Canadian Food Inspection Agency
Agence canadienne d'inspection des aliments

Fish Inspection Program

FISH PRODUCTS INSPECTION MANUAL

Canada

FOREWORD

It is my pleasure to make available to Inspection Services Directorate's personnel this Fish Products Inspection Manual - Policies and Procedures. The manual was developed with the full participation of the six inspection regions and in consultation with the Canadian Fishing Industry through the Seafood Industry Policy Advisory Committee (SIPAC).

The Fish Products Inspection Manual is an example of the department's commitment to openness and uniformity in the application of regulations and will be made available to industry and other interested parties. The manual supersedes all current directives, policy and procedural documents on the subjects covered.

The manual will assist Inspectors and other Inspection personnel in meeting the demands of changing technology in the fish processing industry while ensuring the Fish Inspection Program is applied uniformly and consistently within and between regions. The Fish Inspection Program must evolve along with the industry it regulates and fundamental tools such as this manual will be expanded and amended to meet the challenge and remain a valuable instrument for the Inspector.

Peter Meyboom
Deputy Minister

Fish Products
Inspection Manual

BULLETIN

TO: All Holders of the Fish Products Inspection Manual

SUBJECT: INSPECTION AND LABELLING OF FISH PRODUCTS THAT HAVE RECEIVED SOME HEAT TREATMENT BUT ARE NOT READY-TO-EAT

Note: **This bulletin supersedes and replaces Bulletin no. 37*. Please remove this bulletin from your manual.**

The purpose of this bulletin is to inform manual holders of the specific labelling requirements for fish products that are not ready-to-eat but could be perceived as such by consumers. Examples of those products are: frozen blanched crab legs, frozen "flash fried" breaded fish portions, frozen fillets with grill marks.

** Bulletin 37 has been superseded in order to include sections indicating conditions to allow this type of fish product to be imported and/or sold in Canada. Furthermore, sections prescribing the minimum temperature and time of cooking and also sections related to salted/dried molluscan shellfish have been removed. The requirements for salted/dried molluscan shellfish will be dealt within a separate document. Until this document is developed, section 6(1)(b) of the Fish Inspection Regulations applies to these products.*

The following labelling requirements have been established to address potential health and safety hazards from pathogenic organisms which could be related to the consumption of the products that are the subject of this Bulletin:

- The statement "**This is a raw product. It must be properly cooked prior to use**," or similar must be present in close proximity to the common name.
- Statements such as "ready-to-eat", and similar statements giving any impression that the fish product can be consumed without further heat treatment, are not permitted on the label [section 27 FIR].
- Placing cooking instructions on the label is optional. However, if present the cooking instructions must be sufficient to ensure safety of the product.

- If a vignette is present on the label, and this vignette creates an impression that the product is ready-to-eat, the statement "Serving suggestions" or similar must be on, or adjacent to the vignette [section 27, FIR].

- In cases when storage conditions are mandatory [as per section B.01.007.(1.1)(b)(ii) of the Food and Drug Regulations] they must be present on the label. It is strongly recommended that storage conditions are also placed on the labels of those products on which this information is not required by the Regulations, e.g., frozen "flash fried" breaded fillets.

A fish product that has been subjected to heat treatment but is not a ready-to-eat product must be labelled in accordance with the requirements presented in this bulletin before it will be permitted entry into Canada and/or be sold in Canada.

Mary Ann Green
Director
Fish, Seafood and Production Division

TO: All Holders of the Fish Products Inspection Manual

SUBJECT: USE OF THE "CANADA INSPECTED" LOGO

The purpose of this bulletin is to inform manual holders of the changes to the requirements for the use of the "Canada Inspected" logo on labels of fish products. The changes are as a result of the new approach to the Quality Management Program (QMP) and Regulatory Verification.

As of the date of this bulletin, the requirements of section 28 of the Fish Inspection Regulations shall be applied as follows:

- Establishments registered under the Fish Inspection Regulations are entitled to use the "Canada Inspected" logo on fish product(s) prepared under an acceptable QMP;
- No application for use of the logo is required;
- There is no requirement for the labels bearing the logo to be evaluated and accepted by fish inspection authorities;
- An establishment is recognized to have an acceptable QMP following the issuance of a valid certificate of registration;
- Only fish products that are considered "Product of Canada" are eligible for use of the logo;
- The emblem of the logo shall present a maple leaf and its form and design shall be chosen from the examples of the logos shown below;
- There are no restrictions as to the size and the colour of the logo, however, it must be separate and distinct, and it cannot interfere with any mandatory labelling information;

- Controls for use of the logo must be addressed in the QMP Plan. The policies and procedures pertaining to system verification and compliance verification of the QMP Plan apply for the purpose of assessing QMP controls related to the CI logo.

- Entitlement to use the CI logo is nullified if the QMP is found to be unacceptable, as described in the Facilities Inspection Manual, and/or when the registration certificate is inactivated, suspended, voided, or revoked.

Under no circumstances can a processor that is not federally registered use the logo on their fish products.

Richard Zurbrigg
A/Director
Fish, Seafood and Production Division

EXAMPLES OF "CANADA INSPECTED" LOGO

With Registration Number

Without Registration Number

TO: All Holders of the Fish Products Inspection Manual

SUBJECT: REMOVAL OF FOREIGN COUNTRY CERTIFICATION REQUIREMENTS

The purpose of this bulletin is to inform manual holders that the Foreign Country Certification Requirements will no longer be included in Chapter 10 of the manual. The requirements will however be made available in the Export Section of the the Fish, Seafood and Production section of the CFIA Web site. This will allow for more timely updates of the requirements, and make them available to all interested parties. The URL for the requirements is:

http://www.cfia-acia.agr.ca/english/anima/fispoi/export/Cert10/reqexie.shtml

Please remove the Foreign Country Certification Requirements from your manual.

Cameron Prince
Director
Fish, Seafood and Production Division

TO: All Holders of the Fish Products Inspection Manual

SUBJECT: DETERMINATION OF PERCENT FISH IN BREADED AND BATTERED FISH

N.B. This Bulletin supersedes and replaces Bulletin no. 38

The purpose of this bulletin is to inform manual holders of the procedures to be used in the determination of percent fish flesh in breaded and battered fish.

Effective immediately, the attached method, no. 996.15 - Fish Flesh Content (FFC) in Frozen Coated Fish Products, from the "Official Methods of Analysis" of the Association of Official Analytical Chemists (AOAC), will be the accepted method for the Canadian Food Inspection Agency for determining fish flesh in breaded or battered fish.

To account for the inherent variability of the method the following adjustment factors will be applied:

- 2% for raw breaded product and batter-dipped product;
- 4% for pre-cooked products.

A sample unit is defined as one of a number of individual containers, or a portion of a fish or a primary container examined or evaluated as a single unit.

Note: The attached methodology and associated tolerances will be applied when final product sampling for determination of percent fish is utilised.

Cameron Prince
Director
Fish, Seafood and Production Division

35.1.03

AOAC Official Method 996.15
Fish Flesh Content (FFC)
In Frozen Coated Fish Products
First Action 1996

(Applicable to the determination of the FFC in frozen coated fish products.)

(*Caution*: Use protective gloves when immersing and holding test sample in water bath set at >43°C.)

A. Principle

Method uses *(1)* combination of heat and H_2O to breakdown adhesive properties of coating (batter and/or breading) and *(2)* hands to assist in determining when coating's ability to adhere to flesh's frozen surfaces is diminished and can be easily removed.

B. Apparatus

(a) *Waterbaths*.--- Primary (17- 49°C) and secondary(17-30°C).
(b) *Thermometers.*--- Two*;* immersion type, capable of accurately measuring to ± 1°C.
(c) *Thermometer holders.* --- Two*;* with clips.
(d) *Balance*. --- Capable of accurately weighing to 0.1 g.
(e) *Stop watch*. --- Capable of reading seconds.
(f) *Paper towel*.
(g) *Spatula* --- 4 in. (ca 10 cm) blade with rounded tip.
(h) *Nut pick*.

C. Preparation of Test Sample

Maintain integrity of frozen test sample by storing in freezer until ready to remove batter and/or breading. Take into account all applied coating when weighing coated test samples.

D. Determination

Set primary H_2O bath temperature between 17- 49°C. Set secondary H_2O bath temperature between 17-30°C.

Weigh and record weight of each test sample while it is hard frozen. Using hands, immerse and hold test sample in primary H_2O bath until batter and/or breading becomes soft and can be removed easily from still-frozen flesh.

Remove test sample from H_2O bath and blot lightly with enough paper towel to absorb excess H_2O. Complete blotting in ≤ 7 s. Scrape and remove batter and/or breading from flesh with spatula. If batter and/or breading is difficult to remove, using hands, redip and hold partially debattered or debreaded test sample in secondary H_2O bath until batter and/or breading becomes soft and can be removed easily from still-frozen flesh.

Remove test sample from H_2O bath and blot lightly with enough paper towel to absorb excess H_2O. Complete blotting in ≤ 7 s. Scrape and remove batter and/or breading from flesh with spatula. When necessary, repeat redipping procedure and use nut pick to remove batter and/or breading from any voids (holes, spaces, or depressions) until all batter and/or breading has been removed from still-frozen flesh. Reweigh and record weight of debattered and/or debreaded test sample.

(Note: Several preliminary trials may be necessary to determine optimum H_2O bath temperatures, dip times, and number of dips required for debattering and/or debreading test samples. The correct dip time is the minimum time of immersion in H_2O baths required before batter and/or breading on test sample can be

scraped off easily, provided that debattered or debreaded test sample is still solidly frozen.)

As a guide, no more than 1 initial dip (17- 49°C) and 2 redips (17-30°C) for a maximum of 2.5, 0.5, and 0.5 min, respectively, should be necessary.

E. Calculations

Calculate content of fish flesh, %, in test sample as follows:

$$\% \text{ Flesh} = (W_d / W_b) \times 100$$

where W_d = weight of debattered and/or debreaded test sample; W_b = weight of battered and/or breaded test sample.

Reference: J. AOAC *Int*. **80,** 1235(1997).

Revised: March 1998

TO: All Holders of the Fish Products Inspection Manual

SUBJECT: Labelling of Live and Shucked Molluscan Shellfish

The purpose of this bulletin is to inform manual holders of the requirements concerning indication of shelf-life and harvesting area on labels applied to:

a) live molluscan shellfish, and
b) shucked molluscan shellfish,

when shipped and marketed in Canada.

