REPORT OF THE USAHA/AAVLD COMMITTEE ON AQUACULTURE

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The Committee met on October 11, 2009 at the Town and Country Resort in San Diego, Calif., from 12:30-4:30 p.m. There were 16 members and 15 guests present. The Committee session opened with introduction of chairs.

Update on the VHS qRT-PCR
Dr. Beverly Schmitt, National Veterinary Services Laboratory, USDA-APHIS-VS

Canadian Assay and Cornell Laboratory qRT-PCR has been evaluated by the National Veterinary Services Laboratory (NVSL), but there are not currently enough samples for full validation. If validation can be worked, it would appropriate for use. NVSL needs input on if the Canadian qPCR (detects multiple strains but lower sensitivity) or the Cornell assay (detects specifically VHS strain IVb at a higher sensitivity) would best fit the current need. The Canadian assay is currently a 2 step PCR, but NVSL attempting to convert to 1 step PCR.

Strongly recommended the utilization of a technical working group consisting of stakeholders to help determine the fit for purpose of the PCR assay.

The new NVSL is complete and was moved into in the end of August.

Update on the interim Viral Hemhorragic Septicemia (VHS) Federal Rule:
Dr. Gary Egrie, USDA-APHIS-VS

The Interim Rule was published September 9, 2008, with the effective date initially set for November 10, 2008. On October 28, implementation was delayed 60 days (January 10, 2009) to allow for comments to be addressed. On January 2, 2009, implementation delayed indefinitely.

VHS Public Comments - What we Heard:

- Length of time that testing results from nonsecure water sources would be valid is too short
- 72-hour visual inspection
- Validity of interstate certificate of inspection
- Availability and cost of services
- Proscriptive methods for water treatment
- Requirements to test fish going to live fish markets

The indefinite delay is attributed to:

- Wide range of positions from stakeholders across the country
- Difficult to find middle ground that still accomplishes the intent of the Federal Order
- We desire to publish a reasonable, scientifically valid, implementable rule
- Federal Order remains in effect

Next steps include:

- Publish a proposed rule incorporating what we heard in the comments
- Proposed rule
    - Will have performance standards
    - Be more flexible
    - Allow VS to respond more quickly

APHIS Aquaculture Program Updates:
Dr. Gary Egrie

A significant amount of VHS surveillance has been conducted from 2007 to present. There was an increase in surveillance outside of the Great Lakes States in FY 2010, and an increase in the flexibility of the cooperative agreements. APHIS continues to coordinate education and outreach activities with Fish and Wildlife Service (FWS) and the National Oceanic and Atmospheric Agency (NOAA).

National Aquatic Animal Health Plan (NAAHP)
Dr. Gary Egrie

The NAAHP was drafted by the National Aquatic Animal Health Task Force – led by APHIS-VS, the U.S. FWS, and National Marine Fisheries Service, par of NOAA. The plan includes:

- PURPOSE – To provide a framework for how APHIS, FWS, and NOAA should develop programs for diseases that affect the health of aquatic animals (finfish, crustaceans, and mollusks)
- STATUS – Notice of availability was published in the Federal Register on August 21st and will be open for public comment period through October 2009
- NAAHP is not a regulation, it is a roadmap for how Federal agencies will work together to protect aquatic resources.
- NAAHP provides general principles and guidelines for how the U.S. Federal agencies with jurisdiction over aquatic animal health should take action to protect *farmed and wild resources*, facilitate safe commerce, and make available laboratory testing, training, and other programs as needed to implement the NAAHP

Three primary recommendations have been developed:

- Create a National Advisory Committee
- Develop a national aquatic health laboratory network
- Develop a secure information system

NAAHP Secure Information System
Dr. Gary Egrie

The NAAHP Secure Information System is being initiated this fiscal year. It is intended to provide States, Tribes, industry, the Federal Government and other stakeholders with the tools necessary to:

- Support reporting of aquatic animal diseases
- Protect aquatic animal resources
- Support movement and certification documentation
- Produce reports, maps, and other documentation for surveillance and disease management purposes

National Animal Health Reporting System (NAHRS) update:
Dr. Jerry Heidel, USDA-APHIS-VS

NAHRS is working on a list of aquatic animal diseases. In efforts to standardize lists of aquatic pathogens, the list within the NAAHP will be utilized as a guideline.

NAHRS is also working on case definitions for diseases, which includes efforts to synonymize the Blue book and OIE will provide case definitions and harmonizing test protocols.

Aquatic Animal Diagnostic Laboratory Network:
Dr. Kevin Snekvik, Washington State University

Background on recent developments regarding the desire by university, state, federal and private laboratories involved in aquaculture disease diagnosis to form a laboratory network for disease diagnosis and surveillance. The USDA provided a survey to laboratories involved in aquaculture testing in order to get information regarding interest in being involved in aquaculture testing. The following numbers are derived from the survey:

Total number of laboratories that received request	81
Total number of laboratories that responded	54

Number of laboratories interested	35
Number of laboratories not interested	19
Laboratories that have not responded	27
Interested laboratories actively testing for path.	20
Included USFWS Fish Health Centers & USGS	

Benefits of a laboratory network

- Uniform Testing SOP's across the US
    - Laboratories
    - USDA-APHIS
    - NVSL
- Better trained staff within laboratories
- Assay development (interlaboratory test evaluation)
- Disease prevalence/ Freedom

Development of Draft Laboratory Network Plan

- 2008 USAHA-AAVLD Funding Resolution
- NAAHP Completion
- USDA Webinars with NAHLN, NPIP, National Plant Pathogen Network, AVMA
- Draft Plan Development Process
    - Goodwin/ Snekvik
    - USDA, USFWS, NOAA Fisheries
    - USAHA-AAVLD Aquaculture Committee
    - Network Discussion Group (Friday)

Dr. Andy Goodwin covered the draft aquaculture laboratory network plan developed by the Co-chairs and modified by the subcommittee on the laboratory network. The document is included following this report.

