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**CHAPTER 2, SUBJECT 1
CERTIFICATES OF REGISTRATION**

1. SCOPE

This subject outlines the policies and procedures governing the registration of fish processing establishments that are under the jurisdiction of the *Fish Inspection Act* and *Fish Inspection Regulations*.

2. AUTHORITIES

Fish Inspection Act, R.S. 1985, c. F-12
Fish Inspection Regulations, C.R.C., c. 802
Canadian Food Inspection Agency Fees Notice

3. POLICY

3.1 General

3.1.1 Any establishment, including a fishing vessel, where fish and fish products are processed for export (which includes shipment from one province to another) must have a certificate of registration issued in accordance with the *Fish Inspection Regulations* (FIR). Establishments where fish and fish products are processed for export will hereafter be referred to as registered establishments.

There are a number of exceptions to the requirement to process or to store fish for export in a registered establishment. These exceptions are set out in subsections 14(2) and 14(3) of the FIR and include, but are not limited to, the following:

- ▶ Persons licenced to catch fish under the *Fisheries Act* may process their catch as whole or dressed unfrozen fish or as salted or pickled fish (fisher-packers). Fisher-packers may not process fish roe for export. Processing may occur on board their vessel or on shore at a location that is owned or leased by the fisher-packer. When processing occurs on shore, a person that did not participate in catching the fish must not assist with processing the fish. Fish must not be processed when there is a condition that may lead to serious contamination or to product that is tainted, decomposed or unwholesome.
- ▶ Fish imported into Canada by a person holding a valid

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import licence that is exported for direct sale to the consumer without further processing.

- ▶ Final products processed by a registered establishment may be stored in an unregistered cold-storage or other unregistered locations prior to marketing provided that the fish is not further processed in any manner at the unregistered establishment.
- ▶ Live fish, including live lobsters and crabs, and fresh whole or dressed fish, may be washed, iced or boxed at an unregistered establishment. Exceptions to this includes:
 - shellfish;
 - scallop adductor muscle after unloading from catch vessel;
 - echinoderms;
 - fish raised in an aquaculture operation; and
 - crustaceans, other than noted above;

which must all be processed, which includes washing, boxing and icing, at a registered establishment. Note that an unregistered establishment cannot dress or grade fish unless the dressing or grading is needed to preserve product quality and safety before delivery to a registered establishment.

- ▶ Fishing vessels that are not registered may freeze whole or dressed fish, other than shellfish, echinoderms or crustaceans provided that the fish are destined for further processing at a registered establishment. Shrimp are excluded from the types of crustaceans identified above and may be frozen by an unregistered vessel provided they are then delivered to a registered establishment for further processing.
- ▶ Fishing vessels that are not registered may remove the adductor muscles from scallops with or without the roe attached.
- ▶ Initial actions taken by a fisher or an unregistered establishment to preserve the safety and quality of fish before delivery to a registered establishment for further processing before export. These actions would be limited to those that are considered necessary to preserve the quality and safety of the fish, and would include freezing, dressing or icing as long as they were performed in compliance with the FIR.

Federal registration is available to all Canadian fish

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processing establishments where the operator of the establishment is willing and able to comply with the requirements of the FIR (see Section 3.5).

- 3.1.2 An establishment's certificate of registration includes all buildings that are found at a single location and that are used together as part of its operation(s) (see Chapter 2, Subject 3 of this manual).
- 3.1.3 An establishment located in Canada that processes fish, and sells that fish via the Internet or mail order sales to a person located outside of the province where the establishment is located, would be subject to the requirements of the FIR and must be registered. These cases should be carefully evaluated to determine whether or not there is intent to export fish as companies that advertise fish via the Internet or via mail order catalogues for only intra-provincial sale would not be subject to the requirements of the FIR and therefore do not require registration.
- 3.1.4 When actions taken to export fish are performed entirely by the consumer of the fish without assistance from any other person, then those actions are exempt from the inspection requirements of the FIR, since the fish is being exported by a person for their own personal consumption. Examples include cases where a person purchases fish from an establishment, and then transports it across a border for that person's own consumption, or processes the fish and then transports the fish across a border for his or her own personal consumption. In this example, the establishment from which the fish was exported need not be registered.
- 3.1.5 All fish processing and fish products in a registered plant must be identified and included in the QMP Plan. Although fish products for intra-provincial sale are not subject to the FIR, it is not possible to leave them out of the Quality Management Program (QMP) Plan.

Once a fish plant is federally registered, all of its facilities, equipment and processing operations are subject to regulatory requirements at all times, regardless of whether the fish products produced in it are for export or intra-provincial trade.

A person may request the operator of a registered establishment to custom process fish for that individual's own personal consumption. Such cases could include the custom processing of sport caught fish. The registered establishment must include the controls they will

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implement for that service in their QMP Plan.

3.2 Administration of Certificates of Registration

3.2.1 The authority to issue and to take other actions with respect to an establishment's certificate of registration rests with the President of the CFIA or delegate. Regional Directors have been identified as delegates to the President for these activities.

3.2.2 Regional Directors will establish a process to issue, renew, suspend, revoke, reinstate, amend, inactivate, or reactivate a certificate of registration in their region in accordance with these policies and procedures. The process should include maintenance of adequate records of all registered establishments, including all relevant information and documents in cases where an application for a new or renewed certificate of registration or a request for reinstatement, inactivation, reactivation, or amendment is refused. Records should include the reason(s) for the refusal. The procedures should identify the appropriate personnel who will be involved in the different steps of the process. The identity of appropriate personnel to perform these tasks will be based on factors such as their job descriptions, designation as an inspector under the authorities of the Fish Inspection Act, and appropriate training and experience.

3.3 Certificates of Registration for New Establishments

3.3.1 Upon accepting an application with all required information and payment of fees, the CFIA will issue a certificate of registration for a new establishment provided that it meets the requirements of Schedules I and II of the FIR, it is free from serious contamination, and it has an acceptable QMP Plan. The process to evaluate the application and verify that the applicant will meet the conditions of registration should be determined by personnel with appropriate training and experience to verify compliance with the FIR.

