approved NAAPTN protocols for all NAAPTN testing
 - iii) Report all results to the NAAPTN office in a timely manner
 - iv) Perform all proficiency tests required by the NAAPTN
 - v) Perform assays on other samples provided by the NAAPTN as part of the development of protocols for new NAAPTN pathogens

6) Development of test protocols

- a) For the trial period, protocols will be developed only for VHSV and will include both a cell culture-based screening test / PCR confirmation protocol sufficient to support international trade and a quantitative PCR protocol for consideration as an alternative screening test for VHSV

- b) For the full NAAPT_N, protocols will be developed for pathogens that meet any of the following criteria (in order of priority)
 - i) OIE listed pathogens needed to support export markets
 - ii) Pathogens listed in the NAAHP
 - iii) Other pathogens important for interstate trade or the protection of natural aquatic resources
 - iv) Other pathogens important for export
 - v) Emerging pathogens
 - c) Protocols to be developed under the NAAPT_N in accordance with Chapter 1.1.2 Principles of Validation of Diagnostic Assays for Infectious Diseases, OIE Manual of Diagnostic Tests for Aquatic Animals, 2006 in order to meet the following goals
 - i) Acceptable for trade and protection of natural aquatic resources (sensitivity, accuracy)
 - ii) Standardized reagents available
 - iii) Greatest possible standardization to reduce costs (especially applicable when testing for multiple pathogens that can share a common testing pathway)
 - iv) Least possible expense consistent with i and ii above.
 - d) Protocols will be developed by a NAAPT_N Sub-Committee.
- 7) Roles and responsibilities
- a) APHIS
 - i) As part of the trial NAAPT_N
 - (1) Establishing cooperative agreements with each participating laboratory to provide funding as described in Section 8.a.
 - (2) Provide other funding for the development of the NAAPT_N as described in Section 8.a.
 - (3) Appoint an additional member to the NAAPT_N protocol development sub-committee
 - (4) Provide positive and negative tissue samples for virus isolation of VHSV for proficiency testing of NAAPT_N laboratories
 - (5) Provide any required VHSV standards to NAAPT_N laboratories
 - (6) Ensure the availability of approximately 100 VHSV known VHSV-positive and 300 negative qPCR test samples for participating laboratories. The positive samples may be any fish species but must be suitable for use in the NAAPT_N VHSV protocols and should be from populations that may reasonably be expected to harbor VHSV

- (7) Collect all proficiency and testing data from NAAPT_N laboratories, analyze that data to describe laboratory and assay performance, report the findings to the NAAPT_N Committee
- (8) Conduct an on-site inspection of participating non-federal laboratories to insure compliance with NAAPT_N guidelines
- (9) Recognize VHSV test results from NAAPT_N laboratories as sufficient for APHIS endorsement of export health certificates, recognizing that individual importing countries may have their own specific requirements.

ii) For the full NAAPT_N

- (1) Establishing cooperative agreements with each participating laboratory to provide funding as described in Section 8.b.
- (2) Provide other funding for the development of the NAAPT_N as described in Section 8.b.
- (3) Appoint an additional member to the NAAPT_N protocol development sub-committee
- (4) Establish a NAAPT_N office with a similar structure to that of the NPIP office.
- (5) Provide proficiency testing samples to NAAPT_N laboratories
- (6) Provide any required standards to NAAPT_N laboratories
- (7) Procure and ship test samples, needed to support the development of new test protocols, to participating NAAPT_N laboratories.
- (8) Collect all proficiency and testing data from NAAPT_N laboratories, analyze that data to describe laboratory and assay performance, report the findings to the NAAPT_N committee.
- (9) Recognize results from NAAPT_N laboratories as sufficient to support export

b) USFWS

i) For the trial NAAPT_N

- (1) Fulfill its role on the USFWS/AFS-FHS Joint Inspection Committee
- (2) Conduct an on-site inspection of participating USFWS laboratories to insure compliance with NAAPT_N guidelines
- (3) Serve on the protocol development sub-committee
- (4) Serve on the full NAAPT_N committee
- (5) Recognize test results from NAAPT_N laboratories as sufficient for export certification

- ii) For the full NAAPT_N
 - (1) Fulfill its role on the USFWS/AFS-FHS Joint Inspection Committee
 - (2) Serve on the protocol development sub-committee
 - (3) Serve on the full NAAPT_N committee
 - (4) Recognize test results from NAAPT_N laboratories as sufficient for export certification