Section B.01.007(1.1)(b) of the Food and Drug Regulations requires that the durable life and instructions for proper storage of pre-packaged product be indicated, if different from normal room temperature, for all food products having a durable life of 90 days or less.

a) Live molluscan shellfish falls into the category indicated above. However, Health Canada recognises that in some cases it is very difficult to predetermine a "best before" date for this product. Its shelf-life may vary from one week to months depending on a variety of factors. Based on this, the following decision was made:

   The label on live molluscan shellfish must indicate **either** a "best before" date, **or** the date of harvesting. In both cases the date must be shown in the manner demonstrated in section B.01.007(4)(d) and (5) of the Food and Drug Regulations: "the day of the month shall be shown after the month and shall be expressed in numbers". The use of Julian calendar dating is unacceptable. The label must also bear a statement "Keep refrigerated".

   It is recommended that all pertinent information that would enable a consumer to identify and discard any dead molluscs found in a package, is placed on the label or on a retail counter where the molluscs are displayed.

When live molluscs are wet-stored, the harvesting date will be the date when the molluscs are removed from the wet storage. However, the harvesting area indicated on the label remains the area where the molluscs were originally harvested (additionally, the wet storage area may be indicated) unless the wet-storage lasted more than 14 days. In a situation where the wet storage exceeds 14 days, the harvesting area shown on the label should be the area where the shellfish was wet-stored.

b) In the case of shucked molluscan shellfish, the label must indicate the area where the molluscs were harvested, the processing day and, if the product is sold fresh, the "best before" date and the statement "Keep refrigerated". The dates must be indicated in the manner demonstrated in section B.01.007(4)(d) and (5) of the Food and Drug Regulations: "the day of the month shall be shown after the month and shall be expressed in numbers". The use of Julian calendar dating is unacceptable.

All other mandatory information, i.e.,:

. common name;
. net content (for oyster and clam meats that are not frozen, net contents must be expressed in fluid measure or by count);
. country of origin;
. name and address of the processor;
. list of ingredients, when applicable; and
. grade, when applicable

must also be present on the label of live and shucked molluscan shellfish.

Cameron Prince
Director
Fish, Seafood & Production Division

TO: All Holders of the Fish Products Inspection Manual and All Holders of the Metal Can Defects Manual

SUBJECT: CONTAINER INTEGRITY EVALUATION SAMPLING AND TOLERANCE PLAN FOR CANNED FISH AND CANNED FISH PRODUCTS

NOTE: This bulletin supersedes and replaces Bulletin no. 15 of the Fish Products Inspection Manual. Please remove this bulletin from your Manual.

The purpose of this bulletin is to inform manual holders that inspectors of the Canadian Food Inspection Agency will follow the sampling and tolerance plan outlined below for container integrity evaluation of all canned fish and fish products. The procedures to be followed reflect the requirements of the Government of Canada Visual Inspection Protocol dated March 1, 1995, and are used to assess lot compliance according to Canadian requirements. The Visual Inspection Protocol may be accessed on the Health Canada website at the following URL:

http://www.hc-sc.gc.ca/datahpb/datafood/english/pub/mbhaz/visual-e.html

Four aspects of the following sampling and tolerance plan are not reflected in the Government of Canada, Visual Inspection Protocol and will be retained by the Fish, Seafood and Production Division, CFIA:

i) suspended inspections will continue to be offered (Fish Products Inspection Manual, Chapter 2, Subject 1);

ii) re-inspections will not be limited to lots that have been culled as outlined in the Government of Canada Visual Inspection Protocol (Fish Inspection Regulations, Section 10);

iii) a minimum sample consisting of 6 units will be selected for destructive examination (teardown and sectioning) from **all lots being inspected**. Destructive examination procedures as outlined in the Metal Can Defects Manual will be carried out on the canner's end for a two-piece can, and on the canner's

end and the manufacturer's end for a three-piece can; and

iv) the definition of a lot (from the Fish Inspection Regulations): "lot" with respect to fish, other than fresh fish, means a shipment or part of a shipment of fish that is of the same species, is processed in the same manner by the same producer, is packaged in the same size of container and bears the same label.

1. DESTRUCTIVE SAMPLING

Any defects identified from the destructive examination are to be used to determine lot compliance.

2. INITIAL AND SUSPENDED INSPECTIONS - COMPLIANCE SAMPLING

Initial Inspection:

A sample consisting of 200 units shall be inspected with labels removed.

A maximum of 5 sample units may be withdrawn from any single case in the lot. This will require a minimum of 40 cases to be opened when conducting an initial or suspended inspection. If the number of cases in the lot is less than 40 then all of the cases will be opened and the sample units per case adjusted accordingly.

A sample for destructive examination (teardown and sectioning) is obtained from the 200 can sample.

If no serious defects are found, the lot passes initial inspection.

If one or more serious defect(s) is (are) found, a suspended inspection may be offered if the lot has the potential to be culled or reconditioned. If the option to suspend an initial inspection is not requested by the owner/agent, then the lot fails the initial inspection and a re-inspection may be offered.

Suspended Inspection:

If a suspended inspection is granted, the owner/agent must remove defective units from the lot according to a cull proposal that has been approved by the CFIA. The defective units will be disposed of in a manner acceptable to the CFIA.

Once the culling operation is completed the initial inspection resumes and a new sample consisting of 200 units shall be inspected with labels removed.

A maximum of 5 sample units may be withdrawn from any single case in the lot. This will require a minimum of 40 cases to be opened when conducting an initial or suspended inspection. If the number of cases in the lot is less than 40 then all of the cases will be opened and the sample units per case adjusted accordingly.

A sample for destructive examination (teardown and sectioning) is obtained from the 200 can sample.

If no serious defects are found, the lot passes initial inspection.

If one or more serious defect(s) is (are) found then the lot is rejected.

3. INITIAL INSPECTION - MECHANICAL SCREENING

The Fish, Seafood & Production Division, CFIA, recognizes the Canned Screening Program utilized by the British Columbia Canned Salmon Industry.

The British Columbia canned salmon industry may assess lots under the Mechanical Screening Program, using check weighing equipment, double-dud detectors and a biased sample. This assessment is to ensure that the lot meets Canadian requirements regarding container integrity before being offered for sale.

During a Quality Management Program (QMP) audit the Canadian Food Inspection Agency will receive documented information from the can-screening line-audit program, which will indicate whether the equipment used to carry out the screening process was operating and operated correctly. This information, in conjunction with a review of the submitted Can Screening Report, will be used to determined whether approved mechanical screening procedures were followed.

If the lot contains equal to or less than **25** serious defective units per 100,000 units the lot passes initial inspection.

If the lot contains more than **25** serious defective units per 100,000 units, the lot fails initial inspection and may be submitted for reinspection.

A compliance sample will be obtained from a mechanical screening line during a QMP audit.

4. REINSPECTION

When a re-inspection has been granted the owner/agent may

cull defective units from the lot according to a cull proposal that has been approved by the CFIA. Re-inspections will not be limited to lots that have been culled.

A sample consisting of 1250 units shall be inspected with labels removed.

A maximum of 5 sample units may be withdrawn from any single case in the lot. This will require a minimum of 250 cases to be opened when conducting a reinspection. If the number of cases in the lot is less than 250 then all of the cases will be opened and the sample units per case adjusted accordingly.

A sample for destructive examination (teardown and sectioning) is obtained from the 1250 can sample.

If no serious defects are found the lot passes reinspection.

If one or more defect(s) is (are) found, the lot fails reinspection.

5. GENERAL

Only Inspectors who have successfully passed a recognized container integrity course are permitted to carry out container integrity evaluations.

NOTE

In accordance with the Government of Canada Visual Inspection Protocol, if at any time during an inspection a leaker, flipper or swollen can is found, the inspection shall be discontinued until such time that the lot has been evaluated to determine if the defect is due to under-processing or post-process contamination. If the defect is due to under-processing or post-process contamination the lot fails, and no suspended inspection or reinspection of the lot shall be permitted.

Cameron Prince
Director
Fish, Seafood & Production Division

TO: All holders of the Fish Products Inspection Manual

SUBJECT: EXPORT OF LIVE MOLLUSCAN BIVALVE SHELLFISH TO FRANCE

1. In April 1997, French authorities indicated that they require live molluscan shellfish exported from Canada to France to originate from establishments on an approved list.

   Currently, no other European Union member states require Canadian exporters of live molluscan shellfish to be on an approved establishment list.

   The "Canadian List of Exporters Approved for the EU" is available on the CFIA Internet. Any additions to this list should be sent to NHQ to be forwarded to French authorities.

2. Effective immediately, all cartons of live shellfish exported to France must have one of the following statements clearly marked on each container or label thereon:

   "For Direct Human Consumption Only";

   OR

   "Not For Relaying or Depuration"

3. All exports to the European Union, including live shellfish to France, will continue to be certified by CFIA inspectors, in accordance with EU Directives.

Cameron Prince
Director
Fish, Seafood & Production Division

TO: All holders of the Fish Products Inspection Manual

SUBJECT: RESPONSIBILITY FOR LABELLING OF POUCHED AND CANNED FISH

The purpose of this bulletin is to inform manual holders of the policy concerning responsibilities for proper labelling of pouched/canned fish.

As per the Fish Inspection Regulations, proper labelling of pouched/canned fish is the responsibility of the processor.

Normally, labels are applied in the plant (or the warehouse) where the processing takes place. However, in some cases unlabelled cans/pouches are sold to the distributor and the distributor applies their own labels. In these situations, labelling is delegated from the processor to the distributor. This practice is acceptable but must be supported by a written agreement stating that the distributor accepts responsibility for label compliance. The processor remains responsible for providing the distributor with complete and truthful information regarding the product which is required for proper labelling.

Please note that the production code on each pouch/can must always be applied at the plant.

Cameron Prince
Director
Fish, Seafood and Production Division

TO: All holders of the Fish Products Inspection Manual

SUBJECT: USE OF THE TERM "DOLPHIN FRIENDLY" AND SIMILAR NON-MANDATORY STATEMENTS ON LABELS

The purpose of this bulletin is to inform manual holders of the guidelines to be followed when statements such as "Dolphin friendly", "Dolphin safe", etc., are placed on labels of canned tuna.

Section 27 of the Fish Inspection Regulations reads: "No person shall package any fish or mark or label any container of fish in a manner that is false, misleading or deceptive."

