

USDA APHIS Registration Program for U.S. Exporters of Live and Dead Finfish and Crustacean Commodities intended for Food Service, Retail Use and Further Processing for Human Consumption Regulated under Canada's Schedule III

1 Purpose

To ensure that all USDA APHIS registered facilities that export susceptible species of aquatic animals (<http://www.inspection.gc.ca/animals/aquatic-animals/diseases/susceptible-species/eng/1327162574928/1327162766981>) to Canada have mitigations in place to address the risks of disease introduction that are listed as conditions on the *Statement of the Exporter* (see Annex I) which then allows Canada to waive zoosanitary export health certification.

2 Initial Pre-Export Inspection by a USDA APHIS Veterinary Medical Officer

The exporting company or production facility must undergo and pass an initial pre-export inspection by a USDA APHIS Veterinary Medical Officer to verify compliance with Canada's export requirements on the *Statement of the Exporter* (see Annex I and Annex II). All criteria used in the Registration Program Inspection Checklist (see Annex III) must be reviewed and certified as acceptable by APHIS personnel.

2.1 Components of the Inspection

The following activities are conducted during an APHIS Veterinary Medical Officer inspection:

2.1.1 Examination by visual inspection of the aquatic animals to verify that the population(s) at the registered facility(ies) is/are free from clinical signs of diseases of concern to Canada.

- Inspection and verification of the export procedures and assessment of facility personnel knowledge and ability to implement these procedures to ensure that the aquatic animal population(s) is/ are free from clinical signs of diseases of concern to Canada.

2.1.2 Animal Management Requirements:

The following three requirements must be verified for ALL SHIPMENTS for LIVE AND/OR DEAD aquatic animals for FOOD SERVICE, RETAIL USE and FURTHER PROCESSING in Canada.

The OIE listed disease(s) are compulsorily notifiable to the competent authority in the exporting country and/or reports of suspicion of non-OIE diseases of concern are investigated by the competent (USDA APHIS or state) authority.

- Verification that the registered facility has a standard operating procedure (SOP) and that facility personnel know the procedures for the mandatory notification to USDA APHIS and state authorities of OIE notifiable diseases of aquatic animals, as well as of suspected clinical signs of disease and/or unusual morbidity or mortality.
- "Diseases of concern" refers to Canada's list of susceptible species with the associated diseases of concern as per the website:
<http://www.inspection.gc.ca/animals/aquatic-animals/diseases/susceptible-species/eng/1327162574928/1327162766981>

The aquatic animals to be exported are not under any restriction by the exporting country's competent authority or intended for destruction of slaughter for disease control purposes.

- Verification that the registered facility has an SOP and that facility personnel know the procedures for communication with USDA APHIS and state authorities to check that the aquatic animal population(s) to be exported to Canada is/are not under disease control restrictions.
- Where SOPs need to be developed, the facility will work with an USDA APHIS accredited veterinarian.
- Verification that communications regarding disease control restrictions by USDA APHIS and state authorities are recorded by the registered facility.
- Verification that the registered facility has in place procedures to notify facility personnel in the event that a population of aquatic animals are not eligible for export to Canada due to movement restrictions or a destruction order imposed by USDA APHIS and state authorities for disease control purposes.

The transport water and/or ice that is used for cultured aquatic animals is sourced from the premises of origin of the aquatic animals, or for cultured and/or wild aquatic animals, has been treated in a manner that will prevent the introduction of disease(s) of concern to Canada.

- Verification that if the registered facility uses water and/or ice for transportation, the water and/or ice are sourced from water that is free of diseases of concern to Canada or, treated in a manner which will destroy diseases of concern to Canada. Suggested means of verification are inspection of packaging process with transport water and/or ice and review of SOP; or inspection of water treatment process and review of SOP and water quality records; or review of water/ice supplier records.

In addition to verification of the above requirements, if the exporting company or production facility ships aquatic animals for FURTHER PROCESSING the following two requirements must be verified:

If being shipped live, the aquatic animals were examined within 96 hours prior to export and showed no visible lesions.

OR

If being shipped dead, the aquatic animals were examined post-harvest/slaughter prior to freezing or processing and showed no visible lesions.