A newly registered establishment must meet all requirements of Schedule I of the FIR, including those that apply to establishments constructed after they came into force in April, 1999.

The CFIA will work co-operatively with applicants to provide them with adequate information on all regulatory

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requirements. The applicant must take appropriate corrective actions when they do not meet these requirements before the certificate of registration will be issued.

A certificate of registration will not be issued for an establishment when the Regional Director has determined that there are reasonable grounds to believe that the applicant will not comply with the FIR.

3.3.2 An establishment will be considered a "new" establishment for the purposes of an application for a certificate of registration when:

- a) it has not been previously federally registered under the FIR; or
- b) it had previously been registered, and a sufficient period of time has elapsed after the registration expired such that the establishment, and/or any previously developed QMP Plan, may not comply with the requirements of the FIR, and in the opinion of the Regional Director or delegate, a Systems Verification and/or a Schedule I and II inspection must be performed to verify compliance; or
- c) it is currently registered under the Meat Inspection Act or the Canada Agricultural Products Act but has not yet been registered under the Fish Inspection Act and Regulations; or
- d) in the case of a currently registered establishment, the processing facilities are moved from either:
 - i) one building to another at the location identified on its Certificate of Registration; or
 - ii) the location identified on its Certificate of Registration to any other location.

3.4 Renewal of Certificates of Registration for Existing Establishments

3.4.1 Upon receiving an application, the CFIA will renew a certificate of registration for an existing establishment that is currently registered, provided that it meets the requirements of the FIR.

3.4.2 The process to renew a certificate of registration will include a review of the information in the application, and a review of the status of the establishment and its

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QMP Plan. When there has been no opportunity to conduct any Compliance Verification activities at an establishment during the past year, an inspector should verify compliance with Schedule I before renewing the certificate of registration.

- 3.4.3 The establishment is responsible to apply for renewal of their certificate of registration before it expires. No fish may be processed for export at an establishment with an expired certificate of registration.

3.5 Refusal to Issue or Renew a Certificate of Registration

- 3.5.1 A certificate of registration will not be withheld from an establishment when the operator of the establishment is willing and/or able to comply with the FIR through co-operation with the CFIA.

The Regional Director's decision to refuse to issue or to renew a certificate of registration will be the result of the operator of the establishment showing a willful, reckless, or negligent disregard for complying with the conditions of the certificate as prescribed by the FIR. Examples of when a Regional Director will refuse to issue or renew a certificate of registration for an establishment include, but are not limited to, the following:

- a) there are reasonable grounds to believe that the applicant or the operator of the establishment has provided false information to the CFIA for the purpose of obtaining a certificate;
- b) the establishment is not free from serious contamination;
- c) the establishment is not operated in accordance with its QMP Plan;
- d) the operator has not taken actions in response to a complaint that suggests that the fish processed at the establishment may present a risk to the health of consumers, or has not informed the CFIA when their actions indicate that the complaint was valid and the health of consumers is at risk; or
- e) the operator of the establishment otherwise fails to comply with the FIR or a condition of the certificate of registration.

- 3.5.2 A certificate of registration will not be renewed if the

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establishment has unpaid fish inspection fees (see Chapter 2, Subject 3 of this manual).

3.6 Expiry of a Certificate of Registration

3.6.1 A certificate of registration expires one year after the date of issue. In the case of a certificate of registration that is renewed before expiry, this will be one year from the date which is identified upon the existing certificate of registration.

3.6.2 Once a certificate of registration has expired, no processing of fish or fish products for export may take place at that establishment. The certificate may be renewed at a later date. The expiry date for the certificate of registration will be one year following the date of issue.

3.7 Certificates of Registration Not Assignable or Transferable

3.7.1 A certificate of registration is issued to the applicant in respect of the establishment identified upon the certificate. A certificate of registration is not assignable or transferrable to any other person, nor is it assignable or transferrable to any other establishment.

3.7.2 The owner of an establishment cannot transfer the certificate of registration to another person or company during a change of ownership of that establishment. A change in ownership of an establishment will be considered to have occurred when the owner, (e.g., person, partner(s) or company) identified in the application for the certificate of registration has (have) transferred the controlling interest of the establishment to another person(s) or company.

This does not include a change in shareholder status, or the transfer of ownership of a parent company, provided that the immediate ownership of the registered establishment remains the same (see Section 3.8 below).

3.8 Amendment of a Certificate of Registration

3.8.1 The holder of a valid certificate of registration may request its amendment. An amendment would be required in situations where there are changes in:

- an officer of the company named in the application for the certificate provided that person was not the sole or part owner of the establishment;

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- ▶ the legal name of the establishment;
- ▶ the size of the processing area; or
- ▶ the types of fish processing operations conducted at the establishment.

3.8.2 Upon written request by the holder of a certificate of registration, the CFIA will amend the certificate, provided that all the necessary information has been supplied and the establishment meets the requirements of the FIR.

When the amendment concerns a change in the size of the processing area, the establishment may require inspection to verify compliance with the requirements of Schedule I as a result of any renovations.

When the amendment concerns a change in processing operations, a systems verification of the amendments to the QMP Plan should be conducted to verify that adequate controls have been implemented.

3.8.3 The certificate of registration will not be amended if the establishment has unpaid fees (see Chapter 2, Subject 3 of this manual).

3.9 Certificate of Registration Becomes Void

3.9.1 A certificate of registration becomes void in any one of the following situations:

- a) there is a change in the ownership of the registered establishment identified on the certificate of registration (see section 3.7);
- b) the establishment is subject to receivership, or the owner has made an assignment in bankruptcy with regards to the registered establishment (see section 3.11 below regarding a temporary certificate of registration);
- c) the owner of the establishment permanently ceases to operate it as a fish processing business (see section 3.10 below regarding inactivation of the certificate when the owner of the establishment plans to temporarily cease fish processing activities);
- d) the operator of the establishment surrenders the certificate of registration to the CFIA; or

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e) the registered establishment and/or the equipment or conveyances contained in it are destroyed or damaged to the extent that it is not possible to conduct fish processing or storage operations in compliance with the FIR.

