

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.