It is the responsibility of the importer to ensure that all information contained on labels of canned tuna is truthful. All importers of canned tuna who wish to place such statements on the labels must develop their own procedure to ensure that the tuna they distribute was harvested using methods not injurious to dolphins. Upon request, documentation providing proof of these methods must be available to an Inspector of the Canadian Food Inspection Agency. In instances where the importer cannot provide proof that the statements are accurate, the lot in question is to be rejected for false labelling.

Cameron Prince
Director
Fish, Seafood and Production Division

TO: All holders of the Fish Products Inspection Manual

SUBJECT: APPROVED FOOD ADDITIVES PERMITTED IN FISH EXPORTED TO THE EUROPEAN UNION (EU)

The purpose of this bulletin is to make modifications to Chapter 10 of this manual concerning the tolerances and guidelines for additives permitted in fish and fish products exported to the European Union. This includes the following EU countries: Austria, Belgium, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Luxembourg, Netherlands, Portugal, Spain, Sweden, and the United Kingdom.

Acts and Regulations

Council Directive No. 95/2/EC of 20 February 1995 concerning permitted food additives, other than colours & sweeteners that are permitted in fish and fish products intended for human consumption.

Tolerances and Guidelines - AMENDMENT

Currently states:
Phosphates not permitted.

Additions / Amendments:

Benzoic or Sorbic Acid - *may be used singly or in combination	-	Semi-preserved fish products, including fish roe products	2000.0 ppm
	-	Cooked shrimp	2000.0 ppm
	-	Salted, dried fish	200.0 ppm

Sulphites *expressed as sulphur dioxide (SO_2)	-	Dried, salted fish of Gadidae species	200.0 ppm
	-	Fresh and frozen cephalopods	150.0 ppm
	-	Fresh and frozen crustaceans	150.0 ppm
	-	Crustaceans of the families: Penaeidae, Soleneridae and Aristedae	
		- up to 80 units	150.0 ppm
		- between 80 to 120 units	200.0 ppm
		- over 120 units	300.0 ppm
		- cooked	50.0 ppm
Phosphates *expressed as P_2O_5	-	Surimi	1000.0 ppm
	-	Frozen fillets of unprocessed[1] fish	5000.0 ppm
	-	Frozen molluscan shellfish	5000.0 ppm
	-	Frozen crustacean products	5000.0 ppm
	-	Fish and crustacean paste	5000.0 ppm
Calcium disodium EDTA	-	Canned and bottled fish, crustaceans and molluscs	75.0 ppm
Boric Acid	-	Caviar (Sturgeon's eggs)	4.0 ppm

[1] Unprocessed refers to fish in its raw state, excluding products such as smoked or marinated fish

David Rideout
Director General
Fish Inspection Directorate

TO: All Holders of the Fish Products Inspection Manual

SUBJECT: ACTION LEVEL ON MOISTURE IN SCALLOP MEATS

N.B. This bulletin supersedes Bulletin no. 19A

The purpose of this bulletin is to inform manual holders that the action level for moisture content in scallop meats has been changed from 81% to 81.0%. As of now, all lots of scallop meats with a moisture content of 81.0% or higher will be rejected. In some instances, on the decision of the Regional Director of Inspection, reconditioning may be allowed for shipments which exceed this moisture level. The change to 81.0% means that a moisture content of 80.9% will be accepted while a moisture content of 81.0%, 81.1%, etc., will result in a rejection.

In order to ensure uniformity, moisture assessments will be determined using the attached method.

David Rideout
Director General
Inspection Directorate

DETERMINATION OF MOISTURE CONTENT OF SCALLOPS

Moisture content of scallops is to be performed on all lots of scallops which are sampled. **This method, however, will only be concerned with frozen scallops, both IQF and block frozen.**

Sampling

Samples for moisture analysis are to be taken from the samples collected for other purposes, as indicated by INIM.

Sample Preparation

- Remove surface glaze from the scallops under running water until no ice can be felt on the surface of the scallops but it is evident that ice crystals remain within the product (the interior of the product remains frozen). Block frozen product should be gently broken up to individual scallops or scallop pieces and ice within the block should be removed until the surface of the product is free of ice.

- Place the scallops on a sieve of appropriate size and drain for 1 to 1½ minutes. Determine the net weight of the scallops.

- Obtain a total of approximately 100 g of scallop meat from the five sample units.

- Comminute the 100 g sample until a homogenous blend is attained.

- Collect the homogenous sample into a clean, dry, sealable plastic cup or glass bottle. Store the sample in a refrigerator until required. Ensure that the prepared sample is still homogenous prior to weighing. If liquid separates from the sample, thoroughly reblend before use.

Determine the % moisture in the scallops as indicated below (in accordance with section 2, Chapter 2 of the Chemical Methods Manual, beginning at #8 "Procedure").

Procedure

Accurately weigh a container of appropriate size. Add approximately 10 g of the comminuted sample and reweigh. Place the container in a vacuum oven at 100°C and less than 100mm Hg for approximately 5 hours, or until of constant weight. Cool in a dessicator and weigh.

Calculation

$$\text{Moisture} = \frac{100\ (p-a)}{p} \text{ percent}$$

p = weight in g of sample
a = weight in g of dried sample

TO: All Holders of the Fish Products Inspection Manual

SUBJECT: CRITERIA FOR ASSIGNING NEW COMMON NAMES FOR FISH IN CANADA

The purpose of this bulletin is to inform manual holders of the guidelines to follow in order to assign a new common name for a species of fish.

1. Common names for fish in Canada will be determined in accordance with the Canadian values of fairness and honesty in the marketing of fish.

2. The scientific name of the fish will be provided to DFO by the person applying for a new acceptable common name.

3. Proposed common names for the marketing of fish which are provided by the applicants will be given full consideration by DFO.

4. DFO, Inspection Directorate is responsible to conduct the research regarding common names applied to a species. The Inspection Directorate will consult the various applicable reference sources and select the acceptable common name following the guidelines listed below:

   - the new common name has not previously been used for another species (as identified in "The Canadian Fish List");

   - the new common name is not similar to, and does not resemble the name of a fish having a higher market value than the fish being reviewed ;

   - whenever possible, the new common name is harmonized with the names assigned to this species by the *ministère de l'Agriculture, des Pêcheries et de l'Alimentation du Québec - MAPAQ* (*Pêches - Terminologie - Noms des espèces halieutiques à potentiel commercial au Québec*) and the United States Food & Drug Administration - USFDA (The Seafood List);

- it is recognized that MAPAQ guidance will be the primary reference in determination of acceptable common names in French;

- where the common name proposed by the applicant is not contrary to current policy, and is similar to the name for that species found in references, the proposed name will become the acceptable common name;

- the name of the geographic location where the fish have been harvested may be added to the common name of the fish (e.g., Southwest Atlantic hake);

- Canadian trade interests will be considered in determining acceptable common names.

This policy will be incorporated in Chapter 9 (Labelling/Coding Requirements) of this manual at a later date.

David Rideout
Director General
Inspection Directorate

TO: All Holders of the Fish Products Inspection Manual

SUBJECT: LABELLING OF SCALLOPS EXPORTED TO FRANCE

Effective June 26, 1996, all frozen, canned or semi-preserved scallops of the family *PECTINIDAE* may be sold in France under the name "Saint-Jacques" with a requirement that the scientific name be shown immediately after the term "Saint-Jacques". The label must also show the country of origin, either in conjunction with the scientific name, or in prominent characters on the same side of the label as the scientific name.

If the shipment consists of both the species *Chlamys varia* and *Chlamys opercularis* then the term "pétoncle" may replace the term "Saint-Jacques". If the shipment consists only of the species *Chlamys opercularis* then the term "vanneau" may be used.

Labels currently in use may continue to be used until September 26, 1996, at which time the labels for all scallop shipments exported to France must meet the above requirements.

David Rideout
Director General
Inspection Directorate

TO: All Holders of the Fish Products Inspection Manual

SUBJECT: ARTIFICIALLY COLOURED COOKED SHRIMP - U.S.A.

The purpose of this bulletin is to inform manual holders of a recent change in the United States Food and Drug Administration (USFDA) policy concerning the use of artificial colours on cooked shrimp.

Earlier this year the Office of Seafood, USFDA, decided to permit the use of an artificial colour, FD&C Red No. 40 (Allura Red in the Canadian Food and Drug Regulations), on cooked shrimp if the principal display panel indicates the product as being artificially coloured cooked shrimp and the colouring agent used is declared in the list of ingredients.

In accordance with the Food and Drug Regulations, colouring agents are not permitted on cooked shrimp sold in Canada. Therefore if product is imported and labelled as "artificially coloured", the lot is to be rejected for non-permitted additives. Also, if imported shrimp are suspected to contain a colouring agent, specifically allura red, the lot should be detained, sampled and analysed for the presence of this agent.

David Rideout
Director General
Inspection Directorate

TO: All Holders of the Fish Products Inspection Manual

SUBJECT: NET CONTENT DETERMINATION - FROZEN LOBSTER MEAT **INTERIM** PROCEDURE

The purpose of this bulletin is to inform manual holders of the procedures to be used in the determination of net content of domestic or imported frozen lobster meat.

Effective immediately, the attached procedure will be used by DFO Inspection staff for determining the net content in frozen lobster meat.

This procedure is designated as interim until the Net Content Determination Policy and Procedures document is finalized and distributed to all manual holders. Until such time, this product must be sampled using the Codex Sampling Plan, AQL 6.5, and lot compliance must be determined using the criteria set out in the *Consumer Packaging and Labelling Act* and *Regulations* and the *Weights and Measures Act* and *Regulations*.

David Rideout
Director General
Inspection Directorate

DRAFT - May 2, 1996

NET CONTENT DETERMINATION
FROZEN LOBSTER MEAT INTERIM PROCEDURE

1. SCOPE

This document outlines the interim procedure governing the net content determination of domestic and imported frozen lobster meat.

2. AUTHORITIES

Fish Inspection Act. R.S.C., 1985, c.F-12; Section 3(c) and 3(i)

Fish Inspection Regulations. C.R.C., 1978, c.802;

Consumer Packaging and Labelling Act and *Regulations*

Weights and Measures Act and *Regulations*

3. POLICY

All frozen lobster meat imported into or processed in Canada, will be examined for net content determination as per the interim procedure outlined in this document.

4. PROCEDURE

4.1 Sampling

The lot is sampled in accordance with the appropriate sampling plan specified in the Net Content Policy and Procedures Document.