3.9.2 Once a certificate of registration for an establishment becomes void, no fish or fish products may be processed for export at the establishment until a new certificate of registration has been issued for the establishment.

3.10 Inactivation of Certificate of Registration

3.10.1 A certificate of registration may be temporarily inactivated upon written request by the operator of a registered establishment. Inactivation is a status of the registration that allows the operator of an establishment to maintain the certificate of registration for the establishment during a period when no processing of fish and fish products for export is taking place.

There are a number of situations in which the operator of an establishment may inactivate the certificate of registration. These include:

- ▶ the establishment operates on a seasonal or intermittent basis, and is now closed;
- ▶ fish or fish products continue to be processed in the establishment, but not for export;
- ▶ the establishment will temporarily be used for another commercial activity; or
- ▶ the establishment operators decide to cease operations in order to make changes to the QMP Plan or the establishment.

3.10.2 The Regional Director will make the decision with respect to the acceptability of the request to inactivate the registration following a review of the information provided by the operator. Inactivation will not be granted if the establishment has unpaid fees (see Chapter 2, Subject 3 of this manual), or the inactivation is requested for fraudulent purposes or to bypass the operator's responsibilities to comply with the conditions of registration.

3.10.3 During the period while an establishment's Certificate of Registration is inactivated, the establishment must comply with the conditions applicable to the status of

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inactivation. No regulatory verification activities will be undertaken in the establishment by the CFIA during this time.

3.10.4 There must be no processing of fish or fish products for export in an establishment once its certificate of registration has been inactivated.

3.10.5 The period of inactivation cannot extend beyond the expiry date of the current certificate of registration.

3.10.6 A holder of a certificate of registration that has been inactivated may request that it be reactivated. Upon written request by the holder of the inactivated certificate, the CFIA will reactivate the certificate of registration following verification that the establishment complies with all conditions of registration prescribed by the FIR to operate the establishment to process fish for export.

3.11 Temporary Certificate of Registration

3.11.1 When the certificate of registration for an establishment becomes void because of receivership or bankruptcy as described in section 3.9, the receiver or trustee in bankruptcy may wish to continue operating the establishment while its future is being determined. The receiver, or the trustee in bankruptcy, may apply for a temporary certificate of registration, which allows the establishment to continue producing and exporting fish and fish products.

3.11.2 Upon receiving an application, the CFIA will issue a temporary certificate of registration to an establishment provided that it meets the requirements of the FIR.

3.11.3 The maximum period of time for a temporary certificate of registration to be valid is 240 days from the date of issue.

3.11.4 A temporary certificate of registration is not assignable or transferrable.

3.12 Suspension of a Certificate of Registration

3.12.1 A Regional Director may suspend an establishment's certificate of registration in situations where the operator of the establishment is unable or unwilling to comply with the FIR. Actions leading to the suspension of an establishment's certificate of registration will be conducted in accordance with the Fish Inspection Program

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Compliance Management Process.

The following situations provide examples of when the CFIA will take actions leading to the suspension of an establishment's certificate of registration:

- ▶ the operator of the establishment has not taken actions to respond to information questioning the safety of fish that was processed or stored in the establishment, or has not informed the CFIA when their actions indicate that the fish is a hazard to the public; or
- ▶ a compliance verification identifies non-conformities and the operator of the establishment is unwilling or unable to address the non-conformities through the development and implementation of an acceptable Corrective Action Plan.

3.12.2 A CFIA Regional Director may, upon request by the holder of the certificate, reinstate a certificate of registration which has been suspended once it has been verified that all instances of non-compliance have been corrected and the requirements of the FIR have been met. The request to reinstate the certificate must be provided in writing within 30 days of the suspension. Assessment criteria used to determine if the certificate of registration should be reinstated will include:

- ▶ an evaluation of the written submission;
- ▶ if applicable, on site verification of any corrective actions; and/or
- ▶ interviews with management and operators through a formal hearing and/or on site visits.

3.13 Revocation of a Certificate of Registration

3.13.1 A Regional Director may revoke an establishment's certificate of registration. Enforcement actions that lead to the revocation of an establishment's certificate of registration will be conducted in accordance with the Fish Inspection Program Compliance Management Process.

Revocation of the certificate of registration will occur following its suspension when the request to reinstate the certificate was denied.

A certificate of registration may also be revoked in situations where there are reasonable grounds to believe

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that the operator of the establishment has provided false information for the purposes of obtaining a certificate.

3.13.2 A CFIA Regional Director may, upon request by the holder of the certificate, reinstate a certificate of registration which has been revoked once it has been verified that all instances of non-compliance have been corrected and the requirements of the FIR have been met. The request to reinstate the certificate must be provided in writing within 30 days of the revocation. Assessment criteria used to determine if the certificate of registration should be reinstated will include:

- ▶ an evaluation of the written submission;
- ▶ if applicable, on site verification of any corrective actions; and/or
- ▶ interviews with management and operators through a formal hearing and/or on site visits.

3.13.3 A CFIA Regional Director may revoke a certificate of registration when an inspector is unable to contact the operator of the establishment for a period of 90 days. This action will not be taken for seasonal operations or establishments with an inactive certificate of registration.

4. PROCEDURES

4.1 General

4.1.1 An establishment will be issued one certificate of registration that will include all of the processing operations conducted within the establishment as requested by the applicant.

Establishments that wish to export shellfish to the United States must be listed on the Interstate Certified Shellfish Shippers List (ICSSL). Refer to Chapter 1 of the Canadian Shellfish Sanitation Program - Manual of Operations for more information on ICSSL listings (to be issued at a later date).

4.1.2 A certificate of registration for an establishment must identify all of the types of processing operations that may be conducted within the establishment (see Appendix B of Chapter 2, Subject 3 of this manual for guidelines on operation types). No processing operation can take place unless the establishment is registered for that type of

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operation as identified on the certificate.

- 4.1.3 Each certificate of registration will be assigned a unique registration number.

Refer to Chapter 1 of the Canadian Shellfish Sanitation Program - Manual of Operations for more information concerning the registration number of an establishment that is listed on the ICSSL (to be issued at a later date).