- Verification that the registered facility has an SOP and training materials and that facility personnel know the procedures to identify visible lesions and other abnormalities that could be clinical signs of disease.
- Verification by inspection (direct observation or demonstration) that the registered facility adequately completes examination of animals that would allow them to identify any visible lesions that could be clinical signs of disease; and that facility personnel know this must be completed within 96 hours prior to export or 96 hours post-harvest prior to freezing or processing in compliance with the facility specific SOP.
- Verification through review of 96 hour inspection log.

The aquatic animals and/or products were derived from a population that has not experienced any unusual morbidity (signs of illness) or unusual mortality (death) within 3 months prior to export.

- For cultured aquatic animals:
 - Verification through review of the registered facility's morbidity and mortality records that the population(s) of aquatic animals has/have not had any unusual morbidity or mortality since the last inspection.
- For wild aquatic animals:

- o Verification through review of the registered facility's catch records that the population(s) of aquatic animals has/have not had any unusual morbidity or mortality since the last inspection.
- o Verification through review of Fish and Wildlife Service database (<http://www.fws.gov/wildfishsurvey/database/page/intro>) of no disease occurrence.

In addition to verification of the above requirements, if the exporting company or production facility ships LIVE aquatic animals for FOOD SERVICE, RETAIL USE and FURTHER PROCESSING the following two requirements must be verified:

To the best of my knowledge, the shipment is free from visible ectoparasites and intermediate hosts.

- Verification that the registered facility has an SOP and that facility personnel know the procedures for the identification of visible ectoparasites and intermediate hosts. Suggested means of verification are inspection (direct observation or demonstration) of the facility specific procedure for the identification of visible ectoparasites and intermediate hosts; or through review of the SOP.

To the best of my knowledge, only those species specified in the import permit are included in the shipment and the shipment is free from fellow travelers.

- Verification that the registered facility has an SOP and that facility personnel know the procedures for verification that only the aquatic animal species on the import permit is included in the shipment. Suggested means of verification are inspection (direct observation or demonstration) of the facility specific procedure for verifying that only the species of aquatic animals on the import permit are included in the shipment; or through review of the SOP.

2.1.3 Packaging and Shipping Requirements:

The following four requirements must be verified for ALL SHIPMENTS for LIVE AND/OR DEAD aquatic animals for FOOD SERVICE, RETAIL USE and FURTHER PROCESSING in Canada.

The aquatic animals are packaged in shipping containers, holding units and/or conveyances that are either new or cleaned and disinfected.

- Verification that the registered facility uses shipping containers of new materials, or that previously used containers have been cleaned and disinfected. Suggested means of verification include inspection (direct observation or demonstration) of shipping processes or disinfection protocols; inspection of the new shipping containers; review of shipping container disinfection SOP; or review of facility specific shipping container ordering, use and sanitation (if applicable) SOP.

The shipping containers and/or holding units prevent release of the shipping contents (eg. water or animals) while en route.

- Verification that the registered facility uses shipping containers that prevent the release of water and/or animals while en route. Suggested means of verification include inspection of shipping protocols; inspection of the shipping containers; or review of facility specific shipping container ordering, use and sanitation (if applicable) SOP.

The aquatic animal(s) being presented for importation are packaged in a manner which prevents contact or exchange of animals or water between different shipments of aquatic animals on the same conveyance.

- Verification that the registered facility packages the aquatic animals or products to be exported so that animals and/or water do not contact other shipments of aquatic animals in the same conveyance and that exchange of aquatic animals and/or water between shipments is prevented. Suggested means of verification include inspection of packaged aquatic animals or products, or review of facility specific shipping container use or packaging SOP.

The package was labeled indicating the detailed contents, including the location in which the aquatic animal(s) was (were) born, the taxonomic name of the aquatic animal(s), whether the aquatic animal(s) was(were) wild or farmed, and the number or biomass of the aquatic animal(s) in the shipment.

- Verification that the registered facility uses labels with the following relevant information:
Location in which the aquatic animals were born
Taxonomic name of the aquatic animals
Indication that the aquatic animals were farmed or wild origin
Number or biomass of the aquatic animals
- Suggested means of verification include inspection of labeled aquatic animals or products or review of facility specific labeling SOP.

Annex I:

Statement from the Exporter
for live and/or dead finfish and crustaceans exported to Canada for food service and/or retail use

Canadian Import Permit No. _____

I. Origin of Aquatic Animals

Name of the Exporter Company/Production Facility: _____

Address of the Exporter Company/Production Facility: _____

USDA APHIS Facility Registration Number: _____

II. Destination of Aquatic Animals

Name of the Importer: _____

Address of the Importer: _____

III. Transport Information

Transport means and conveyance identification: _____
(e.g. flight number, bill of lading etc.)