4.2 Sample Preparation

The sample units are thawed by submerging in cool running or circulating water, at ambient temperature, until a core meat temperature of between 10°C (50°F) and 15°C (59°F) is reached. This may be accomplished by using a sink with running tap water or a circulating waterbath. This may also require allowing the product to sit at room temperature until the minimum core temperature of 10°C (50°F) is reached.

4.3 Weight Determination

4.3.1 After thawing, each container is opened and the core meat temperature is measured and recorded.

4.3.2 Transfer product to a No. 8 sieve, distributing evenly over the surface of the mesh.

4.3.3 Without shifting the product, incline the sieve at an angle of 20° to 30° and drain for a period of 1 to 1½ minutes.

4.3.4 Transfer the drained product to a tared pan and weigh. The resultant figure shall be considered the net content for that sample unit.

5. LOT COMPLIANCE

Analysis of results and lot compliance are determined as specified in the Net Content Policy and Procedures Document.

TO: All Holders of the Fish Products Inspection Manual

SUBJECT: FISH INSPECTION REGULATIONS - SECTION 6(2)(a) - IDENTITY OF THE ESTABLISHMENT PACKING FISH

The purpose of this bulletin is to clarify the interpretation of Section 6(2)(a) of the *Fish Inspection Regulations* (FIR).

Section 6(2)(a) of the FIR states that "No person shall import into Canada or attempt to import into Canada any fish unless:

(a) the identity of the establishment at which the fish is packed and the day, month and year of packing are legibly marked on one end of the carton or case in which the containers of fish are shipped."

The master carton may identify the packer of the fish by either the packer's name or by code. When a code is used to identify the packer and/or date of packing, the importer is responsible for providing Inspection Directorate with a key that identifies the name of the establishment and/or date of packing.

David Rideout
Director General
Inspection Directorate

TO: All Holders of the Fish Products Inspection Manual

SUBJECT: HISTAMINE COMPLIANCE GUIDELINES FOR FISH AND FISH PRODUCTS

The purpose of this bulletin is to clarify the current histamine guidelines for fish and fish products as approved by the National Inspection Policy Committee (NIPC), November 1993.

Background:

Histamine presence below 50 mg/100 g is used as an indicator of decomposition. Histamine presence above 50 mg/100 g is used as an indicator of a harmful substance.

Individual sample unit limit:

20 mg/100 g: for enzyme-ripened products, such as, anchovies, anchovy paste and fish sauces

10 mg/100 g: for all other types of products, such as, canned or fresh or frozen tuna, mackerel and mahi-mahi

50 mg/100 g: is the upper tolerance level for fish products, and any sample with a unit level exceeding this amount will result in the lot being rejected with no right of reinspection

Sampling Plan:

Initial Inspection:	Sampling Plan 1, (AQL 6.5), Fish Product Standards and Methods Manual
Reinspection:	Sampling Plan 2, (AQL 6.5), Fish products Standards and Methods Manual

(Reinspection of the lot is only permitted if no sample unit exceeded 50 mg/100 g in the initial inspection.)

Acceptance Number:

The acceptance number is the lower acceptance number shown in the sampling plans, corresponding to the number for decomposition.

The acceptance number for sample units with levels of histamine greater than 50 mg/100 g is zero.

B.J. Emberley
Director General
Inspection Directorate

TO: All Holders of the Fish Products Inspection Manual

SUBJECT: STATUS OF BULLETINS AND AMENDMENTS

BULLETINS

The status of bulletins for the Fish Products Inspection Manual is as follows:

BULLETIN NO.	SUBJECT	STATUS
1	Registration cards	In Force
2	Suspended Inspection for Fish Products Contaminated by Poisonous or Harmful Substances	In Force
3	Certification of lots under the DFO Pilot Sampling Project	Superseded by Bulletin no.7
4	New Tolerance for PCB's and Mercury-Federal Republic of Germany	In Force
5	Fish Health Protection Regulations - Smoked Fish	In Force
6	Labelling and Weight Determination of Sliced Smoked Salmon	In Force
7	Certification of Lots from Plants Operating Under an Effective QMP	Incorporated into Ch.3, Su.1 of the Facilities Inspection Manual
8	Use of the "Canada-Inspected" logo	Incorporated into Ch.3, Su.1, Appendix E of the Facilities Inspection Manual
9	Use of the Codex Sampling Plan for Sensory Inspection of All Fish Products	In Force

10	Prohibition of the Common Name "Salmon Trout" for Oncorhynchus Mykiss	In Force
11	Safety Precautions to be Followed in the Sensory Evaluation of Canned Fish and Fish Products	In Force
12	Amendments to Certificates of Inspection	In Force
13	Certification of Vessels Under Schedule III and Certification of Products Originating from Said Vessels	In Force
14	EEC Requirements - Fish Products for Personal Use	In Force
15	Sampling and Tolerance Plan for Canned Fish and Canned-Fish Products Container Integrity Evaluation	In Force
16	Detention of Domestic Fish Products Being Sampled for Initial Inspection	In Force
17	Inspection and Certification of Fish Landed by Vessels of Canadian and Foreign Origin	In Force

AMENDMENTS

The following amendments to the manual have been issued:

AMENDMENT NO.	CHAPTER/SUBJECT
1 (7 July 89)	Chapter 3, Subject 1 - Imported Fish and Fish Products Inspection New Chapter 10 - Export Certification
2 (20 Aug. 90)	Chapter 3, Subject 1 - Imported Fish and Fish Products Inspection

3 (25 Feb. 94)	Chapter 3, Subject 1 - Imported Fish and Fish Products Inspection (supersedes ch.3 su.1 of amend. nos. 1 and 2) Chapter 3, Subject 2 - Cost Recovery for Import Inspections New Chapter 5, Subject 1 - Inspection of Live Crab and Lobster New Chapter 11 - Consumer and Trade Complaints

B.J. Emberley
Director General
Inspection and Enforcement

TO: All Holders of the Fish Products Inspection Manual

SUBJECT: SAFETY PRECAUTIONS TO FOLLOWED IN THE SENSORY EVALUATION OF CANNED FISH AND FISH PRODUCTS

The purpose of this bulletin is to inform all personnel involved in the sensory evaluation of canned fish and fish products of the precautionary steps which must be followed prior to the sensory evaluation of such products. The term "canned" includes all fish and fish products which have been subjected to a heat process as defined under Section 34 of the Fish Inspection Regulations whether packed in metal or glass containers, pouches or any other hermetically sealed container.

1) Metal containers must have their labels removed and end seams and side seams must be checked for integrity;

2) Glass containers and their caps must be checked for acceptability;

3) Pouches must be checked for punctures, holes, acceptability of seals and any other defects which may adversely affect the integrity of the pouch;

4) Any containers which are unacceptable as defined in 1), 2) and 3) above or which show signs of swelling or gas production **SHALL NOT BE SUBJECTED TO SENSORY ANALYSIS**. Other containers from the same lot or code shall not be subjected to sensory evaluation until it has been proven beyond a doubt that the swelling or gas production is not due to under processing.

These criteria have been set for the safety of the evaluators and must be followed at all times.

B.J. Emberley
Director General
Inspection, Regulations and Enforcement

5) The United States Food and Drug Administration (FDA) in Washington, D.C., has also been consulted; they have received requests from some sectors of the U.S. aquaculture industry to use the name "Salmon Trout" and have not approved its use. The FDA is now enforcing this decision and does not foresee any change in this position. In the interest of harmonization of trade in fish products with the U.S., it would not be appropriate to allow the use of "Salmon Trout" as a common name for rainbow trout exported to the U.S.

B.J. Emberley
Director General
Inspection, Regulations and Enforcement

TO: All Holders of the Fish Products Inspection Manual

SUBJECT: Use of the Codex Sampling Plan for Sensory Inspection of All Fish Products

The purpose of this bulletin is to confirm to all Inspectors that the current Codex sampling plan (AQL 6.5 with a lower acceptance number for decomposition) is to be used for sensory inspections of **ALL** fish products (including those such as salt fish and pickled fish which, in the past, have been subject to inspection using non-AQL sampling plans).

B.J. Emberley
Director-General
Inspection Services Directorate

TO: All Holders of the Fish Products Inspection Manual

SUBJECT: Labelling and Weight Determination of Sliced Smoked Salmon

This bulletin is being issued to clarify previous correspondence on this subject dated October 20, 1989 and March 7, 1990 and will be incorporated into the Labelling Policy which will form Chapter 9 of this Manual.

1) Where the skin has been detached from the flesh of the product but is included in the package, the weight of the skin must be excluded from the net weight of the product.

2) Where the skin has been detached from the flesh of the product and is not included in the package, the net weight of the product shall be the total contents of the package.

3) Where the skin is still attached to the flesh of the product or is partially attached to maintain "kosher" requirements, the weight of the skin shall not be included in the net weight of the product unless the label indicates that the skin is included in the declared weight.

NOTE: The weight of the plastic dividers inserted between the smoked salmon slices shall be excluded from the declared weight of the product.

B.J. Emberley
Director General
Inspection Services Directorate

TO: All Holders of the Fish Products Inspection Manual

SUBJECT: Suspended Inspection for Fish Products Contaminated by Poisonous or Harmful Substances

This bulletin sets out a modification to Initial Inspection, Chapter 2, Subject 1 / Section 4.8.

The following policy will supersede that which currently exists in the body of the manual for this item, and will remain in effect for a six month period from the date of issuance of this bulletin. This will provide a period in which to assess the impact of this policy, at which time an amendment will be issued, as necessary.

4.8 "When inspection of the sample shows that the lot does not comply with the requirements of the Fish Inspection Regulations, i.e. the acceptance number is exceeded, an inspector shall suspend the decision on the initial inspection provided:

a) the fish or containers thereof do not have in or upon them contamination by poisonous or harmful substances; and

b) the owner/agent is able to demonstrate to the satisfaction of the inspector that the defect(s) in the lot can be successfully removed through culling or reworking.

Notwithstanding the above the Regional Director of Inspection has the authority to permit a suspended inspection for lots found contaminated by poisonous or harmful substances. This is permitted provided the owner/agent supplies a precise explanation of the source of the contamination and submits a proposal which demonstrates an acceptable method for complete removal of the substances by culling, reworking or reconditioning. Any decision to permit the culling, reworking or reconditioning of any lot must be reported to National Inspection Headquarters in a derogation report. Where there is no practical way to cull, rework or recondition the lot, a suspended inspection will not be considered.

A suspended inspection would not be offered under the following circumstances:

> Where a lot of canned fish consisting of only one code does not comply with the Fish Inspection Regulations due to decomposition, contamination or taint, a suspended inspection cannot be offered, as it is impossible to determine which cans would be affected."

