PREMISES FREEDOM EVALUATION PACKAGE

Signed Declaration of Compliance with APHIS Premises Freedom for Export

1. This request is for (please select one):
   ☐ A. Initial evaluation for premises freedom health status
   ☐ B. Renewal evaluation for premises freedom health status
   During the consecutive 12-month period from (insert dates as mm/dd/yyyy)
   _____ to _____.

2. Company/organization name:

3. Registered Aquaculture Export Facility (RAEF) Approval Number (if facility was previously assigned one):
   _____

4. Name and physical address of facility to be evaluated:

5. Mailing address or address of headquarters (if different from physical address of facility above):

6. Contact person/representative at facility:
   Name:
   Position/Title:
   Telephone Number:
   Email Address:

7. USDA Accredited Veterinarian:
   Name:
   National Accreditation Number (NAN):
   Telephone Number:
   Email Address:

8. As the veterinarian of record for this facility, I certify:
   a. I am BOTH USDA Accredited Category II AND licensed to practice veterinary medicine in the state where this facility is physically located (see #4 above).
   b. I have a Veterinarian-Client-Patient Relationship with this facility.

c. I reviewed the APHIS Criteria for Establishing Premises Freedom for Pathogens of Concern in Aquaculture Settings, and understand the testing and biosecurity components required for a facility to obtain and maintain premises freedom per APHIS.

d. I reviewed the APHIS Criteria for Establishing Premises Freedom for Pathogens of Concern in Aquaculture Settings, and have verified the following:

   i. There is a ***single distinct animal population*** on this facility which is treated as a single epidemiologic unit (as defined in the "Steps to Establishing Premises Freedom" section in the criteria linked above).

      1. If this facility has more than one population, then I will submit a separate Premises Freedom Evaluation package for each population seeking Premises Freedom approval.

   ii. Animal and water flow patterns and critical control points are identified especially with respect to potential pathways of pathogen introduction.

e. I confirmed this facility is seeking premises freedom evaluation and approval at the following standard (select one of the options below).

☐ i. Premises freedom per APHIS (APHIS Criteria for Establishing Premises Freedom for Pathogens of Concern in Aquaculture Settings), or

☐ ii. Premises freedom per a destination country's specified export requirements. If so, indicate the country(ies) below.

f. I verified this facility tested for the applicable pathogens of concern marked in Table 1 below during the past consecutive 12 months at one of the following design prevalence levels (select one of the options below).

☐ i. 95% confidence for 2% assumed pathogen prevalence level (AAPL) per APHIS (APHIS Criteria for Establishing Premises Freedom for Pathogens of Concern in Aquaculture Settings), or

☐ ii. An alternative design prevalence described below [e.g., 95% confidence for 5% assumed pathogen prevalence (APPL)].

g. I verified all testing for the applicable pathogens of concern selected in Table 1 below meet the following criteria:

   i. The sampling plan and animal collection were conducted under my supervision.

   ii. The animals collected for testing represent the entire population of applicable disease-susceptible animals on the premises/at the facility. Susceptible species

are either based on the current WOAH Manual of Diagnostic Tests for Aquatic Animals for a given pathogen of concern, or as defined by a destination country.

iii. The sampling plan prioritizes moribund animals, if present, which are collected and tested separately from apparently healthy animals.

iv. The testing was conducted at a laboratory using an "APHIS-Approved method" for WOAH-listed pathogens, and the testing was conducted at either an "APHIS-Approved method" or "Approved Laboratory" for non-WOAH pathogens in accordance with the APHIS Aquatic Animal Testing Requirements for EXPORT.

v. If pooling of tissues or animals of the samples is performed, then they were done in accordance with APHIS guidelines specified in the APHIS Criteria for Establishing Premises Freedom for Pathogens of Concern in Aquaculture Settings.

h. I verified this facility has biosecurity practices in place that address all the pathways of introduction risk (e.g., critical control points) for each of the pathogens selected in Table 1 below.

i. I completed the Critical Control Point Workbook for each of the pathogens of concern selected in Table 1 below, and have submitted it to APHIS as part of the Premises Freedom Evaluation package for this facility.

j. I will provide to APHIS, upon request, the relevant documentation and analyses on which these attestations are based.

k. I have conferred with the facility's aquatic animal health team (as applicable) regarding all conditions of this declaration.

l. I will report directly to the APHIS Area Veterinarian in Charge (AVIC) if this facility receives a suspect or positive laboratory report, or observe pathognomonic visual evidence of, any of the pathogens selected in Table 1 below or other unusual morbidity or mortality events.

m. I understand the records and documentation supporting the testing and biosecurity claims for this facility will be retained by the client and/or myself for a period of at least 3 years, and available upon request to APHIS.