- 4.1.4 An establishment receiving a new certificate of registration will normally be given a registration number that has not previously been used.

However, where there is a transfer of ownership of a currently registered establishment, the Regional Director may, upon request, issue a certificate of registration to the new owner which bears the same registration number and/or establishment name as the original certificate of registration. This will require verification that the use of the same registration number will not create difficulties in tracing product origin.

- 4.1.5 CFIA Regional Directors will designate personnel to maintain and update information related to the registered fish processing establishment in the appropriate CFIA databases, including its current regulatory status.

Personnel should take the necessary steps to verify that the names of establishments with new or renewed certificates are added to, or maintained on, the appropriate lists of registered establishments maintained by the CFIA.

- 4.1.6 The name of the establishment will be removed from any export list of registered establishments maintained by the CFIA when a certificate of registration expires, is suspended, revoked or declared void. The CFIA will notify the establishment that their name will be removed from the lists prior to taking this action. Upon written request, the CFIA may allow an establishment to remain on an export list for a specified period of time (depending on the nature of the product and the volume of inventory) when the following conditions are met:

- ▶ the establishment has product in storage that was processed when it had a valid registration;
- ▶ the product is in compliance with the FIR;

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- ▶ the operator of the establishment can demonstrate sufficient controls on their inventory such that they will only export product that was processed when the registration was valid;
- ▶ there are no reasonable grounds based on objective observations and/or past performance of regulatory compliance, to believe that the owner intends to conduct fraudulent activities; and
- ▶ the arrangement between Canada and the foreign country concerning the administration of the export list allows for establishments to remain on the list after their registration has expired.

4.1.7 All records concerning the administration of an establishment's certificate of registration will be maintained in accordance with the CFIA's *Recorded Information Management Policy*.

4.2 Issuing a New Certificate of Registration

4.2.1 Any person wishing to obtain a certificate of registration for a new fish processing establishment must submit a properly completed "Application for Registration of Fish Processing Establishments" form (see Appendix A) to the designated office in their region. The applicant should be the operator of the establishment (this can be the owner of the establishment, one of the partners owning it, a key officer of the company owning it, or the manager of the establishment when it is operated on behalf of an owner or company).

The following information must be included with the application:

- ▶ the full business name, business address and business telephone number of the applicant and, if applicable, the full names of partners or officers of the company. This section should include a description of the ownership of the establishment indicating whether it is privately owned by an individual or a partnership, or owned by a corporation. In addition, where the establishment is operated by a partnership or a corporation, the full names of all partners, or officers of the corporation;
- ▶ a description of the types of process operations intended to be conducted. See Appendix B of Chapter 2, Subject 3 for guidelines on process operations;

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- ▶ the types of fish products intended to be produced, stored or exported;
- ▶ a product description of each type of fish product intended to be produced, stored or exported;
- ▶ a process flow diagram that identifies each step in the process operation for each type of fish product; and
- ▶ a detailed diagram of the establishment with dimensions of the processing area.

Details described above that are not included in the application form may be included in the applicant's QMP Plan. The QMP Plan is a document outlining the Quality Management Program (QMP) that will be implemented in the establishment, and should accompany the application.

The application should include a self-verification of the QMP Plan by the operator of the establishment. This is a document signed by the applicant that attests that they have validated the critical limits of the CCP's and verified that the QMP plan meets the criteria of the Reference Standard (see Section 6.0 of the QMP Reference Standard). A self verification checklist may be used by the applicant and is included as Appendix C of this Chapter.

The application for a certificate of registration for a new establishment must be accompanied by full payment of the appropriate fee. See Chapter 2, Subject 3 for more details on the calculation of the appropriate registration fees.

4.2.2 Personnel with appropriate training and experience will evaluate each application for a certificate of registration for a new establishment. This evaluation will include, but is not limited to, the following:

- a) a review of the information submitted for the purposes of identifying the applicant and the establishment (i.e., name, address, telephone number, etc. and, if applicable, the names of partners or officers of the corporation operating the establishment) and verification that the information is complete and accurate;
- b) a review of the self-verification of the QMP;
- c) a Systems Verification of the QMP Plan to verify that

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it meets the requirements of the QMP Reference Standard (see Chapter 3, Subject 2 and Chapter 3, Subject 4, of this manual); and

- d) an on-site inspection of the establishment to determine its compliance with criteria prescribed by the FIR, including activities to verify:
- ▶ the requirements set out in Schedules I and II (see Appendix E);
 - ▶ freedom from serious contamination; and
 - ▶ the relevant elements of the QMP Plan (such as process flow diagram and plant layout) to identify that it meets the criteria of the QMP Reference Standard.

The applicant may be provided with the registration number upon submitting their application and full payment, prior to completion of the above steps. This may be done in order to allow the applicant to take appropriate steps to design packaging materials or to apply for inclusion on export lists such as the EU List. If the applicant expresses an interest in exporting to the EU, and an inspector has verified that they will comply with the requirements of Schedules I and II of the FIR, then the inspector may take appropriate actions to request an addition to the EU list.

- 4.2.3 When the evaluation described in subsection 4.2.2 indicates that an applicant has met all the requirements of the FIR, including payment of all fees, and there are no reasonable grounds based on objective observations and/or past performance of regulatory compliance to believe that the applicant will not comply with the FIR, a certificate of registration will be issued and sent to the applicant. This certificate of registration will be signed and dated by the Regional Director. The certificate of registration cover letter (Appendix D) will accompany the signed copy of the certificate of registration that is delivered to the establishment.

Records of the evaluation should be maintained on file that include the following:

- ▶ Schedule I and II reports (see Appendix E);
- ▶ Self Verification Checklist;
- ▶ Systems Verification Report;
- ▶ Application Form.

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- 4.2.4 When the evaluation described in subsection 4.2.2 indicates that the applicant has failed to meet the requirements of the FIR, a certificate of registration will not be issued. The CFIA will contact the applicant to inform them of the requirements that have not been met.
- 4.2.5 To facilitate ongoing processing operations during the transfer of ownership of an establishment, the new certificate of registration may be issued to coincide with the date the transfer of ownership takes place.
- 4.2.6 Compliance verification of a newly registered establishment will be performed as described in Chapter 3, Subject 3 of this manual.