IV. Description of the Aquatic Animal Consignment

Date of export as appears on the consignment (i.e. bill of lading): _____

Species (scientific name)	Common name	Origin	Live or Dead	Description of the aquatic animals and/or product	Quantity and/or total weight kg)	Lot identifier or date code	Country of Origin of the aquatic animals and/or product
		☐ Cultured ☐ Wild	☐ Live ☐ Dead				
		☐ Cultured ☐ Wild	☐ Live ☐ Dead				
		☐ Cultured ☐ Wild	☐ Live ☐ Dead				
		☐ Cultured ☐ Wild	☐ Live ☐ Dead				
		☐ Cultured ☐ Wild	☐ Live ☐ Dead				
		☐ Cultured ☐ Wild	☐ Live ☐ Dead				
		☐ Cultured ☐ Wild	☐ Live ☐ Dead				

V. Health Information

I, the undersigned, declare that the live and/or dead finfish and crustaceans described above and intended for export for food service and/or retail use in Canada satisfy the following requirements:

For **live** and **dead** aquatic animal commodities:

1. The exporting company/production facility listed above is currently registered with USDA APHIS for the purposes of exporting aquatic animals to Canada for purposes of food service and/or retail use, and has passed the most recent inspection by USDA APHIS. Date of inspection _____
2. The transport water and/or ice that is used for cultured aquatic animals is sourced from the premises of origin of the aquatic animals, or for cultured and/or wild aquatic animals, has been treated in a manner that will prevent the introduction of disease(s) of concern.

AND for **live** aquatic animal commodities:

3. To the best of my knowledge, the shipment is free from visible ectoparasites and intermediate hosts.
4. To the best of my knowledge, only those species specified in the import permit are included in the shipment and the shipment is free from fellow travelers.

IV. Packaging and Shipping

1. The aquatic animals are packaged in shipping containers, holding units and/or conveyances that are either new or which have been cleaned and disinfected.
2. The shipping containers and/or holding units prevent release of the shipping contents (eg. water or animals) while en route.
3. The aquatic animal(s) are packaged in a manner which prevents contact or exchange of animals or water between different shipments of aquatic animals on the same conveyance.
4. The package was labeled with the following information: commodity (by species); whether commodity is wild/farmed; location of broodstock from which the commodity is derived; and number (or biomass) of animals in the shipment

Name of exporting company employee: _____

Position within the exporting company: _____

Signature: _____ Date: _____

Annex II:

Statement from the Exporter
for live and/or dead finfish and crustaceans exported to Canada for further processing for human consumption

Canadian Import Permit No. _____

I. Origin of Aquatic Animals

Name of the Exporter Company/Production Facility: _____

Address of the Exporter Company/Production Facility: _____

USDA APHIS Facility Registration Number: _____

II. Destination of Aquatic Animals

Name of the Importer: _____

Address of the Importer: _____

III. Transport Information

Transport means and conveyance identification: _____
(e.g. flight number, bill of lading etc.)

IV. Description of the Aquatic Animal Consignment

Date of export as appears on the consignment (i.e. bill of lading): _____

Species (scientific name)	Common name	Origin	Live or Dead	Description of the aquatic animals and/or product	Quantity and/or total weight kg)	Lot identifier or date code	Country of Origin of the aquatic animals and/or product
		☐ Cultured ☐ Wild	☐ Live ☐ Dead				
		☐ Cultured ☐ Wild	☐ Live ☐ Dead				
		☐ Cultured ☐ Wild	☐ Live ☐ Dead				
		☐ Cultured ☐ Wild	☐ Live ☐ Dead				
		☐ Cultured ☐ Wild	☐ Live ☐ Dead				
		☐ Cultured ☐ Wild	☐ Live ☐ Dead				
		☐ Cultured ☐ Wild	☐ Live ☐ Dead				

V. Health Information

I, the undersigned, declare that the live and/or dead finfish and crustaceans described above and intended for export for further processing in Canada satisfy the following requirements:

For **live** and **dead** aquatic animal commodities:

1. The exporting company/production facility listed above is currently registered with USDA APHIS for the purposes of exporting aquatic animals to Canada for purposes of further processing for human consumption, and has passed the most recent inspection by USDA APHIS. Date of inspection _____
2. The transport water and/or ice that is used for cultured aquatic animals is sourced from the premises of origin of the aquatic animals, or for cultured and/or wild aquatic animals, has been treated in a manner that will prevent the introduction of disease(s) of concern.
3. ☐ **a)** If being shipped live, the aquatic animals were examined within 96 hours prior to export and showed no visible lesions.