9. I understand that if APHIS finds errors or shortcomings in the testing data, laboratory reports or biosecurity practices for this facility, APHIS' recognition of Premises Freedom will not be issued until concerns are addressed. If this facility is renewing their Premises Freedom approval and issues are identified, Premises Freedom recognition will be suspended for further APHIS review, which may interrupt trade to countries requiring Premises Freedom declaration.

10. I understand that in order to maintain Premises Freedom, this facility must continue to meet the testing and biosecurity requirements described above.

_____
Signature of Accredited Veterinarian

_____
Name of Accredited Veterinarian

_____
National Accreditation Number (NAN)

_____
State and License #

_____
Date

All the following documents must be submitted to APHIS as part of the Premises Freedom Evaluation Package:

1. Signed Declaration of Compliance with APHIS Premises Freedom for Export
2. Table 1. Pathogens of Concern
   - *Use the instructions on the table to determine how many tables must be submitted based on the number of susceptible species and pathogens of concern.*
3. Critical Control Point Workbook
   - *Use the instructions in the workbook to determine how many workbooks must be submitted based on the number of populations in the facility.*

PREMISES FREEDOM EVALUATION PACKAGE

Table 1. Pathogens of Concern

Complete the table below to indicate the pathogens of concern for which this facility is seeking a Premises Freedom Evaluation and approval.

- A single table may be completed if the facility is seeking approval for only 1 susceptible species which is susceptible to several pathogens of concern (e.g., *Litopenaeus vannamei* is susceptible to TSV, YHV, and IHHNV); or >1 species which are susceptible to the same pathogens (e.g., *Salmo salar* and *Oncorhynchus mykiss* to VHS and *Gyrodactylus salaris*).

- If the facility is seeking premises freedom approval for >1 susceptible species to different pathogens (e.g., *Cyprinus carpio* to SVC and *Morone saxatilis* to RSIV) then a separate table must be completed for each species.

Species (scientific name AND common name)**:**

Pathogen Name	Abbreviation or Common Name	Facility tested negative at the level selected in Declaration Statement 8.f.
Fish Pathogens: WOAH-Listed		
Aphanomyces invadens	Epizootic ulcerative syndrome (EUS)	☐
Epizootic hematopoietic necrosis virus	EHNV	☐
Gyrodactylus salaris		☐
Infectious salmon anemia virus HPR-deleted	ISAV pathogenic	☐
Infectious salmon anemia virus HPR0	ISAV non-pathogenic	☐
Infectious hematopoietic necrosis virus	IHNV	☐
Koi herpesvirus	KHV	☐
Red sea bream iridovirus	RSIV	☐
Salmonid alphavirus	SAV	☐
Spring viremia of carp virus	SVCV	☐
Tilapia lake virus	TiLV	☐
Viral hemorrhagic septicemia virus	VHSV	☐

Pathogen Name	Abbreviation or Common Name	Facility tested negative at the level selected in Declaration Statement 8.f.
Fish Pathogens: Others		
Aeromonas salmonicida	furunculosis	☐
Ceratomyxa shasta		☐
Channel catfish virus	CCV	☐
Heterosporosis		☐
Infectious pancreatic necrosis virus	IPN	☐
Lactococcus garvieae		☐
Largemouth bass virus	LMBV	☐
Myxobolus cerebralis	MXY Whirling disease	☐
Oncorhynchus masou virus	OMV	☐
Piscine myocarditis virus	PMV	☐
Piscirickettsia salmonis	PRS	☐
Renibacterium salmonarum	Bacterial kidney disease (BKD)	☐
Salmon Gill Poxvirus	SGPV	☐
Schyzocotyle acheilognathi	Asian tapeworm	☐
Tetracapsuloides bryosalmonae	Proliferative kidney disease	☐
Viral nervous necrosis/ Viral encephalopathy retinopathy	VNN/VER	☐
Yersinia ruckeri	Enteric redmouth disease	☐
Mollusk Pathogens: WOAH-Listed		
Abalone herpesvirus		☐
Bonamia ostreae		☐
Bonamia exitiosa		☐
Marteilia refringens		☐
Perkinsus marinus	Dermo	☐
Perkinsus olseni		☐
Xenohaliotis californiensis	Withering syndrome of abalone	☐

