Criteria for Establishing Premises Freedom for Specific Pathogens in Aquaculture Settings

APHIS VS is the Competent Authority for aquatic animal health, and provides oversight and approval regarding this premises freedom definition, as well as the designation for facilities that meet the requirements.

The following requirements must be met in order for APHIS to consider an aquatic animal premises as free of a given pathogen of concern, unless specific requirements are otherwise outlined and approved through the premises' participation in the VS Commercial Aquaculture Health Program Standards (CAHPS) or according to criteria established with a trading partner.

1. **Specific Pathogen Surveillance**
   At a minimum, the premises must maintain at least two years of historically negative specific pathogen surveillance, which meets the sampling and testing requirements below, in order to be eligible for premises freedom of a given pathogen of concern. Populations are monitored for health abnormalities. Any suspicions or detections of disease, pathogens or agents of concern are reported to APHIS.

   a. Sampling
      i. The sampling plan is designed for testing of representative fish to provide 95% confidence that disease(s) of concern will be detected in the population given a prevalence detection threshold of 2% or less. Sampling preference should be on the susceptible species, at the appropriate life stage and at times of the year when temperature and season offer the best opportunity to detect the pathogen, as well as moribund animals when available.
         1. To achieve this confidence, sampling of 175 animals will typically suffice; however, populations with fewer than 1,500 animals may be eligible to reduce the total sample size. The "Animal Sample Size Calculator" can be used to determine these sample sizes. To calculate, 1) input 85% into the "Diagnostic Test Sensitivity (Sn)" box in the top left hand corner; 2) locate the population size under "Herd or Flock Size"; 3) then locate the 2.00% "Prevalence of Disease" column to find the minimum sample size for the population of interest (https://www.aphis.usda.gov/aphis/ourfocus/animalhealth/ceah-toolbox/overview-calculators-tools).
         2. Certain premises may contain multiple epidemiologically distinct populations (i.e., separate populations without clear avenues for pathogen exchange between them). If so, each epidemiologically distinct population should be sampled separately, following the specifications described in this document.
      ii. Sampling and testing are conducted twice annually, at a minimum to be conducted three or more months apart.
      iii. Samples are collected and submitted by an USDA Accredited Veterinarian.

   b. Testing
      i. Test method used is at least 85% sensitive for the pathogen of concern, assuming 100% specificity following confirmatory testing.
      ii. Testing is performed at a laboratory acceptable to APHIS (i.e., laboratory test method is approved by APHIS for a specific pathogen of concern; laboratory is accredited by AAVLD; or laboratory is accredited by ISO9001 series).

2. **Risk Mitigations Are In Place**

In order to develop appropriate risk mitigation, the premises must undergo risk evaluation for the pathways of disease introduction specific to premises. These mitigations must be outlined in a written, effective biosecurity plan, with associated activity logs, addressing pathogens of concern in all of the following areas:

   a. Animals
      i. Only animals of equal or higher health status are allowed onto the farm
      ii. Animals must be separated by life stage on the farm and/or adhere to all-in all-out management practices

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

   c. Feed
      i. Feed ingredients DO NOT contain pathogen(s) of concern for susceptible or vector species.

   d. Vectors/Fomites
      i. Cleaning and disinfection protocols are appropriate for pathogens of concern.
      ii. Fallowing is instituted for "hard breaks" between year classes/life stages, as appropriate for pathogens of concern.
      iii. Parasite, pest, and predator management as appropriate for pathogens of concern.