

Criteria for Establishing Premises Freedom for Pathogens of Concern in Aquaculture Settings

[National Aquaculture Health Plan & Standards (NAHP&S) Health Inspection Option]

- I. Authority
- II. Definitions
- III. Steps to Establishing Premises Freedom
- IV. Maintaining Premises Freedom
- V. Additional Guidance on Premises Freedom

I. *Authority*

APHIS is the Competent Authority for protecting and promoting the health of farm-raised aquatic animals. APHIS oversees this premises freedom definition and the designation of facilities that meet these premises freedom requirements. Additionally, under the [National Aquaculture Health Plan & Standards \(NAHP&S\): 2021-2023 | Animal and Plant Health Inspection Service \(usda.gov\)](https://www.usda.gov/nahp), APHIS provides official health inspection options to certify the health of farm-raised aquatic livestock and support the safe and secure movement of aquatic animals, one of which is premises freedom from pathogens of concern.

II. *Definitions*

- **Approved laboratory:** A laboratory with oversight from APHIS for conducting pathogen testing for the purposes of official surveillance, testing, and export requirements.
- **Approved assay:** A laboratory procedure which has been reviewed and approved by APHIS to test for the presence of a specific pathogen for the purposes of official surveillance, testing, and export requirements.
- **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.
- **Premises:** Includes a tract of land or water, and all its buildings, maintained by a single set of services and personnel for aquaculture.
- **Pathogen of concern:** Any infectious pathogen that causes significant impact to aquaculture, aquatic animal production, and/or trade or movement. This typically includes, but is not limited to, pathogens listed by the National List of Reportable Animal Diseases (NLRAD), World Organisation for Animal Health (OIE), and emerging pathogens.
- **Risk pathway:** A route by which pathogens of concern might be introduced onto a premises. These typically include animals, water, feed, vectors, and fomites.

- **Surveillance:** A systematic series of evaluations to determine the health status of a population or region using observational, passive, and targeted approaches in conjunction with test results.

III. *Steps to Establishing Premises Freedom*

For a premises to establish premises freedom for a specific pathogen of concern, it must complete steps 1-5 over two consecutive years as described below. Recognition of premises freedom will be determined by APHIS and a letter will be issued.

- 1. Identify the pathogens of concern to the premises and decide whether premises freedom is needed.**
 - a. A premises may decide that establishing and maintaining premises freedom for a given pathogen of concern will support their business needs. For example, premises freedom may be required for some international export markets including the APHIS Registered Aquaculture Export Facility (RAEF) inspection program, and/or as part of an APHIS program such as the Comprehensive Aquaculture Health Program Standards (CAHPS).
 - b. The pathogen(s) of concern may vary based on the business needs.
 - i. For APHIS programs (such as CAHPS) or as part of a facility's aquatic animal health program, the pathogens of concern may be facility dependent.
 - ii. For international export markets, the pathogens of concern may vary by the destination country. The export requirements to a given country are posted on APHIS' [Live Animal Exports \(Moving Animals to Another Country\) \(usda.gov\)](#) web page.
- 2. Verify if a certain type of testing laboratory must be used, and whether sampling must be conducted by an accredited veterinarian (AV).**
 - a. The type of testing laboratory depends on the purpose for establishing premises freedom.
 - i. For enrollment in an APHIS program such as CAHPS, testing must be done at an APHIS-Approved laboratory ([see live aquatic animal export testing guidance](#)).
 - ii. For international export, the testing laboratory type depends on the destination country. The guidance for live aquatic animal export testing is posted here ([live aquatic animal export testing guidance](#)).
 - b. Whether sampling must be conducted by an accredited veterinarian depends on the purpose for establishing premises freedom.
 - i. For enrollment in an APHIS program such as CAHPS, sampling must be conducted by or under the supervision of an accredited veterinarian or other APHIS approved collector.
 - ii. For international export, sampling must be conducted by or under the supervision of an accredited veterinarian or other APHIS approved collector.
 - iii. Use the APHIS National Veterinary Accreditation Program (NVAP) [self-search tool](#) to find a local accredited veterinarian.
- 3. The premises must have a written biosecurity plan that addresses all the potential pathways of introduction for the pathogens of concern.**
 - a. A risk evaluation should be conducted by the facility in consultation with APHIS to determine the potential pathways of introduction based on the type of animals, the production method used, and their end use.

- b. Once these pathways are identified, the written biosecurity plan must address the biosecurity practices in place to mitigate pathogen introduction through these routes. At a minimum, the written biosecurity plan must address the following pathways (see i. through iv. below), with associated activity logs, available for review (e.g., annual inspections and upon request), ensuring that biosecurity practices are implemented and followed.
 - i. Animals
 - 1. Only animals of equal or higher health status are allowed onto the farm (e.g., animals are sourced from other premises that meet APHIS' premises freedom for at least the same diseases of concern as the receiving farm).
 - 2. Animals must be separated by life stage on the farm and/or adhere to all-in all-out management practices.
 - ii. Water
 - 1. Incoming water originates from a secure water source free from pathogens of concern, such as well or ground water, OR
 - 2. Incoming water is treated and/or managed in a manner to prevent the introduction of pathogens of concern.
 - iii. Feed
 - 1. Feed ingredients DO NOT contain pathogen(s) of concern for susceptible or vector species.
 - iv. Vectors/Fomites
 - 1. Cleaning and disinfection protocols are appropriate for pathogens of concern.
 - 2. Fallowing is instituted for "hard breaks" between year classes/life stages, as appropriate for pathogens of concern.
 - 3. Parasite, pest, and predator management as appropriate for pathogens of concern.
- c. The biosecurity plan must be reviewed and approved by APHIS on an annual basis.