4.3 Renewal of a Certificate of Registration

- 4.3.1 The CFIA will send the holder of a certificate of registration a notice of renewal, at least 60 days before its expiry, to advise them that their certificate will expire. The notice of renewal should include:
- a) a bilingual cover letter, stating that the certificate of registration will expire, identifying the date when it will expire, explaining the requirements for renewal, and advising that no fish may be processed for export once the certificate has expired. This letter must also identify the complete CFIA address where the client is to return their application with full payment, in addition to a contact location (see sample letter in Appendix B);
 - b) a registration application form (Appendix A).
- 4.3.2 Prior to expiration of the establishment's certificate of registration, the CFIA may contact the person to remind them that their certificate will expire and to determine the person's intent with regard to renewal of the establishment's certificate of registration.
- 4.3.3 Processing of fish with the intent to export must cease following the expiration of a certificate of registration.
- 4.3.4 When renewing their certificate of registration, the operator of a registered establishment should submit a properly completed Application For Registration form.

A person applying to renew an existing certificate of registration does not need to provide the following information as long as it has been previously submitted and there have been no changes:

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- ▶ the types of fish products intended to be produced, stored or exported;
- ▶ a product description of each type of fish product intended to be produced, stored or exported;
- ▶ a process flow diagram that identifies each step in the process operation for each type of fish product; and
- ▶ a detailed diagram of the establishment.

When there have been changes to this information, the person applying to renew their existing certificate of registration should indicate that there has been a change in the appropriate section of the Application for Registration form. Details about the change should not accompany the form, since this information should be included as part of the establishment's QMP Plan. The CFIA will verify that the establishment's QMP Plan is accurate, and reflects the current processing conditions during the next scheduled Compliance Verification.

4.3.5 The CFIA will review the information submitted by the applicant to renew their certificate of registration and the status of the establishment and its QMP Plan before renewal. For establishments that have not had a compliance verification conducted in the past year, an inspector will verify its compliance with Schedule I requirements and the status of the QMP Plan (see Appendix E).

4.3.6 The certificate of registration will be recommended for renewal when the review of the application indicates that:

- ▶ the information provided by the applicant is complete and accurate;
- ▶ the establishment is in compliance with the FIR; and
- ▶ payment for all applicable fees is included and establishment has no unpaid fees (see Chapter 2, Subject 3 of this manual).

The certificate of registration will be signed and dated by the Regional Director, and forwarded to the applicant. The certificate of registration cover letter (Appendix D) will accompany the signed copy of the certificate of registration that is delivered to the establishment.

4.3.7 When a certificate of registration is renewed, the

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certificate issued will have the same registration number as the original Certificate of Registration.

4.3.8 An inactivated certificate of registration will no longer be valid after its expiry date and must be renewed. A request to renew an inactivated certificate will be treated as a request for reactivation unless the holder of the certificate is simultaneously requesting another inactivation. See section 4.9 below for further details.

4.3.9 The CFIA will contact the applicant when the information provided to renew their certificate of registration is not complete and/or accurate. Every effort will be made to obtain the necessary information before the expiry of the certificate to allow the establishment to operate. Efforts to contact the applicant to acquire the necessary information should be documented and kept on file. The Regional Director may use discretion to renew the certificate of registration for an establishment that is willing and able to comply with the FIR but has not been able to provide the necessary information before the expiration of the certificate.

4.3.10 If an establishment chooses to allow its certificate of registration to expire for a short period of time because of seasonal availability of products, or other factors, the establishment may renew its certificate at a later date, provided that all fees have been paid and the establishment meets all other requirements of the FIR. The date of issue displayed on the certificate of registration will correspond to the date that it became effective, and will not be back dated to correspond with the expiry date of the old certificate.

It may not be necessary to remove an establishment from an export list if it's certificate of registration expired and it plans to renew its certificate at a later date provided the establishment can demonstrate product compliance and the necessary controls described above. See Section 4.1.6 above.

4.4 Refusal to Renew A Certificate Of Registration

4.4.1 The Regional Director may refuse to renew a certificate of registration when:

- ▶ the applicant has provided false or misleading information;
- ▶ the review of the status of the establishment and its QMP Plan indicates that the operator is unwilling or

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unable to comply with the conditions of registration based on objective observations and/or past performance of regulatory compliance; or

- ▶ the establishment has unpaid fees (see Chapter 2, Subject 3).

Documents justifying the refusal to renew the certificate of registration should be kept on file. The Regional Director will notify the applicant in writing and provide an explanation of the reasons why the certificate of registration will not be renewed.

- 4.4.2 If the applicant is able to take corrective actions to demonstrate compliance with the conditions of registration and/or reinstate their credit privileges, the Regional Director may renew their certificate of registration.

4.5 Suspension or Revocation of a Certificate of Registration

- 4.5.1 The Regional Director will provide the operator of an establishment whose certificate of registration is suspended or revoked with a written notice of the suspension or revocation. The notice should be delivered by hand or by registered mail to the operator as appropriate.

- 4.5.2 A certificate of registration will be revoked following a suspension if the operator has not requested a reinstatement within 30 days following the initial notice of suspension. The Regional Director will provide the operator of an establishment whose certificate of registration is revoked with a written notice of the revocation. The notice should be delivered by hand or by registered mail to the operator as appropriate.

- 4.5.3 A certificate of registration will be revoked if an inspector is unable to contact the operator of an active establishment for a period of 90 days. The inspector must document and keep records of each attempt to contact the establishment. The Regional Director will provide the operator of an establishment whose certificate of registration is revoked with a written notice of the revocation. The notice should be delivered by registered mail to the mailing address provided by the operator on their application for registration.