Pathogen Name	Abbreviation or Common Name	Facility tested negative at the level selected in Declaration Statement 8.f.
Mollusk Pathogens: Others		
Clam neoplasia		☐
Haplosporidium nelsoni	MSX	☐
Hemocytic neoplasia of oysters		☐
Juvenile oyster disease (JOD)	Roseovarius Oyster Disease (ROD)	☐
Marteiliodes chungmuensis		☐
Mikrocytos mackini	Denman Island Disease	☐
Mucochytrium quahogii	Quahog Parasite Unknown	☐
Ostreid herpesvirus -1	OsHV1	☐
Crustacean Pathogens: WOAH-Listed		
Acute hepatopancreatic necrosis disease	AHPND; Early mortality Syndrome (EMS)	☐
Aphanomyces astaci	Crayfish plague	☐
Decapod iridescent virus 1	DIV1; Shrimp hemocyte iridescent virus (SHIV)	☐
Hepatobacter penaei	Necrotizing hepatopancreatitis (NHP-B)	☐
Infectious hypodermal and hematopoietic necrosis virus	IHHNV	☐
Infectious myonecrosis virus	IMV; IMNV	☐
Macrobrachium rosenbergii nodavirus	MrNV; White tail disease	☐
Taura Syndrome virus	TSV	☐
White spot syndrome virus	WSSV	☐
Yellow head virus-1	YHV-1	☐
Crustacean Pathogens: Others		
Baculovirus penaei virus	BPV	☐
Covert Mortality Nodavirus	CMV	☐
Enterocytozoon hepatopenaei	EHP	☐
Hepatopancreatic parvovirus	HPV	☐
Laem-Singh Virus	LSV	☐

Pathogen Name	Abbreviation or Common Name	Facility tested negative at the level selected in Declaration Statement 8.f.
Crustacean Pathogens: Others cont.		
Mourilyan Virus	MV	☐
Penaeus vannamei nodavirus	PvNV	☐
		☐
Other Pathogens (write in below)		
		☐
		☐
		☐
		☐

PREMISES FREEDOM EVALUATION PACKAGE

Critical Control Point (CCP) Workbook

Complete the tables below for all 5 potential pathways of pathogen introduction (i.e., critical control points) for the population for which this facility is seeking a Premises Freedom Evaluation and approval.

- A single Critical Control Point Workbook must be completed if there is only 1 population on the facility and there is only 1 water source.
    - For example: There is 1 population of *Oncorhynchus mykiss* on the facility which has only 1 water source via freshwater well.
- If the facility is seeking premises freedom approval for >1 population on the facility, then a separate Premises Freedom Evaluation package, including separate Critical Control Point Workbooks, must be completed for each population.
    - For example: The *Litopenaeus vannamei* broodstock are determined to be a separate population than the other lifestages for grow out on a given facility, then a Premises Freedom Evaluation package must be completed for the broodstock population and a separate one for the grow out population.
- If the facility is seeking premises freedom approval for only 1 population on the facility, but there is >1 water source, then a single Critical Control Point Workbook must be completed, and the "CCP 2: Water" section below must be completed for each water source.
    - For example: There is 1 population of *Oncorhynchus mykiss* on the facility which has 3 water sources (freshwater well, municipal, and chlorinated surface water), so a single Critical Control Point Workbook must be completed, and the "CCP: Water" section must be completed for water source # 1 (freshwater well), water source # 2(municipal), water source #3 (chlorinated surface water).

Critical Control Point 1: Animal Source(s)

A. Indicate the total number of distinct animal populations at the facility.

Number of distinct animal populations = _____

B. If there is more than one distinct animal population at the facility, then list the name the facility uses to identify the population for which this Critical Control Point Workbook applies. See the instructions above for completing Critical Control Point Workbook for other populations in this facility (if applicable).