B.J. Emberley
Director General
Inspection Services Directorate

Recipients of the Fish Products inspection Manual - Policies and Procedures are reminded that they must complete the registration card found inside the cover and mail it to national Headquarters as soon as possible.

Those individuals who received both the English and French versions are reminded they must complete the registration card for each manual.

B.J. Emberley
Director general
Inspection Services Directorate

CHAPTER 12: SAMPLING

CHAPTER 13: PRODUCT STANDARDS WORKSHOPS

CHAPTER 14: NET CONTENT DETERMINATION

* to be issued at a later date

Amend.no.3 25/02/1994

DEFINITIONS

Agent: Someone acting on behalf of another person. The agent of the owner of the fish can be the plant manager, the assistant plant manager, the quality control manager or another company official who has control over the fish.

The agent of the owner of buildings where the fish is stored can be the director of the warehouse/refrigerated warehouse or his/her assistant, or the operator of a transport company if the fish is in transit.

Consumer: The final user of a product. (i.e. a person or an institution, such as a hospital, hotel, organization or restaurant which purchases a product for its own use.)

Consumer or Trade Complaint: Any verbal or written communication initiated by a consumer or a representative of an organisation expressing dissatisfaction with a fish or fish product. A consumer or trade complaint can be classified as either a health and safety issue or an other issue.

Container: Any type of receptacle, package, wrapper or confining band used in packaging or marketing fish.

Crown: The Government of Canada, the Head of State for which is Her Majesty Queen Elizabeth as represented in Canada by the Governor General.

Culling: Removal of defective units from a lot of fish or fish products.

Decomposed: Fish that has an offensive or objectionable odour, flavour, colour, texture or substance associated with spoilage.

Defective Unit: Any sample unit which does not comply with the requirements of the Fish Inspection Regulations (FIR).

End-of-Line Inspection: Inspection of a product which is packed into its final product form for that processing facility and which is not subject to any further processing other than freezing.

Fish: Any fish, including mollusks and crustaceans, and marine animals (marine being defined as "of, found in, produced by the sea"), and any parts, products or by-products thereof.

Import: a shipment of fish imported into Canada is to be treated as an import if the product is so defined by Customs and Excise.

For further details concerning the definition of an import, see Chapter 3, Subject 1 of this manual, Section 3.3 - Imports.

Importer of Record: the organisation or person that the Department of Fisheries and Oceans can hold responsible to meet the requirements of the Fish Inspection Regulations with respect to the importation of fish and fish products.

Inspector: A person designated as an Inspector pursuant to Section 17 of the Fish Inspection Act.

Legal Proceedings: Begins with the laying of an information and continues until all appeal routes have been exhausted.

Limitation Period: The period of time during which a charge may be laid; after the limitation period for a particular offence has expired, the person or company can no longer be charged with that offence.

The Limitation Period for summary conviction offenses in Canada, under the Criminal Code, is six months (Section 721 (2) of Criminal Code). All Fish Inspection Act violations are summary conviction offenses. Seizure of fish and containers and consequent legal action must take place within six months of the date of the alleged offence.

Mandatory Inspection List (MIL): is a list that:

a) is published monthly by the Department and is available from an inspector; and

b) sets out the imports of fish that have failed to pass a type of inspection set out in the table to section 6.3 of the FIR.

Lot: A collection of readily identifiable units of product which are processed and/or handled under uniform conditions.

Lot Size: The number of units of product in a lot.

Minister: Minister of Fisheries and Oceans.

On-Line Inspections: Inspections which occur at critical points during the in-plant process (e.g: immediately after candling).

Poisonous or harmful substances: Includes bacteria of public health significance, Paralytic Shellfish Toxin, regulated pesticides, P.C.B.'s, mercury, or other contaminants which exceed established tolerances or guidelines.

Processor: Any person or company which processes fish (as defined in the Fish Inspection Act) for import or export.

Product Inspection: The process of measuring, examining, testing or otherwise comparing a sample unit with the applicable requirements. An "inspection" must result in a decision on the acceptability of the lot. In order for an inspection to be completed, the following steps must be executed:

i) the identity of the lot must be confirmed;
ii) the lot must be sampled;
iii) the sample units must be examined;
iv) a decision must be made on the status of the lot; and
v) the decision must be communicated to the owner of the lot.

Raw Material Inspections: Inspections of fish or any additional ingredients to be added to, on, or with the fish.

Reasonable Grounds: Any set of circumstances that would permit an Inspector to believe that an offence under the Fish Inspection Act has been committed.

Reconditioning: A process which eliminates bacteria of public health significance by heat treatment.

Regrouping by Code: means to subdivide that product into groups which have the same processor and date of production. If there is any reason to subdivide further, it is to be done at the discretion of the inspector.

Retail: Any product for sale in a store or directly to a consumer.

Reworking: Removal of defects from units in a lot (e.g: candling, trimming).

Sample: A collection of one or more sample units drawn from a lot.

Sample Size: The number of sample units drawn from a lot.

Sampling: The process of drawing or selecting product units from a lot.

Sampling Plan: A specific instruction which indicates the number of sample units to be inspected from the lot and the acceptance numbers for determining the acceptability of the lot.

Shipment: for the purpose of invoicing the notification fee, a shipment is defined as that quantity of product which is notified to an inspection office and imported by the same importer on the same transport vessel or carrier. A shipment can consist of any number of products from any number of packers.

Subject to Inspection: Any fish or fish products, whether imported or domestically produced, may be inspected for compliance with the Fish Inspection Regulations.

Summary Conviction Proceedings: Proceedings defined by the Criminal Code of Canada or any Federal Statute where a Provincial Court Judge, Magistrate, or Justice has sole jurisdiction over the matters brought before him/her.

Suspect Codes: Codes that may contain defective product.

Suspension of the Initial Inspection: The action taken by an inspector to suspend the decision of an inspection once the owner/agent decides to cull, recondition, or rework the lot.

Tainted: Fish that is rancid or has an abnormal odour or flavour.

Trade: Any person or company purchasing products at any location other than a retail location.

Unit: The unit of product is the individual item inspected in order to determine the acceptability of the lot. It may be an ingredient, a component of an end product, or the end product itself. The unit of product may or may not be the same as the unit of purchase, supply, production, or shipment.

Unwholesome: Fish that has in or upon it bacteria of public health significance or substances toxic or aesthetically offensive.

Wholesaler: Any intermediary between a processor and retailer.

New 31/01/1989

CHAPTER 1

INTRODUCTION

1. PURPOSE OF THE MANUAL

The purpose of the Fish Products Inspection Manual is to provide Inspectors with the policies and procedures to be employed when applying the Fish Inspection Regulations and other related regulations governing the inspection of fish and fish products. It will contribute to the uniformity of interpretation and consistency in the application of regulations. The manual provides more detail than is possible in regulations, but does not by itself have any legal standing.

This manual is not intended to be all inclusive. It is to be used in conjunction with other appropriate source material to provide the interpretation tools required by inspectors in the inspection of fish and fish products. It is meant to be a reference source and not a training manual.

This manual does not contain the official grade standards described for various fish products nor the policies or procedures governing facility inspections. These topics are addressed in the Product Standards Manual and the Facilities Inspection Manual respectively.

2. DEVELOPMENT OF THE POLICIES AND PROCEDURES

The policies and procedures in this manual have been developed using the process established for the development and approval of policies, standards and procedures for the National Fish Inspection Program.

The Process:

(1) Staff in the Regions and at Headquarters involved in the formulation of proposed policies, standards and procedures will forward these to Planning, Coordination and Review (PCR) Branch at Headquarters for inclusion in appropriate Inspection manuals.

(2) The first draft is distributed by PCR to Regional and Headquarters Directors of Inspection for review and comment within three weeks of receipt.

(3) PCR will forward comments to the originator or to Headquarters as appropriate. If comments are:

(a) editorial only, then the necessary adjustments will be made by PCR staff who will forward the document to Directives Management for finalization (see step 7);

(b) substantive, a second draft will be prepared and returned to PCR.

(4) If a second draft is prepared (or if revisions are made as a result of the Seafood Inspection Policy Advisory Committee (SIPAC) input at any stage) the document will be distributed by PCR to Regional and Headquarters Directors of Inspection for review and comment within three weeks of receipt.

(5) After review, if there are:

(a) no disputes, then PCR will send the document to Directives Management for finalization;

(b) disputes, PCR will identify the nature of the problem and forward to the Director General, Inspection Services Directorate, with copies to all Directors of Inspection.

(6) The Director General will render a decision on any disputes within two weeks of receipt. The document will be revised accordingly by PCR and forwarded to Directives Management for finalization.

(7) Directives Management edits the finalized document, arranges for translation and forwards the material to offices of collateral responsibility (eg. Legal Services, Official Languages, Internal Audit) for review and approval.

(8) The document or section is then forwarded for sign-off by the appropriate authority, printed and distributed to manual holders via the Directives Management group.

3. ORGANIZATION OF THE MANUAL

The Fish Products Inspection Manual - Policies and Procedures is divided into chapters of related inspection elements which are further sub-divided into subjects.

As a general rule, each subject contains a number of standard headings. When the nature of the subject does not lend itself to the standard format, other appropriate headings are used.

Scope:

Describes the subject to be covered and identifies any exclusions. It also makes reference to other subjects and chapters within the manual and other related manuals.

Authorities:

Identifies all sections under the Fish Inspection Act and Regulations and other relevant regulations, that must be enforced in order to achieve the objectives of the section.

Policy:

Provides direction regarding the application of the regulation pertinent to the section.

Procedures:

Provides the step-by-step process to be followed when applying the regulations pertinent to this subject.

Forms/Documents:

Provides a list of all forms and documents that are completed when following the procedures.

A Table of Contents is included in the Manual, listing the chapter and section titles. A cross-reference of regulations is also included.

4. DISTRIBUTION OF THE MANUAL

The Manual is to be distributed to all inspectors, district/area supervisors, and regional and Headquarters Inspection personnel involved in the inspection of fish and fish products. Other members of the Department may request a copy of the manual and it will also be provided to industry on request. A fee will be levied for industry copies.

All manuals are serially numbered, and registered to a position, as assigned on a master distribution list.

The Director of Planning, Coordination and Review is responsible for establishing the distribution requirements and ensuring that an effective distribution list is maintained.