4.6 Reinstatement of a Certificate of Registration

- 4.6.1 The holder of a certificate of registration which has been suspended or revoked may apply for reinstatement of the

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certificate by writing to the CFIA Regional Director within 30 days of the date of the suspension or revocation. The request for reinstatement may be in the form of an appeal of the suspension or revocation or as a written Corrective Action Plan describing how compliance will be achieved.

The operator of the establishment must not process fish for export until the certificate of registration is reinstated.

4.6.2 After receiving an establishment's request for reinstatement, the CFIA will evaluate the request and verify the establishment's compliance with the FIR. This will include a review of the circumstances which led to the suspension or revocation being taken, and a review of the Corrective Action Plan submitted. Other possible actions include:

- ▶ an on-site inspection of the establishment to verify its compliance with the FIR;
- ▶ a formal hearing with the operator of the establishment; and
- ▶ any other actions deemed to be appropriate.

If required, this review may take longer than the thirty days provided for the operator to request reinstatement of the certificate.

4.6.3 Cost recovery fees, as set out in Chapter 2, subject 3 of this manual, must be paid in full before the reinstatement of a certificate of registration.

4.6.4 The decision to reinstate the certificate of registration will be based on factors such as:

- ▶ an evaluation of the corrective actions to verify that they result in compliance with the FIR;
- ▶ the ability of the operators of the establishment to demonstrate a clear understanding of their responsibilities to develop and maintain a QMP Plan that meets the requirements of the Reference Standard, and their commitment to its implementation;
- ▶ the ability of the operators of the establishment to take the necessary actions to control any non-compliant products that were implicated in the suspension or revocation of the certificate of

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registration.

The Regional Director will notify the operator of the establishment of the reinstatement by means of a letter sent by registered mail or other suitable means. This letter will state the effective date of reinstatement of the certificate of registration.

The reinstated certificate of registration will carry the same expiry date as the original certificate.

4.6.5 When the operator of the establishment has failed to submit an acceptable Corrective Action Plan or implement actions to comply with the FIR, the request for reinstatement of the certificate of registration will be denied. The Regional Director will inform the applicant of this decision by means of a letter sent by registered mail or other suitable means. This letter will explain the reason(s) for denial of the application and will advise the applicant of the instances where regulatory requirements have not been met.

4.6.6 The Regional Director may reinstate a certificate of registration of an establishment that was revoked when an inspector was unable to contact the operator following a period of 90 days when the operator is able to provide the reasons why nobody could be contacted and a corrective action plan that provides a suitable contact person for the establishment.

4.6.7 The decision of the Regional Director not to reinstate a certificate of registration that has been revoked is final and is not subject to further appeal.

4.6.8 A subsequent request for a certificate of registration for an establishment where the original certificate was revoked, and the request to reinstate the revoked certificate was denied, will be treated as a request for a new establishment.

4.7 Amendment of a Certificate of Registration

4.7.1 An operator of a registered establishment who wishes to amend its certificate of registration should submit a completed Application for Registration form to the CFIA Regional Director in their region. This form is attached to this subject as Appendix A.

When the amendment requested involves a change in the operations that are conducted at the establishment, the QMP Plan must be amended to reflect these changes. The

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operator should review and amend their plan in order that all the necessary controls are implemented to address the new operations to ensure they are performed in compliance with the FIR. A self-verification of the amended QMP Plan must also be conducted by the operator of the establishment to validate the critical limits of the CCP's and to verify that the QMP plan meets the criteria of the Reference Standard (see Section 6.0 of the QMP Reference Standard). The amended QMP Plan, and the self-verification, should be submitted at the same time as the application for amendment.

4.7.2 The CFIA will review each application for amendment of a certificate of registration. This will include a review of the reason(s) for the request and any supporting documents. Where applicable, the review of the request for amendment will include the following:

- ▶ a review of the self-verification submitted;
- ▶ an review of the amended QMP Plan submitted in relation to the application for amendment;
- ▶ an on-site verification of the establishment to determine its compliance with the FIR; and/or
- ▶ any other actions deemed necessary to verify that the establishment is, and will remain, in compliance with the FIR.

If the request for amendment of a certificate of registration is missing essential information such as the amended QMP plan, or a self-verification, then the CFIA will contact the applicant and request that these documents are made available before taking further actions.

4.7.3 When the review described in subsection 4.7.2 indicates that the application is complete and all requirements of the FIR have been met (including the payment of any associated fees, as identified in Chapter 2, Subject 3 of this manual), an amended certificate of registration will be issued to the applicant. This certificate of registration will be signed and dated by the Regional Director.

4.7.4 An amended certificate of registration will carry the same expiry date as the original certificate, and will be modified to reflect all the changes which have been approved by the Regional Director.

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4.7.5 The certificate of registration will not be amended when the review described in subsection 4.7.2 indicates that the application for amendment is: 1) not complete and the applicant is unable or unwilling to provide the appropriate documents; or 2) does not meet the requirements of the FIR. The Regional Director will notify the applicant by means of a letter sent by registered mail or other suitable means. This letter will explain the reason(s) for the denial of the application, and advise the applicant of the instances where the regulatory requirements have not been met.

4.7.6 When the request for amendment is refused, the case should be reviewed to determine if the further actions are required.

4.8 Change of Ownership of an Establishment

4.8.1 A change of ownership of an establishment will require the new owners of the establishment to apply for a certificate of registration.

The certificate of registration will remain valid if the holder of the certificate ceases to be in control of the registered establishment when the holder is an officer of a corporation, or a manager acting on behalf of an owner of the establishment or a company that owns the establishment. This includes situations where a manager that is identified as the holder of the certificate quits, retires, dies, is incapacitated, demoted or fired. However, the CFIA must be notified by the owner(s) of this change in advance, or immediately after in situations where advance notice is not possible, and the owner(s) must also request an amendment to the certificate.

4.8.2 An inspector should review the conditions related to the change of ownership to determine if a Systems Verification of the QMP Plan is necessary. Systems Verification is necessary when the new owners have made changes that affect the implementation of the original plan such as changes to the plant and/or its operations.

4.8.3 If the establishment continues operation after a change in ownership, there is no need to meet requirements of Schedule I that were applicable after April 1999.