4. Identify the number of distinct populations that exist on the premises.

- a. Before testing can begin, it is important to know if there is more than 1 population on the premises.
 - i. Most premises contain a single population of animals. While there may be different parts of the premises (e.g., tanks, grow out ponds, etc.) there is contact between the animals such as shared waters, structures, environment, aerosols, personnel, or equipment.
 - ii. In some cases, there may be more than one population on the premises because they are epidemiologically distinct. This means that the independent populations do not co-mingle with others via direct or indirect means such as shared water, as above.
- b. Testing must be conducted separately for each distinct population for all pathogens of concern.

5. **Develop an annual surveillance plan (i.e., annual testing of the pathogens of concern) for each distinct population (see #4 above).**

If the purpose of establishing premises freedom is for enrollment in an APHIS program such as CAHPS, or international export, then the official health surveillance sampling plan must be reviewed and approved by APHIS prior to sample collection.

- a. **Sample size:** a proper surveillance plan begins with calculating the number of animals to sample from each population on the premises.
 - i. There are several pieces of information that need to be gathered for the sample size calculation. These include the diagnostic sensitivity of the assay being used, the desired confidence level of detecting an infected animal, and the desired pathogen prevalence detection threshold for the population.
 1. Testing laboratories should provide the diagnostic sensitivity (as a percentage) of the assay if known. If unknown, and the assay is APHIS approved, assume the diagnostic sensitivity is 85%.
 2. The confidence level of detecting an infected animal should be 95%.
 3. The pathogen prevalence detection threshold should be 2% or lower.
 4. This information is then entered into the "[Animal Sample Size Calculator](#)".
 - a) Enter the diagnostic sensitivity value (percentage) of the assay into the "Diagnostic Test Sensitivity" box in the top left corner.
 - b) Enter 95% into the "Confidence Level" box in the top left corner.
 - c) Locate the 2.00% "Prevalence of Disease" column in the table and locate the "Herd or Flock Size" row in the table which corresponds with the population size. Where that column and row intersect equals the minimum number of animals to sample.
 2. If animals will be pooled for testing, the sample size will need to be revised (see point c below).
- b. **Animals for sampling:** certain animals should be sampled to increase the likelihood of detecting the pathogens of concern (if present).
 - i. Sampling should represent the entire population. In general, the collected samples should include a mixture of all life stages in the population. Special consideration should be given to sick (moribund) animals when available, and sampling certain life stages or during seasons when environmental conditions offer the best opportunity to detect the pathogen.
 - ii. If the whole animal is not being sampled, then the tissue which is most likely to contain the pathogen of concern should be collected.
- c. **Pooling of samples:** in some cases, pooling of samples prior to testing is allowed as described below.
 - i. Pooling of samples should consider the specific pathogen assay, species, and purpose of testing. If pooling was performed, it should be noted on the laboratory report.
 1. For international export, pooling requirements may depend on the destination country.
 - ii. **If pooling is allowed, it should be performed by the testing laboratory and the criteria listed below must be followed:**
 1. Most adult animals (or their target tissues) may be pooled in sets of up to five animals/tissues per pool.
 2. Smaller animals may be pooled in larger quantities if needed to meet minimum tissue weights for laboratory processing; however, the laboratory should aim to pool the fewest number of animals as possible

to obtain the required amount of tissue needed for initial and confirmatory testing.

3. For shrimp pooling procedures, please request information using the following email: VSAquacultureHealth@usda.gov.
- d. ***Frequency of sampling:*** sampling as part of the surveillance plan must occur regularly to assure the premises is free of the pathogens of concern.
 - i. Annual surveillance plan may consist of either:
 1. At least two surveys per year with a minimum of three or more months apart, or
 2. More frequent (e.g., monthly) surveys equating to the same annual number of tests if approved by APHIS in advance (e.g., through CAHPS).
 - ii. This sampling plan must be conducted over *at least two consecutive years* to establish premises freedom for the pathogens of concern. All test results must be negative for the pathogens of concern.

IV. *Maintaining Premises Freedom*

For a premises to maintain premises freedom for a pathogen of concern, it must meet all the “Steps to Establishing Premises Freedom” in Section III above, as well as ongoing testing, health checks, and reporting as described below.

1. Once premises freedom is established for a given pathogen, the sampling plan must continue without any breaks in sampling frequency to maintain premises freedom.
2. Recognition of premises freedom will be determined by APHIS and a letter will be issued.
3. All test results must be negative for the specific pathogen(s) of concern for which premises freedom is being sought.
4. The health status of the population must be continually monitored. If morbidity or mortality rates exceed the thresholds, then disease investigations must be initiated through the facilities’ accredited veterinarian to determine what level of response is required.
 - a. If there is a suspicion or a detection (i.e., positive test result) of a pathogen of concern, then it must be immediately reported to APHIS (see Section V. below). Pathogens of concern include those listed by the NLRAD, WOAHA, and emerging pathogens.
5. All documents related to premises freedom must be maintained for at least 3 years and available to APHIS upon request.

V. *Additional Guidance on Premises Freedom*

Specific questions regarding the establishment and/or maintenance of premises freedom should be emailed directly to your Export Trade Services office. To find an office for your state, visit the [Trade Contacts | Animal and Plant Health Inspection Service \(usda.gov\)](#) web page, and select your state from the drop down menu under “Animal and Animal Product Imports and Exports” and “Export Trade Services (by State)”.

In the event of a suspect or positive detection of a pathogen of concern, contact the APHIS Area Veterinarian in Charge (AVIC) immediately. APHIS will then work with the premises to determine

next steps. To find the AVIC for your state, visit [Animal Health Contacts | Animal and Plant Health Inspection Service \(usda.gov\)](#) web page, and select your state from the drop down menu under “District Offices (by State)”.