OR
☐ **b)** If being shipped dead, the aquatic animals were examined post-harvest /slaughter prior to freezing or processing and showed no visible lesions.
4. The aquatic animals and/or products were derived from a population that has not experienced usual morbidity (signs of illness) or unusual mortality (death) within 3 months prior to export.

AND for **live** aquatic animal commodities:

5. To the best of my knowledge, the shipment is free from visible ectoparasites and intermediate hosts.
6. To the best of my knowledge, only those species specified in the import permit are included in the shipment and the shipment is free from fellow travelers.

IV. Packaging and Shipping

1. The aquatic animals are packaged in shipping containers, holding units and/or conveyances that are either new or which have been cleaned and disinfected.
2. The shipping containers and/or holding units prevent release of the shipping contents (eg. water or animals) while en route.
3. The aquatic animal(s) are packaged in a manner which prevents contact or exchange of animals or water between different shipments of aquatic animals on the same conveyance.
4. The package was labeled with the following information: commodity (by species); whether commodity is wild/farmed; location of broodstock from which the commodity is derived; and number (or biomass) of animals in the shipment

Name of exporting company employee: _____

Position within the exporting company: _____

Signature: _____ Date: _____

Annex III:

Registration Program Inspection Checklist

for facilities exporting live and/or dead aquatic animals to Canada for food service, retail use
and/or further processing for human consumption

Aquatic Facility

Name of the Exporter Company/Production Facility: _____

Address of the Exporter Company/Production Facility: _____

Phone of the Exporter Company/Production Facility: _____

Email address of the Exporter Company/Production Facility: _____

Date of USDA inspection: _____

For food service and/or retail use:

- ☐ Standard operating procedure (SOP) for mandatory notification of suspected clinical signs of disease and unusual morbidity or mortality.
- ☐ SOP for communication with USDA APHIS to ensure aquatic animal population(s) to be exported to Canada is/are not under disease control restrictions, communications are recorded and facility personnel staff are notified of disease control restrictions.
- ☐ SOP for transport water and/or ice.
- ☐ SOP for identification of visible ectoparasites and intermediate hosts. (Not required if only shipping dead animals)
- ☐ SOP for verification that only aquatic animals on import permit are included in the shipment. (Not required if only shipping dead animals)
- ☐ SOP for packaging and shipping procedures.
- ☐ SOP for labelling packages.

In addition to verification of the above requirements, for further processing the following two requirements must be verified:

- ☐ SOP for identification of clinical signs of diseases within 96 hours prior to export or 96 hours post-harvest/slaughter prior to freezing and/or processing.
- ☐ Morbidity and mortality records for cultured animals and catch records for wild caught animals.

Annex IV:

Maintenance, suspension, revocation or other changes in registration status for U.S. premises registered with USDA APHIS for exporting aquatic animals to Canada for purposes of food service, retail use and further processing for human consumption

1. Entry into USDA APHIS Facility Registration Program – Initial Pre-Export USDA APHIS Veterinary Medical Officer Inspection

The exporting company or production facility must undergo and pass an initial pre-export inspection by a USDA APHIS Veterinary Medical Officer to verify compliance with Canada's export requirements on the *Statement of the Exporter* (see Annex I and Annex II).

- a) If the facility is fully compliant with the conditions of the *Statement of the Exporter*, it will be registered with USDA APHIS as an approved registered facility.
- b) If the facility is not fully compliant with the conditions of the *Statement of the Exporter* and has deficiencies that need to be corrected, USDA APHIS will work with the facility to ensure that corrective action is taken. Once corrective action is completed, the facility must undergo repeated USDA APHIS Veterinary Medical Officer Inspections until the facility is in full compliance with the conditions of the *Statement of the Exporter* in order to become an approved registered facility.
- c) Facilities will not be eligible for export to Canada under the USDA APHIS Registration Program until they have successfully completed and are fully compliant with an initial USDA APHIS Veterinary Medical Officer inspection.