Committee Business

Kathy Kurth proposed Resolution 1 entitled, "Federal funding for an aquatic animal laboratory network". The motion was seconded by Dr. Ehlenfeldt. Agreement on the wording was reached by the committee. A vote was taken and there was unanimous approval of the resolution by the committee.

Dr. David Scarfe proposed Resolution 2 entitled, "Implementation of the national aquatic animal health plan." Agreement on the wording was reached by the committee. A motion to vote was put forth by Dr. Scarfe and seconded by Dr. Heidel. A vote was taken and there was unanimous approval of the resolution by the committee.

Draft Plan for the Implementation of a National Aquatic Animal Pathogen Testing Network (NAAPTN)

USAHA/AAVLD
Committee on Aquaculture

October 11, 2009

Outline

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 NAAPTN 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 NAAPTN
   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 NAAPTN 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 NAAPTN
   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 NAAPTN lab to fully comply with the requirements of the NAAPTN.
   iv) Review and approval by the NAAPTN 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 NAAPTN, 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 NAAPTN 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 NAAPTN Sub-Committee.

7) Roles and responsibilities

a) APHIS
   i) As part of the trial NAAPTN
      (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 NAAPTN as described in Section 8.a.
      (3) Appoint an additional member to the NAAPTN protocol development sub-committee
      (4) Provide positive and negative tissue samples for virus isolation of VHSV for proficiency testing of NAAPTN laboratories
      (5) Provide any required VHSV standards to NAAPTN 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 NAAPTN VHSV protocols and should be from populations that may reasonably be expected to harbor VHSV
      (7) Collect all proficiency and testing data from NAAPTN laboratories, analyze that data to describe laboratory and assay performance, report the findings to the NAAPTN Committee
      (8) Conduct an on-site inspection of participating non-federal laboratories to insure compliance with NAAPTN guidelines
      (9) Recognize VHSV test results from NAAPTN 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 NAAPTN
      (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 NAAPTN as described in Section 8.b.

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

b) USFWS
  i) For the trial NAAPTN
    (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 NAAPTN guidelines
    (3) Serve on the protocol development sub-committee
    (4) Serve on the full NAAPTN committee
    (5) Recognize test results from NAAPTN laboratories as sufficient for export certification
  ii) For the full NAAPTN
    (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 NAAPTN committee
    (4) Recognize test results from NAAPTN laboratories as sufficient for export certification

c) NOAA
  i) For the trial NAAPTN
    (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 NAAPTN guidelines
    (3) Serve on the protocol development sub-committee
    (4) Serve on the full NAAPTN committee
    (5) Recognize test results from NAAPTN laboratories as sufficient for export certification
  ii) For the full NAAPTN
    (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 NAAPTN committee
    (4) Recognize test results from NAAPTN laboratories as sufficient for export certification

d) NAAPTN Committee
  i) Composition: For the full NAAPTN the NAAPTN Committee will be composed of one representative from each NAAPTN laboratory, the co-chairs of the NAAPTN protocol development sub-committee, the APHIS and NOAA members of the NAAPTN protocol-development committee, and an industry representative chosen by the NAA. For the trial NAAPTN, the committee will be composed of the co-chairs of the USAHA/AAVLD Aquaculture Committee, and the non-NAAPTN 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 NAAPTN and the trial NAAPTN
    (3) Annual re-approval of laboratories for participation in the NAAPTN
    (4) Identification of pathogens to be included in the NAAPTN
    (5) Provide an annual report of NAAPTN activities to stakeholders

e) NAAPTN Protocol sub-committee
  i) Composition: The NAAPTN 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 NAAPTN Committee.
  ii) Duties
    (1) Development of protocols as needed in support of the NAAPTN

(2) Annual evaluation of test performance data from NAAPTN labs
(3) Annually recommending to the NAAPTN Committee adoption, continuation, withdrawal, or revision of NAAPTN protocols

8) Funding

a) APHIS responsibilities during the trial NAAPTN
   i) Through cooperative agreements with participating laboratories, APHIS will fund
      (1) Testing expenses calculated by multiplying the required number of tests for NAAPTN 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 NAAPTN 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 NAAPTN 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 NAAPTN Committee at the end of the trial period
b) APHIS funding responsibilities during the full NAAPTN
   i) NAAPTN 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 NAAPTN 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 NAAPTN Committee at the end of the trial period
c) Participating NAAPTN Laboratory fiscal responsibilities during the trial NAAPTN
   i) All expenses not included in 8.a
d) Participating NAAPTN Laboratory fiscal responsibilities during the full NAAPTN
   i) All expenses not included in 8.b

9) Implementation of the full NAAPTN

a) At the end of the NAAPTN trial, a meeting of the NAAPTN Committee will be held to decide if full implementation of the NAAPTN 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 NAAPTN, the NAAPTN system will replace the current “APHIS Approved Protocols” system as testing recognized by APHIS for export health certification purposes or surveillance.
d) The full NAAPTN 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