If the establishment has been left dormant for a period of time, which in the opinion of the Regional Director, has resulted in a condition such that the establishment or the QMP Plan no longer comply with the FIR, then the change of ownership should be treated in the same manner as a

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request for registration of a new establishment.

4.9 Inactivation of a Certificate of Registration

- 4.9.1 An operator of a registered establishment who wishes to inactivate its Certificate of Registration should submit a request for inactivation to the CFIA. The request may be made by using the Application for Registration form (Appendix A) or through a written submission containing the required information. The request for inactivation must include the identity of the establishment; the reason(s) for the request; and the period of time for the inactivation. The request must also indicate whether fish processing operations will be continued in the establishment after the inactivation.
- 4.9.2 The CFIA will review the reason(s) for the request, a review of the compliance history of the establishment, and a verification that all applicable fees have been paid.
- 4.9.3 If the reason(s) for inactivation is(are) valid (see 3.10 above), all fees have been paid, and there is no cause to suspect that the inactivation has been requested for fraudulent purposes based on objective observations and/or past performance of regulatory compliance, the certificate of registration will be inactivated. The Regional Director will notify the operator of the establishment of the inactivation by means of a letter sent by registered mail or other suitable means.
- 4.9.4 If the review indicates that the applicable fees have not all been paid, the reason(s) for the request for inactivation is(are) not acceptable, or fraudulent intention is suspected (e.g., fish products will continue to be processed for export at the establishment), the inactivation will not be granted. The Regional Director will inform the operator of the establishment of this decision not to inactivate by means of a letter sent by registered mail or other suitable means.
- 4.9.5 If the inactivation is granted and the operator of the establishment intends to continue processing fish and fish products for intra-provincial sale, provincial authorities will be contacted so that they may take appropriate actions.
- 4.9.6 Once an inactivated certificate of registration has expired the operator of the establishment may apply for renewal of the certificate as set out in section 4.3. The operator may also apply for continued inactivation of the certificate at the same time. The application for renewal

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of the certificate will be treated as a request for reactivation unless the holder of the certificate simultaneously requests inactivation.

4.9.7 The operator of a registered establishment which has had its certificate of registration inactivated may continue to store and/or export fish and fish products that were produced prior to the inactivation, providing that all of the following conditions are met:

- ▶ the product must be stored in a manner that prevents its contamination;
- ▶ the product must be clearly identified by means of production dates, or other appropriate markings, to verify that it was processed during the time that the establishment held a valid Certificate of Registration;
- ▶ the product must be in final product form, and must be fully packaged;
- ▶ the product must be continuously stored under appropriate conditions; and
- ▶ the product must meet all other provisions of the FIR.

4.10 Reactivation of a Certificate of Registration

4.10.1 The operator of a registered establishment that has had its registration inactivated may request a reactivation of the Certificate of Registration by applying in writing to the CFIA Regional Director in that region.

4.10.2 The CFIA will evaluate a written request for reactivation of a certificate of registration to verify that the establishment complies with the conditions of operating with an active certificate. This evaluation will include a review of the reason(s) for the inactivation, a review of the compliance history of the establishment and the circumstances under which the inactivation was granted. The inspector should take the necessary actions to verify compliance with the FIR before the certificate is reactivated.

4.10.3 If the inactivation was originally requested, and granted, after a Compliance Verification identified non-conformities in the establishment, the evaluation will include appropriate activities to verify that the establishment has implemented the Corrective Action Plan and is in compliance with the FIR.

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4.10.4 When the evaluation described in subsection 4.10.2 indicates that the requirements of the FIR have been met (including the payment of any associated fees, as identified in Chapter 2, Subject 3 of this manual), the certificate of registration will be reactivated.

4.10.5 When the evaluation described in subsection 4.10.2 indicates that the requirements of the FIR have not been met, the certificate of registration will not be reactivated. The Regional Director will notify the applicant by means of a letter sent by registered mail or other suitable means. This letter will explain the reason(s) for the denial of the application, and advise the applicant of the instances where the regulatory requirements have not been met.

4.11 Issuance of a Temporary Certificate of Registration

4.11.1 A receiver or a trustee in bankruptcy for an establishment whose certificate of registration has been voided may apply for a temporary certificate of registration by submitting a properly completed "Application For Registration" form (Appendix A) to a CFIA Regional Director.

4.11.2 The CFIA will evaluate each application for a temporary certificate of registration. This will include a review of the information submitted, a verification that the applicant is the authorised receiver or trustee in bankruptcy, and a review of the recent compliance records of the establishment. Where the review indicates that the information submitted is inadequate, the applicant will be informed that more information is required.

4.11.3 If the review indicates that there are outstanding Corrective Action Plans, or modifications to the establishment or its QMP that could affect the operation of the establishment, an inspector should take the appropriate actions to verify that the establishment and its operations will meet the requirements of the FIR.

4.11.4 When the evaluation indicates that the application is complete and the establishment is in compliance with the FIR, the Regional Director will issue a temporary certificate of registration and forward it to the applicant.

4.11.5 Where the evaluation indicates that the applicant fails to meet the requirements of the FIR, a temporary certificate of registration will not be issued. The Regional Director will inform the applicant of this decision by means of a

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letter sent by registered mail or other suitable means. This letter will provide an explanation of the decision not to issue a temporary certificate.