Directives Management, Administrative Operations Division, is responsible for:

(a) developing a master distribution list that meets the requirements of the Director, Planning, Coordination and Review;

(b) controlling the distribution of manuals and amendments;

(c) keeping the master distribution list up to date; and

(d) maintaining an appropriate quantity of manuals and amendments in reserve for additional distribution when required.

All changes or additions to the distribution list should be forwarded to Manuals Production and Distribution, Directives Management.

A revised Registration Card/Notice of Change is then prepared by Directives Management and sent to the holder for inclusion in the Manual.

The Notice of Change is used to keep the master distribution list up to date. It is important that manual holders provide current registration information to ensure delivery of amendments to the correct location.

5. THE AMENDMENT PROCESS

Suggestions and requests for change/improvements to the Manual can be made by anyone within the department. However, before any amendments to the Manual are made they must undergo the development process described earlier in this chapter and the Director General, Inspection Services Directorate must approve all changes.

Once amendments have been accepted, their production and distribution are the responsibility of Directives Management.

The manual holders are responsible for keeping the manual up to date. Amendments should be inserted as soon as they are received.

A Record of Amendments page is provided in the Manual for recording the insertion of the amendment.

New 31/01/1989

6. THE BULLETIN PROCESS

Bulletins are used for communicating information of an urgent nature that cannot be delayed until the next amendment.

A bulletin may also be used to issue information of a temporary nature that will not be incorporated into the Manual.

When required, Planning, Coordination and Review will initiate action to amend the Manual at the earliest opportunity after a bulletin has been issued.

Bulletins are numbered sequentially and are filed in numerical order in the section provided in the Manual. Upon receipt of a bulletin, manual holders should make a note of it on the first page of any subject affected by the bulletin, thus alerting the reader to the existence of other information pertinent to that subject.

Bulletins are distributed to manual holders through Directives Management.

New 31/01/89

CHAPTER 2, SUBJECT 1

INITIAL INSPECTION

1. SCOPE

This document outlines the regulations, policy and procedures governing the initial inspection of all types of domestic and imported fish and fish products. There are, however, procedures unique to the inspection of imported fish products which are covered in Chapter 3.

2. AUTHORITIES

Fish Inspection Act. R.S.C., 1970, c.F-12; Sections 3(c) and 3(i)

Fish Inspection Regulations. C.R.C., 1978, c.802; (FIR) Part I, General

Section 4 (FIR):

All fish are subject to inspection and an inspector may take samples of fish free of charge for the purpose of inspection.

Section 5 (FIR):

The owner of fish or a person acting on his behalf shall make readily accessible to an inspector any fish or containers for which inspection or reinspection is required under these Regulations.

Section 6 (FIR):

(1) No person shall import, export or process for export or attempt to import, export or process for export:

(a) any fish that is tainted, decomposed or unwholesome or otherwise fails to meet the requirements of these Regulations.

3. POLICY

3.1 An inspection may be performed on any lot of imported or domestic fish and fish product, including containers and ingredients, from the time of initial harvesting to the final marketing of the product.

3.2 An inspection at the retail level is not within the jurisdiction of the Fish Inspection Regulations and potential problems should be referred to the regional office for direction.

3.3 When an inspection is to be performed, the lot must be identified and the owner/agent of the goods must make the entire lot available for sampling and/or inspection to the satisfaction of the inspector.

3.4 The completion of an initial inspection will result in either the failure or acceptance of a lot of fish. In most cases where a lot fails the initial inspection, a reinspection is granted provided the conditions outlined in Chapter 2, Section 2 are met.

3.5 Under certain circumstances, (see Procedures, 5.9), an Inspector may delay rendering a decision on the inspection when the results show that the lot inspected does not comply with the Fish Inspection Regulations. If the owner/agent agrees, the decision on the inspection results is suspended, thus providing the owner/agent of the lot the opportunity to correct the defects in the lot.

NOTE: An offer to suspend the decision on the results of an initial inspection may only be offered once.

4. PROCEDURES

4.1 The type of analysis the inspection will entail must be established prior to commencing the inspection, i.e. - bacteriological, organoleptic, composition, species identification, chemical, weight evaluation, label evaluation, seam evaluation, or a combination of the above.

4.2 The identity of the lot of fish to be inspected must be confirmed. This requires determining as much of the following information on the lot as possible: the location, the common name of the species in the lot, the size of the lot, the identification marks (lot number, codes), the grade, and the moisture content and the size of product if applicable.

4.3 Once the lot has been identified, the inspector has the option to detain the lot until the inspection is completed and the disposition of the lot decided. All import products on the Mandatory Inspection List (MIL) (or products suspected of being in non-compliance with the regulatory requirements) must be detained.

4.4 The inspector must select the appropriate sampling plan and inspection level depending on the type of product to be examined and the analysis required.

4.5 The inspector must determine the sample unit, calculate the lot size and sample size, and withdraw the sample from the lot.

4.6 The inspector must prepare the sample for inspection and ensure that it is assessed against all applicable requirements of the Fish Inspection Regulations.

4.7 The lot of fish passes or fails based on the results of the initial inspection. If the lot passes and is under detention, the lot is released. If the lot fails and is not already under detention, the lot is detained immediately (Chapter 2, Section 3, Detention and Release).

4.8 When inspection of the sample shows that the lot does not comply with the requirements of the Fish Inspection Regulations, i.e. - the acceptance number is exceeded, an inspector shall suspend the decision on the initial inspection provided the following conditions exist:

a) The fish or containers thereof do not have in or upon them any poisonous or harmful substances. In special cases reconditioning may be permitted if the Department determines that bacteria of public health significance would be removed. Any decision regarding reconditioning must be made with full consultation with the Regional Inspection Headquarters; and

b) The inspector determines that the owner/agent is able to correct the defect(s) of the lot through culling or reworking.

A suspended inspection would not be offered under the following circumstances:

Where a lot of canned product consisting of only one code does not comply with the Fish Inspection Regulations due to decomposition, a suspended inspection cannot be offered, as it is impossible to determine which cans contain decomposed product.

4.9 The "Offer to Suspend Initial Inspection" (Appendix B) is to be given or sent immediately to the owner/agent indicating why the lot failed to comply with the regulations and detailing the conditions under which the decision on the results of the initial inspection will be suspended.

4.10 A suspension of the initial inspection will only be granted provided the following conditions are met:

a) The identity of the fish, or containers thereof, has been maintained;

b) The Department receives within 30 days of the owner/agent receiving the notification of the opportunity to suspend the initial inspection a written request to do so;

c) the request to suspend the initial inspection outlines the intended process for culling, reconditioning or reworking the lot and the process is acceptable to the Department; and

d) the owner/agent agrees to dispose of all defective product resulting from the action in c) above, in a manner acceptable to the Department.

If any of the above conditions are not met, the initial inspection procedure re-commences and the owner/agent is notified of the failure of the lot by the Fish Inspection Report, or equivalent (Appendix A), and his/her right to a reinspection by the "Notification of Right to Reinspection" (Appendix C).

4.11 Upon receipt of the owner/agent's written request to suspend the initial inspection, the inspector must evaluate the proposed process for culling or reworking the product to determine if the process is valid. It is recommended that the inspector confer with his/her supervisor during the evaluation. Proposals for reconditioning must be referred to Regional Headquarters.

When evaluating the intended process for culling, the inspector should note that the process must:

a) remove defective units from the lot; or
b) segregate suspect codes from the lot.

In the first instance, all culled product is considered defective with the exception of mislabelled product, (under weights, mis-labelling), and is not eligible for further inspection or reinspection. The rejected product must be disposed of in a manner acceptable to the Department. In the second instance, the culled lot is divided into two lots, one lot which contains all suspect codes. Both lots are subject to inspection/reinspection procedures.

NOTE: The inspector must be satisfied that the proposed culling process describes a realistic means of segregating suspect codes from the original lot as well as a realistic means of culling defective product from those suspect codes. If the inspector is satisfied that the above can be met, the removal of suspect code(s) from the original lot will be permitted provided the suspect codes are combined into one new lot.

4.12 Upon accepting the process for culling, reconditioning or reworking submitted by the owner/agent, the inspector must confirm the conditions, time and place via the letter entitled "Approval of Culling, Reconditioning or Reworking Process" (Appendix D).

4.13 All culling, reconditioning and/or reworking must be done under the supervision of an inspector.

New 31/01/89

4.14 The inspector must ensure that all defective units removed during a culling or reworking process are disposed of in a manner acceptable to the Department.

4.15 Upon completion of the approved culling, reconditioning and/or reworking process, the inspector must sample the lot(s) in accordance with the original sampling plan on a code by code or a lot basis. Only the results from this sample will be used to determine the compliance of the lot(s).

4.16 The owner/agent is notified of the results of the initial inspection by the Fish Inspection Report or equivalent (Appendix A).

If the lot passes inspection, it is released. If the lot fails, the owner/agent is also notified of the right to a reinspection by the "Notification of Right to Reinspection".

5. FORMS/DOCUMENTS

Fish Inspection Report - Appendix A

Sample Letter: "Offer to Suspend Initial Inspection" - Appendix B

Sample Letter: "Notification of Right to Reinspection" - Appendix C

Sample Letter: "Approval of Culling, Reconditioning or Reworking Process" - Appendix D

Flow Chart: "The Initial Inspection and Reinspection Process" - Appendix E.

2	1	A-1
New		31/03/89

New 31/01/89

OFFER TO SUSPEND INITIAL INSPECTION

Dear Sir/Madam:

On (give dates), an inspection was conducted on a lot of fish (or containers of fish) consisting of (identity of the lot) and the results indicate that the said lot of fish does not comply with Section 6 (1) (a) of the Fish Inspection Regulations in that the samples examined were (reasons). This being the case, the Department's policy allows the decision on the results of the inspection to be suspended to permit your firm the opportunity to cull, rework, or recondition the lot under the supervision of an Inspection officer, provided all four of the following conditions are met:

1) DFO receives a written request from you, within 30 days of the date of receipt of this letter, to permit the culling, reworking or reconditioning of the lot;

2) The process for culling, reconditioning or reworking is acceptable to the Department and is capable of being monitored by an inspector;

3) The identity of the fish or containers of fish has been maintained; and

4) Your firm agrees to dispose of all defective product culled from the lot, in a manner acceptable to the Department.

The terms "culling, reworking, and reconditioning" are defined as:

1) "culling" - the removal of defective units from the lot;

2) "reworking" - the removal of defects from the units in the lot (eg. trim or candle);

3) "reconditioning" - the elimination of bacteria of public health significance by heat treatment.