- c) NOAA
 - i) For the trial NAAPT_N
 - (1) Fulfill its role on the USFWS/AFS-FHS Joint Inspection Committee
 - (2) Conduct an on-site inspection of participating NOAA laboratories to insure compliance with NAAPT_N guidelines
 - (3) Serve on the protocol development sub-committee
 - (4) Serve on the full NAAPT_N committee
 - (5) Recognize test results from NAAPT_N laboratories as sufficient for export certification
 - ii) For the full NAAPT_N
 - (1) Fulfill its role on the USFWS/AFS-FHS Joint Inspection Committee
 - (2) Serve on the protocol development sub-committee
 - (3) Serve on the full NAAPT_N committee
 - (4) Recognize test results from NAAPT_N laboratories as sufficient for export certification

- d) NAAPT_N Committee
 - i) Composition: For the full NAAPT_N the NAAPT_N Committee will be composed of one representative from each NAAPT_N laboratory, the co-chairs of the NAAPT_N protocol development sub-committee, the APHIS and NOAA members of the NAAPT_N protocol-development committee, and an industry representative chosen by the NAA. For the trial NAAPT_N, the committee will be composed of the co-chairs of the USAHA/AAVLD Aquaculture Committee, and the non-NAAPT_N lab representatives described in 7.d.i.
 - ii) Duties
 - (1) Final approval of protocols developed by the protocol sub-committee
 - (2) Approval of laboratories for participation in the NAAPT_N and the trial NAAPT_N

- (3) Annual re-approval of laboratories for participation in the NAAPT
- (4) Identification of pathogens to be included in the NAAPT
- (5) Provide an annual report of NAAPT activities to stakeholders

e) NAAPT Protocol sub-committee

- i) Composition: The NAAPT protocol sub-committee will be composed of the members of the USFWS/AFS-FHS Inspection Protocol Committee (including the NOAA and APHIS members), an additional representative appointed by APHIS, and the chair(s) of the NAAPT Committee.
- ii) Duties
 - (1) Development of protocols as needed in support of the NAAPT
 - (2) Annual evaluation of test performance data from NAAPT labs
 - (3) Annually recommending to the NAAPT Committee adoption, continuation, withdrawal, or revision of NAAPT protocols

8) Funding

a) APHIS responsibilities during the trial NAAPT

- i) Through cooperative agreements with participating laboratories, APHIS will fund
 - (1) Testing expenses calculated by multiplying the required number of tests for NAAPT participation by the normal charges per test (based on the unsubsidized commercial rate).
 - (2) An additional \$5,000 to each participating laboratory to cover set-up and administration costs associated with switching to NAAPT protocols
 - (a) Funding for all labs will be an identical amount (as long as all trial obligations are met)
 - (b) APHIS will cancel, at their discretion, cooperative agreements with labs that fail to meet reporting deadlines or that fail to pass an on site inspection by APHIS, USFWS, or NOAA.

ii) APHIS will also fund

- (1) Travel expenses for the protocol development committee
- (2) A training meeting for NAAPT representatives

- (3) Actual travel expenses for those attending the training
 - (4) Development and shipping of proficiency testing samples
 - (5) Development and shipping of additional samples described in 7.a.i.6
 - (6) Collection, analysis, and reporting of lab performance data to the Committee
 - (7) A meeting of the trial NAAPT N Committee at the end of the trial period
- b) APHIS funding responsibilities during the full NAAPT N
- i) NAAPT N laboratory costs associated with validation of new assays per 5.b.v
 - ii) Travel expenses for the protocol development committee
 - iii) Required training and travel for NAAPT N representatives
 - iv) Development and shipping of proficiency testing samples
 - v) Development and shipping of additional samples described in 7.a.i.6
 - vi) Collection, analysis, and reporting of lab performance data to the Committee
 - vii) A meeting of the trial NAAPT N Committee at the end of the trial period
- c) Participating NAAPT N Laboratory fiscal responsibilities during the trial NAAPT N
- i) All expenses not included in 8.a
- d) Participating NAAPT N Laboratory fiscal responsibilities during the full NAAPT N
- i) All expenses not included in 8.b
- 9) Implementation of the full NAAPT N
- a) At the end of the NAAPT N trial, a meeting of the NAAPT N Committee will be held to decide if full implementation of the NAAPT N is appropriate
 - b) If the committee does advise implementation, it will also make any necessary revisions to the program structure
 - c) As new diseases are added to the NAAPT N, the NAAPT N system will replace the current “APHIS Approved Protocols” system as testing recognized by APHIS for export health certification purposes or surveillance.
 - d) The full NAAPT N will be implemented as described in this document, with any revision required (9.b), contingent on the availability of funding.

10) Continuation of the NAAPTN

- a) At an annual meeting, the NAAPTN committee will decide to continue or revise the NAAPTN
- b) If revision is required, such changes will be made by the committee
- c) Continuation is contingent on the availability of funding