2. Maintenance of USDA APHIS Facility Registration Status

Once a registered facility exporting **dead** aquatic animals for food service, retail use and/or for further processing for human consumption has successfully completed and is fully compliant with an initial USDA APHIS Veterinary Medical Officer inspection, the facility will be subject to annual re-inspections for maintenance of approved registered facility status.

Once a registered facility exporting **live** aquatic animals for food service, retail use and/or for further processing for human consumption has successfully completed and is fully compliant with an initial USDA APHIS Veterinary Medical Officer inspection, the facility will be subject to a re-inspection at 6 months in the first year of participation in the registration program and then annual re-inspections beginning in the second year of participation in the registration program for maintenance of approved registered facility status.

Additional facility inspections may be required more frequently, based on the nature of any non-compliance.

During annual maintenance inspections, if the registered facility is found to be non-compliant with any of the conditions on the *Statement of the Exporter*, or upon notification of non-compliance by Canada to USDA APHIS, the facility's registered facility status will be suspended or revoked as per Section 3.

3. Suspension or Revocation of USDA Registered Facility Status

USDA APHIS will suspend or revoke a facility's registration if it is found to be non-compliant with the conditions on the *Statement of the Exporter* during annual maintenance inspections or audit by Canada, or upon notifications of non-compliance from Canada.

During annual maintenance inspection by USDA APHIS or audit by Canada, suspension or revocation of approved registered premises status will occur if it was determined that:

- a) the exporting facility introduced animals, water or other materials of unknown health status resulting in exposure of the facility or aquatic animal populations to infectious agents and risks of disease introduction were not mitigated;
- b) an inspection by USDA APHIS did not occur annually or as otherwise required under Section 3 and 4;
- c) there is suspicion or confirmation of a disease or an outbreak has occurred in the registered facility; or
- d) at any time the aquatic animals and/or products at a registered facility have clinical signs of disease.

Canadian Notifications of Non-Compliance to USDA APHIS:

- a) If Canada notifies USDA APHIS of issues with a shipment due to labeling requirements, USDA APHIS will contact and work with the facility to correct the issue. If a facility has a second incident involving an issue with labeling requirements, USDA APHIS will suspend or revoke the facility's approved registration facility status, on either a provisional or permanent basis and provide the facility a list of any required corrective actions to be taken.
- b) If Canada notifies USDA APHIS of issues with a shipment (i.e. it is refused entry, visible lesions are present on the aquatic animals and/or products, shipping containers do not prevent the release of water while en route etc.)) then USDA APHIS will suspend or revoke the facility's approved registration facility status, on either a provisional or permanent basis and provide the facility a list of any required corrective actions to be taken.

A facility may request to withdraw from a currently approved registered facility status at any time by notifying USDA APHIS.

If the approved registered facility status is withdrawn, the premises will no longer be eligible to export commodities to Canada. Canada will be notified by USDA APHIS of the facility's status change.

4. Regaining USDA Registered Facility Status after Suspension or Revocation

An exporting facility may regain registered facility status only upon satisfactory correction of non-compliance with the conditions on the *Statement of the Exporter* and a satisfactory re-inspection by USDA APHIS.

If the suspension or revocation of a registered facility status is due to a disease outbreak, the disease must have been successfully eradicated and evidence provided to USDA APHIS.

If the suspension or revocation of a registered facility status is due to presence of clinical signs of disease in aquatic animals and/or products, the exporting facility must complete sampling and testing in coordination with criteria to be provided by USDA APHIS (after consultation with Canadian authorities). All test results must be negative for the diseases of concern to Canada.

All corrective actions indicated by USDA APHIS must be completed by the facility before a re-inspection may be requested. If at re-inspection the facility is in full compliance (all required corrective actions completed), the facility will be re-approved by USDA APHIS.

Once an exporting facility has regained approved registered facility status by completing a fully compliant Veterinary Medical Officer re-inspection by USDA APHIS, the facility must undergo **re-inspection at a 6 month**

interval. If the facility is found to be fully compliant at the 6 month re-inspection, then the re-inspection frequency will revert back to an annual interval.

5. User Fees

VS Area Office will charge a user fee for the facility inspection as provided in Title 9 of the Code of Federal Regulation section 130.30.

FINAL