When you have fully complied with all the conditions identified above and when the approved culling, reworking or reconditioning process has been completed, samples will be withdrawn by an Inspector to assess the acceptability of the lot and to complete the initial inspection. Failure to meet all the requirements identified above will mean that the results of the inspection prior to suspension will determine the acceptability of the lot.

_____

Inspector

New 31/01/89

NOTIFICATION OF RIGHT TO REINSPECTION

Dear Sir/Madam:

On (give dates), an inspection was completed on a lot of fish (or containers of fish) consisting of (describe the lot). The results indicate that this lot of fish does not comply with section 6 (1) (a) of the Fish Inspection Regulations.

You are hereby notified that you have the right to appeal this decision, as provided in section 10 (1) of the Fish Inspection Regulations. Should you decide to appeal the decision on this lot of fish, a written request should be made to this office within 30 days of receiving this letter. As well, you are hereby advised that you may:

1) Cull or rework the fish or containers of fish;
2) Request that a duplicate set of samples be withdrawn for private analysis;
3) Request that the lot be reinspected on a code by code basis or on a lot basis;
4) Have yourself and/or your agent (maximum of two persons) attend the sampling and/or reinspection;
5) Request that the reinspection take place in a fisheries administrative center different from that in which the initial inspection occurred, provided that all of the following conditions are met:

   a) the request is made in writing;
   b) you indicate in the written request that you are willing to bear all costs associated with the transportation of the samples; and
   c) product integrity can be maintained during the transport of the samples.

Your intention to do any of the above must be indicated in the letter in which you request the reinspection.

A summary of the results will be provided to you upon completion of the reinspection.

Cull is defined as:
- to remove defective units from the lot.

Rework is defined as:
- to remove defects from the units in the lot, (eg. candle or trim) or to reprocess the product such that the nature of the product is significantly changed.

_____

Inspector

New 31/03/89

APPROVAL OF CULLING, RECONDITIONING OR REWORKING PROCESS

Dear Sir/Madam:

The purpose of this letter is to confirm the date, location and conditions of the (culling, reconditioning or reworking) process to be conducted on (description of lot of fish):

1) the operation will take place on (give date) at (give address);

2) the operation will be performed under the supervision of (name of inspector) Fish Inspector;

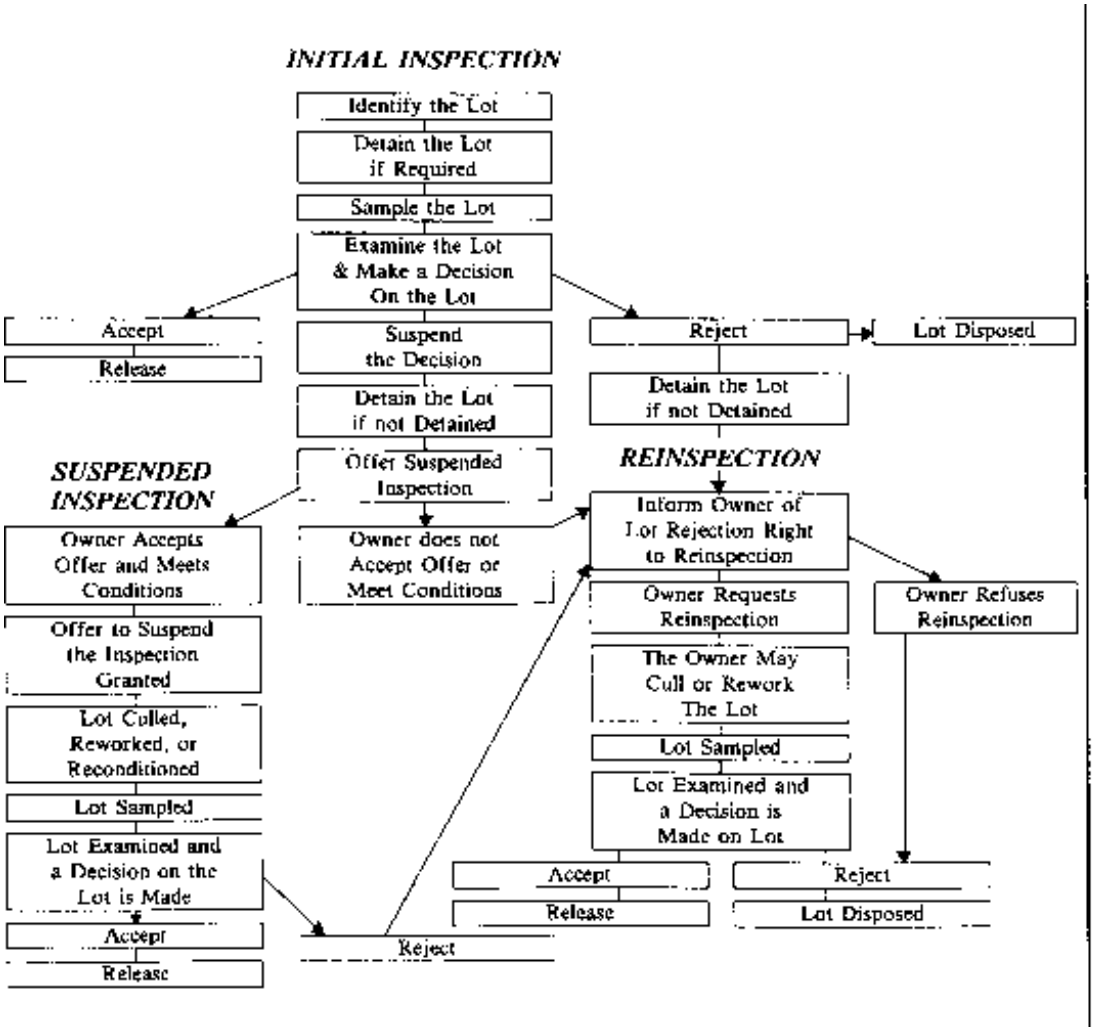
3) (description of lot) will be (culled, reconditioned, or reworked) under the following conditions: (give conditions).

_____

Inspector

New 31/03/89

THE INITIAL INSPECTION AND REINSPECTION PROCESS



New 31/01/1989

CHAPTER 2, SUBJECT 2

REINSPECTION

1. SCOPE

This document outlines the regulations, policy and procedures governing the reinspection of fish and fish products.

2. AUTHORITIES

Fish Inspection Act. R.S.C., 1970, C.F.-12: Part I, Sections 3 and 5.

Fish Inspection Regulations (FIR), C.R.C., 1978, c. 802; Part I, General.

Section 10 (FIR)

(1) Where a person interested in a decision of an inspector in respect of any inspection, grading, marking or other matter under PART I of the Act or these Regulations is not satisfied with a decision of an inspector, he may, by notice in writing, appeal the decision to the Minister who shall, subject to section 11, order a reinspection.

(2) Where a reinspection is made pursuant to subsection (1) and the Minister makes a decision as a result thereof, that decision shall be final.

Section 11 (FIR)

A reinspection shall not be ordered pursuant to section 10 where:

(a) the identity of the fish or containers of fish in dispute has not been preserved;

(b) the request for reinspection was not made within 30 days after the disputed inspection;

(c) the fish or containers of fish have in or upon them any poisonous or harmful substance; or

(d) the fish or containers of fish have been previously reinspected.

New 31/01/1989

3. POLICY

3.1 A reinspection of a lot will only be granted after:

a) an initial inspection has been completed and official written notification of the results has been given to the owner of the goods or his/her agent; and

b) a written request for a reinspection has been received from the owner or agent. Telexes are acceptable.

3.2 In most instances written appeals should be directed to the Area Inspection Chief or equivalent for decision. However, there may be circumstances (e.g. export at Canada-U.S. border), where a reinspection must be performed immediately; in such cases all Fish Inspectors may act on behalf of the Minister and grant a reinspection.

3.3 The reinspection may be conducted in a fisheries administrative center other than that in which the initial inspection occurred, provided the owner meets the conditions detailed in the procedures.

3.4 The reinspection will normally be conducted by three Inspectors trained in the examination of the goods in question. The Inspectors must not have been involved in the initial inspection. The owner may waive, in writing, these requirements if he/she wishes to expedite the reinspection; however, the final decision regarding the number of Inspectors will be made by the Regional Inspection Director and will depend upon the resources available. The owner or agent shall be advised in writing of the decision.

4. PROCEDURES

4.1 Where an initial inspection results in the failure of a lot of fish, the lot must be detained, if not already (Detention and Release, Chapter 2, subject 3).

4.2 The owner/agent is notified of the results by the Fish Inspection Report (Appendix A or equivalent), indicating the reasons for rejection. At the same time the owner/agent is notified of his/her right to a reinspection by the Notification of Right to Reinspection (Appendix B).

4.3 The request for reinspection must be received from the owner/agent within 30 days. The 30 day period will commence the day the Inspector hand delivers the Fish Inspection Report or the date of receipt of the report when sent by registered mail.

New 31/01/1989

4.4 Prior to reinspection, the owner/agent may do any or all of the following, provided the details of the intended work are outlined in the request for reinspection, approved by an inspector, and the work is monitored by an inspector:

a) cull or rework the goods;

b) remove suspect codes from the lot(s);

c) request that a duplicate set of samples be withdrawn for private analysis;

d) request that the lot be reinspected on a code by code or a lot basis.

NOTE: If the owner/agent wishes to have a duplicate set of samples withdrawn for private analysis this request must be made in writing. It must be explained to the owner that the samples are for analysis purposes only and are not to be sold or distributed. Results of any private analysis is for the owner's use only and will not have a bearing on the final decision of reinspection.

4.5 If the product has been rejected during export at the border, the operator of the transport carrier is to sign the Notice of Detention and be given a copy of the Fish Inspection Report or equivalent. If the owner/agent can be reached and is able to provide a written request to the inspector for reinspection at the border, one will be performed. In such cases many of the options available to the owner must be waived. If the owner of the fish cannot be reached or cannot provide a written request for reinspection, the product will be returned to the shipping source.

4.6 If the owner/agent requests the reinspection be conducted in a different inspection district, area, or region, he/she must meet the following conditions:

a) provide a written request to change the location;

b) agree in writing to bear all costs associated with the transportation of the samples; and

c) ensure that product integrity can be maintained during transportation.

4.7 The owner and/or his/her agent (to a maximum of two persons) may attend the sampling and/or reinspection. During the reinspection they shall act strictly as observers and shall not hinder the Inspectors in any way. (They must refrain from discussing the samples or examination results until the reinspection has been completed).