5. FORMS/DOCUMENTS

- Appendix A - Application for Registration of Fish Processing Establishments
- Appendix B - Notice of Expiry of a Certificate of Registration
- Appendix C - Self Verification Checklist
- Appendix D - Certificate of Registration Cover Letter
- Appendix E - Certificate of Registration

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APPENDIX A

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APPENDIX B

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APPENDIX C
SELF VERIFICATION CHECKLIST / LISTE DE CONTRÔLE DE L'AUTOVÉRIFICATION

Plant Name / Nom de l'usine		Registration Number / Numéro d'enregistrement	
Mailing Address / Adresse postale		Telephone: Fax: Téléphone : Télécopieur :	
Plant Manager / Directeur d'usine		Quality Management Coordinator / Coordonnateur de la gestion de la qualité:	
Verifier / Vérificateur		Date of verification / Date de la vérification	
Comments / Commentaires:			
Component / Composante	Yes/Oui	No/Non	Comments/ Commentaires:
1. Management Roles and Responsibilities (Recommended but optional) / Rôles et responsabilités de la direction (Recommandé mais facultatif)			
Development of QMP Described / Élaboration du PGQ - décrite			
QMP Manager Identified / Responsable du PGQ - identifié			
Roles and Responsibilities identified / Préparation de l'organigramme - terminée			
2. Background Product and Process Information / Description du procédé et du produit			
Product Description completed for each type of product / Description du procédé pour chaque catégorie de produits - terminée.			
Process flow diagram completed / Diagramme de fabrication - terminé			
Plant floor diagram completed / Schéma des opérations de l'usine - terminé			

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3. Prerequisite Plan / Programmes préalables			
Plant Environment Program / Programme environnement de l'usine			
Component / Composante	Yes/Oui	No/Non	Comments/ Commentaires:
Standard identified (Minimum FIR) / Norme - définie (minimum RIP)			
Documented sanitation program complete / Programme d'assainissement - documenté			
Documented pest control program complete/ Programme de lutte contre la vermine - documenté			
Hygiene and employee behaviour training complete / Formation en hygiène et comportement des employés - terminée			
Controls and monitoring procedures complete / Mesures de contrôle et procédure de surveillance - terminées			
Corrective action system complete / Système de mesures correctives - terminé			
Record-keeping system (forms) developed / Système de registres (formulaires) - établi			
Recall and Notification Procedures Developed / Procédures de rappel et notification - établi			
4. Regulatory Action Point Plan / Plan des points d'intervention réglementaire			
Minimum Acceptable Product Quality Control / Normes minimales acceptables de qualité			
Product standard identified / Norme du produit - définie			
Controls and monitoring procedures complete / Mesures de contrôle et procédure de surveillance - terminées			
Corrective action system complete / Système de mesures correctives - terminé			
Record-keeping system (forms) developed / Système de registres (formulaires) - établi			

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Input Materials Controls / Matières premières et matériaux d'emballage			
Component / Composante	Yes/Oui	No/Non	Comments/ Commentaires:
Packaging and ingredients identified and acceptable / Matériaux d'emballage et ingrédients - définis et acceptables			
Controls and monitoring procedures complete / Mesures de contrôle et procédure de surveillance - terminées			
Corrective action system complete / Système de mesures correctives - terminé			
Record-keeping system (forms) developed / Système de registres (formulaire) - établi			
Labelling / Étiquetage			
Labelling standard identified (Fish Inspection Regulations) / Normes d'étiquetage - définies (Règlement sur l'inspection du poisson)			
Controls and monitoring procedures complete / Mesure de contrôles et procédure de surveillance - terminées			
Corrective action system complete / Système de mesures correctives - terminé			
Record-keeping system (forms) developed / Système de registres (formulaire) - établi			
RAPs added to process flow diagram / PIR ajoutés au diagramme de fabrication			
5. HACCP Plan / Plan HACCP			
Component / Composante	Yes/Oui	No/Non	Comments/ Commentaires:
Hazard Analysis complete and accurate / Analyse des dangers - terminée et exacte			
Significant hazards identified / Dangers importants - recensés			
Control measures for significant hazards developed / Mesures de contrôle des dangers importants - établies			
Critical limits identified / Limites critiques - identifiées			
Monitoring procedures complete / Procédure de surveillance - terminée			

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Corrective action system complete / Système de mesures correctives - terminé			
Record keeping system (forms) developed / Système de registres (formulaires) - établi			
HACCP Plan documented / Plan HACCP - documenté			
Supporting Standard Operating Procedures complete / Procédures normalisés d'exploitation - établis			
CCPs added to the process flow diagram / CCP ajoutés au diagramme de fabrication			
Verification procedures identified Procédure de vérification - définie			
6. Verification / Vérification			
Critical limits validated / Valider les limites critiques des CCP			
Schedule and methods for annual verification developed / Programme et méthodes pour l'examen annuel développé			
7. Records / Tenue des registres			
Component / Composante	Yes/Oui	No/Non	Comments/ Commentaires:
Method to record changes to QMP plan developed (e.g., QMP Amendment Log) / Méthodes pour tenir un registre des modifications apportées au plan PGQ développés (p.ex. un registre de modifications)			
Signature		Date	

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**APPENDIX D
CERTIFICATE OF REGISTRATION COVER LETTER**

Date

Company name
Address Line 1
Address Line 2
City, Province
Postal Code

Dear (name of applicant)

On behalf of the Canadian Food Inspection Agency (CFIA), I would like to acknowledge the efforts of you and your staff on meeting the requirements of the *Fish Inspection Regulations* (FIR) for the registration of your establishment. Conditions for the registration of your establishment require the development and implementation of a Quality Management Program (QMP) Plan and operating consistent with the principles of HACCP (Hazard Analysis Critical Control Points). In issuing the attached certificate of registration for your establishment, the CFIA is recognising the HACCP-based QMP Plan that was submitted by your establishment. Please note that the certificate of registration is not valid after its expiry date.

The CFIA will conduct regularly scheduled audits of your establishment to verify compliance with the conditions of registration provided by the FIR. Continued compliance with the FIR is essential to maintain your certificate of registration. Establishments with a valid certificate of registration are considered by the CFIA to be in good standing with the requirements of the FIR, allowing the CFIA to provide such assurances to foreign government inspection services.

For example, the CFIA uses the Canadian List of Approved Exporters to the U.S. as certification that the listed establishments are processing in accordance with the requirements of the U.S. Food and Drug Administration's seafood HACCP regulations (21 CFR part 123). This list can be found on the CFIA web site at:

<http://www.inspection.gc.ca/english/anima/fispoi/export/exporte.shtml>

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Please consult with your local CFIA office for more information on the requirements of the FIR or the inclusion of your establishment on an export list.

Sincerely,

Name
Regional Director
Region, Area

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**APPENDIX E
CERTIFICATE OF REGISTRATION**