Name of Population = _____

C. Complete the table below for the distinct animal population list above.

CCP1: Animal Sources (*required*)		
Population #1		
Criteria	**Answer**	
	YES	**NO**
Are only animals of equal or higher health status introduced to the facility? This means all incoming animals are tested at the level indicated on 8.f., for all the pathogens of concern selected in Table 1.	◯	◯
Does the facility maintain health records for at least 3 years for all incoming animals to show they are of equal or higher health status?	◯	◯

Critical Control Point 2: Water Source(s)

A. Indicate the total number of water sources that are epidemiologically linked to the population(s) listed above for this facility.

Number of water sources = _____

B. If there is more than one water source, then list the names and types below.
(examples may include: freshwater well, saltwater well, raw surface water, chlorinated surface water, municipal water, etc.)

Name of Water Source #1 = _____

Name of Water Source #2 = _____

Name of Water Source #3 = _____

Name of Water Source #4 = _____

Name of Water Source #5 = _____

C. Complete the table(s) below for each water source.

CCP2: Water Sources (*required*)		
Water Source #1		
Criteria	**Answer**	
	YES	**NO**
Does this influent water originate from a protected source with no plausible exposure to, or contamination with, the pathogens of concern selected in Table 1? *This includes the absence of other susceptible species to the pathogens of concern in the water source.*	◯	◯
If yes, then proceed to the next table.		
If no, then is this influent water source treated and/or managed in a manner to prevent the introduction of the pathogens of concern selected in Table 1? *Describe all the mitigations steps in place to treat and/or managed this water source.*		

CCP2: Water Sources (*if applicable*)		
Water Source #2		
Criteria	**Answer**	
	YES	**NO**
Does this influent water originate from a protected source with no plausible exposure to, or contamination with, the pathogens of concern selected in Table 1? *This includes the absence of other susceptible species to the pathogens of concern in the water source.*	○	○
If yes, then proceed to the next table.		
If no, then is this influent water source treated and/or managed in a manner to prevent the introduction of the pathogens of concern selected in Table 1? *Describe all the mitigations steps in place to treat and/or managed this water source.*		

CCP2: Water Sources (*if applicable*)		
Water Source #3		
Criteria	**Answer**	
	YES	**NO**
Does this influent water originate from a protected source with no plausible exposure to, or contamination with, the pathogens of concern selected in Table 1? *This includes the absence of other susceptible species to the pathogens of concern in the water source.*	○	○
If yes, then proceed to the next table.		
If no, then is this influent water source treated and/or managed in a manner to prevent the introduction of the pathogens of concern selected in Table 1? *Describe all the mitigations steps in place to treat and/or managed this water source.*		

CCP2: Water Sources (*if applicable*)		
Water Source #4		
Criteria	**Answer**	
	YES	**NO**
Does this influent water originate from a protected source with no plausible exposure to, or contamination with, the pathogens of concern selected in Table 1? *This includes the absence of other susceptible species to the pathogens of concern in the water source.*	◯	◯
If yes, then proceed to the next table.		
If no, then is this influent water source treated and/or managed in a manner to prevent the introduction of the pathogens of concern selected in Table 1? *Describe all the mitigations steps in place to treat and/or managed this water source.*		

CCP2: Water Sources (*if applicable*)		
Water Source #5		
Criteria	**Answer**	
	YES	**NO**
Does this influent water originate from a protected source with no plausible exposure to, or contamination with, the pathogens of concern selected in Table 1? *This includes the absence of other susceptible species to the pathogens of concern in the water source.*	◯	◯
If yes, then proceed to the next table.		
If no, then is this influent water source treated and/or managed in a manner to prevent the introduction of the pathogens of concern selected in Table 1? *Describe all the mitigations steps in place to treat and/or managed this water source.*		

Critical Control Point 3: Feed, feed ingredients and Supplements

A. Do any of the feed, feed ingredients, or supplements contain susceptible species for the pathogens of concern selected in Table 1?
   i. If no, then proceed to the "CCP4: Non-human Vectors" section.

   ii. If yes, then indicate the total number and types of feed sources at the facility:

      Feed Type #1 = _____

      Feed Type #2 = _____

      Feed Type #3 = _____

      Feed Type #4 = _____

      Feed Type #5 = _____

   **Use the extra tables at the end of this workbook if needed to list additional feed types and complete their corresponding table.*

B. Complete the table(s) below for each feed type listed above.

CCP3: Feed/Supplements (*required*)
Feed Type #1
Criteria
Describe below how the feed, feed ingredients, or supplements have been tested, treated, and/or processed to inactivate the pathogens of concern selected in Table 1.

CCP3: Feed/Supplements (*if applicable*)
Feed Type #2
Criteria
Describe below how the feed, feed ingredients, or supplements have been tested, treated, and/or processed to inactivate the pathogens of concern selected in Table 1.

CCP3: Feed/Supplements (*if applicable*)
Feed Type #3
Criteria
Describe below how the feed, feed ingredients, or supplements have been tested, treated, and/or processed to inactivate the pathogens of concern selected in Table 1.

CCP3: Feed/Supplements (*if applicable*)
Feed Type #4
Criteria

Critical Control Point 4: Non-human Vectors

A. Complete the table below.

CCP4: Non-human Vectors (*required*)		
Criteria	**Answer**	
	YES	**NO**
Does the facility practice effective parasite, pest, and predator management and control, as appropriate for pathogens of concern selected in Table 1?	◯	◯

Critical Control Point 5: Fomites and Human Vectors

A. Complete the table below.

CCP5: Fomites and Human Vectors (*required*)		
Criteria	**Answer**	
	YES	**NO**
Does the facility restrict access to the premises including a visitor/provider log, and provides appropriate PPE for anyone entering the facility?	◯	◯
Does that facility ensure that the population(s) are not exposed to any incoming shipping containers or water?	◯	◯
Does the facility ensure equipment and gear are site specific (i.e., not shared with other facilities/populations)?	◯	◯

EXTRA TABLES ONLY IF NEEDED

Complete the extra tables below only if the facility has more feed, feed ingredients or supplement types that did not fit in the tables provided above for Critical Control Point 3.

CCP3: Feed/Supplements (*if applicable*)
Feed Type #___ and Name _____
Criteria
Describe below how the feed, feed ingredients, or supplements have been tested, treated, and/or processed to inactivate the pathogens of concern selected in Table 1.

CCP3: Feed/Supplements (*if applicable*)
Feed Type #7__ and Name _____
Criteria
Describe below how the feed, feed ingredients, or supplements have been tested, treated, and/or processed to inactivate the pathogens of concern selected in Table 1.

CCP3: Feed/Supplements (*if applicable*)
Feed Type #___ and Name ________________
Criteria
Describe below how the feed, feed ingredients, or supplements have been tested, treated, and/or processed to inactivate the pathogens of concern selected in Table 1.

CCP3: Feed/Supplements (*if applicable*)
Feed Type #___ and Name ________________
Criteria
Describe below how the feed, feed ingredients, or supplements have been tested, treated, and/or processed to inactivate the pathogens of concern selected in Table 1.

CCP3: Feed/Supplements (*if applicable*)
Feed Type #___ and Name ________________
Criteria
Describe below how the feed, feed ingredients, or supplements have been tested, treated, and/or processed to inactivate the pathogens of concern selected in Table 1.

CCP3: Feed/Supplements (*if applicable*)
Feed Type #___ and Name _________________
Criteria
Describe below how the feed, feed ingredients, or supplements have been tested, treated, and/or processed to inactivate the pathogens of concern selected in Table 1.

CCP3: Feed/Supplements (*if applicable*)
Feed Type #___ and Name _________________
Criteria
Describe below how the feed, feed ingredients, or supplements have been tested, treated, and/or processed to inactivate the pathogens of concern selected in Table 1.

CCP3: Feed/Supplements (*if applicable*)
Feed Type #___ and Name _________________
Criteria
Describe below how the feed, feed ingredients, or supplements have been tested, treated, and/or processed to inactivate the pathogens of concern selected in Table 1.

CCP3: Feed/Supplements (*if applicable*)
Feed Type #___ and Name _____
Criteria
Describe below how the feed, feed ingredients, or supplements have been tested, treated, and/or processed to inactivate the pathogens of concern selected in Table 1.

CCP3: Feed/Supplements (*if applicable*)
Feed Type #___ and Name _____
Criteria
Describe below how the feed, feed ingredients, or supplements have been tested, treated, and/or processed to inactivate the pathogens of concern selected in Table 1.