New 31/01/1989

4.8 The reinspection will be conducted by three Inspectors trained in the examination of the goods in question, as follows:

a) One of the three Inspectors is appointed as team leader and spokesperson and is solely responsible for presenting the results of the reinspection to the owner/agent.

b) Before the reinspection begins, the team leader shall brief the owner/agent, if present, on how the reinspection will be conducted.

c) The team leader shall prepare the samples for reinspection, ensuring that each sample is clearly identified so that no confusion occurs when summarizing the individual reinspection reports.

d) Prior to the commencement of the reinspection, the team leader shall review the procedures and methods to be followed by the reinspection team:

- Each Inspector shall independently examine each sample and record the results on an individual reinspection report.

- The Inspectors shall not discuss the reinspection during the actual examination; they may request clarification on specific points of procedure from the team leader.

- The individual inspection reports of each team member shall not be given to the owner.

- While preparing the summary report, the team leader may consult each Inspector on his/her individual reports.

- The team leader shall communicate the results of the reinspection to the owner/agent and provide the completed Fish Inspection Report or equivalent.

- All of the Inspectors will be present when the team leader presents the results.

- If the owner/agent is not present at the reinspection, he/she may be informed by telephone of the results. The telephone call will be followed by the Fish Inspection Report, which is sent by registered mail or hand delivered to the owner or agent.

e) The team leader will prepare a final report of the reinspection results, including all documents, for his/her supervisor.

New 31/01/1989

NOTE: The inspection for defects such as parasite infestation, number of bones, and/or foreign material, may be performed by one member of the team.

5. FORMS/DOCUMENTS

Fish Inspection Report (FP 1541) - Appendix 'A'

Notification of Right to Reinspection - Appendix 'B'

Flow Chart: "The Initial Inspection and Reinspection Process" - Appendix C.

2	2	A-1
New	31/01/1989	

New 31/01/1989

NOTIFICATION OF RIGHT TO REINSPECTION

Dear Sir/Madam:

On (give dates), an inspection was completed on a lot of fish (or containers of fish) consisting of (describe the lot). The results indicate that this lot of fish does not comply with section 6 (1) (a) of the Fish Inspection Regulations.

You are hereby notified that you have the right to appeal this decision, as provided in section 10 (1) of the Fish Inspection Regulations. Should you decide to appeal the decision on this lot of fish, a written request should be made to this office within 30 days of the date of receipt of this letter. As well, you are hereby advised that you may:

1) Cull or rework the fish or containers of fish;
2) Request that a duplicate set of samples be withdrawn for private analysis;
3) Request that the lot be reinspected on a code by code basis or on a lot basis;
4) Have yourself and/or your agent (maximum of two persons) attend the sampling and/or reinspection;
5) Request that the reinspection take place in a fisheries administrative center other than that in which the initial inspection occurred, provided that all of the following conditions are met:
   a) the request is made in writing;
   b) you indicate in the written request that you are willing to bear all costs associated with the transportation of the samples; and
   c) product integrity can be maintained during the transport of the samples.

Your intention to do any of the above must be indicated in the letter in which you request the reinspection.

A summary of the results will be provided to you upon completion of the reinspection.

Cull is defined as:
- to remove defective units from the lot.

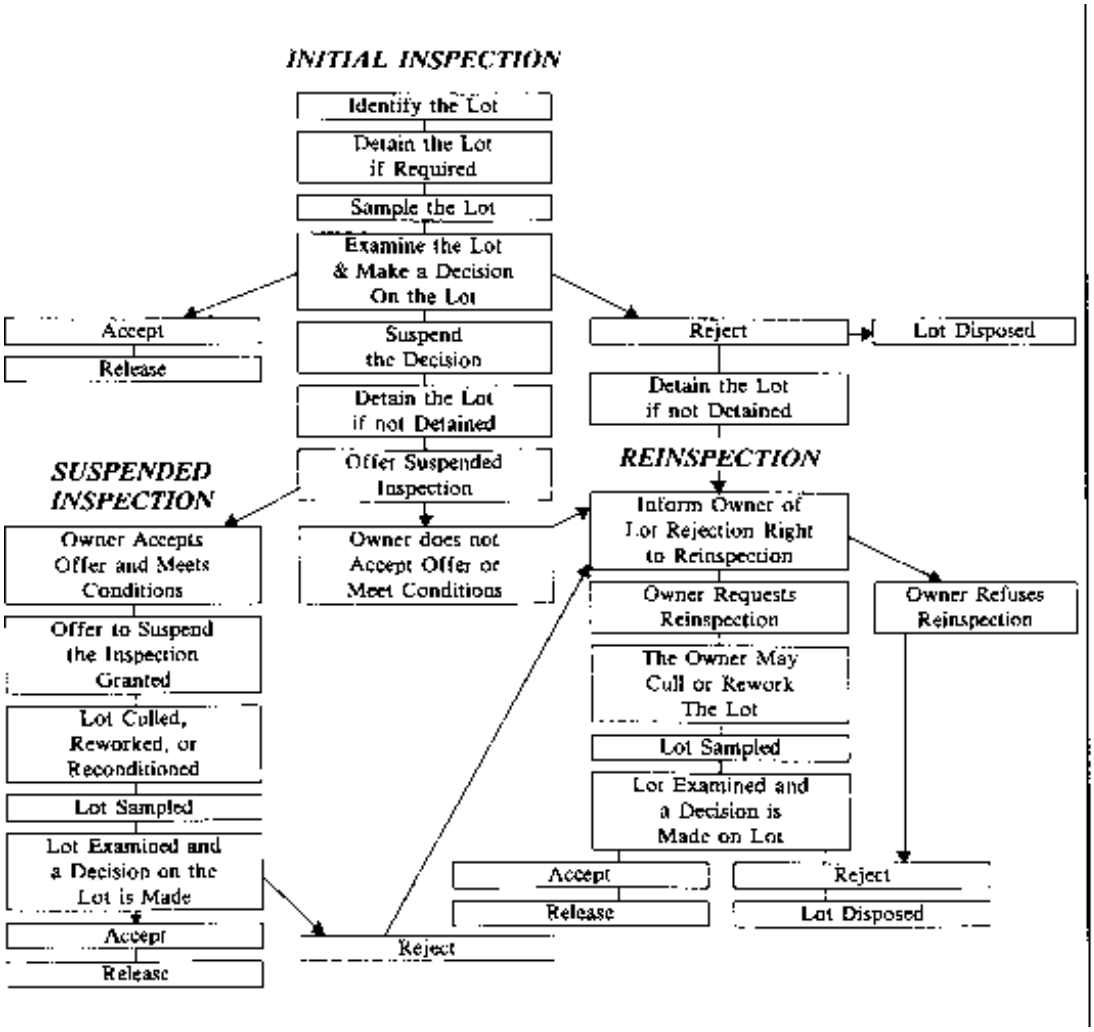
Rework is defined as:
- to remove defects from the units in the lot, (eg. candle or trim) or to reprocess the product such that the nature of the product is significantly changed.

_____

Inspector

New 31/01/1989

THE INITIAL INSPECTION AND REINSPECTION PROCESS



New 31/01/1989

CHAPTER 2, SUBJECT 3

DETENTION/RELEASE

1. SCOPE

This document outlines the policy, procedures and regulations governing the detention and release of fish and fish products.

NOTE: This does not address seizure of product under Section 7 of the Fish Inspection Act (see Chapter 2, Subject 4).

2. AUTHORITIES

Fish Inspection Act, R.S.C., 1970, c.F-12; Part I, Fish and Fish Containers.

Fish Inspection Regulations (FIR), C.R.C., 1978, c. 802; Part I, General.

Section 8 (FIR)

(1) For the purpose of preserving the identity of any fish, an inspector may detain the fish by attaching to any of the fish or any container thereof a numbered tag upon which shall be clearly written

(a) the word "held";

(b) an identification number;

(c) a brief description of the lot detained;

(d) the date; and

(e) the signature of the inspector.

(2) Where any fish is detained pursuant to subsection (1), the inspector shall deliver or mail to the owner or his agent a duly completed notice of detention.

(3) Where any fish is detained pursuant to subsection (1) on premises owned by a person who is not the owner of the fish, a copy of the notice of detention shall be delivered or mailed to that person.

New 31/01/1989

(4) No person shall alter, deface or remove a tag attached to any fish or container thereof pursuant to subsection (1) or move, sell or dispose of any such fish or container thereof unless he has obtained a release from an inspector.

(4.1) Notwithstanding subsection (4), where it is necessary for any fish or container thereof referred to in that subsection to be moved from one warehouse to another, or the owner of the fish or container or his agent has made a reasonable request for the fish or container to be moved under detention, an inspector may permit such fish or container thereof to be moved accordingly.

(5) Where an inspector is satisfied that any fish detained pursuant to subsection (1) meets the requirements of these Regulations, he shall prepare a notice of release and deliver or mail one copy thereof to the owner of the fish or his agent and one copy to the person, if any, on whose premises the fish was found.

3. POLICY

3.1 The Fish Inspection Regulations gives an inspector the authority to detain fish in order to preserve the identity of that fish.

3.2 Fish or fish products must be detained when a suspended inspection is offered, when the fish or fish product fails an initial inspection or when the fish product is on the Mandatory Inspection List (MIL). The inspector also has the option of detaining any lot of fish until an inspection is completed and the disposition of the lot decided.

3.3 Fish under detention remains under the control of the owner, although he/she cannot move the fish unless approval is given by the inspector.

3.4 A request for authorization to move fish under detention must be made in writing by completing the "Request for Movement of Fish Under Detention" (Appendix D).

3.5 Fish will remain under detention until all deficiencies have been corrected and the fish complies with the regulatory requirements, or the fish has been disposed of in a manner acceptable to the Department or, in the case of imports, the fish product is removed from Canada.

3.6 When fish under detention has been dealt with so that it meets the regulatory requirements, it will be released.

3.7 There are no specified time limits for detention in the Fish Inspection Regulations, meaning that fish can be detained indefinitely. However, the initial inspection and reinspection processes must be implemented as soon as possible once the fish has been detained. Fish and fish products which do not comply with the regulations and have failed both initial inspection and reinspection, will be disposed of in a manner acceptable to the Department or, in the case of imports, removed from Canada (lots not in compliance with the labelling regulations will be detained until the labels have been corrected). The owner/agent shall have a maximum of 45 days following notification that the product has been rejected to take action. If the owner/agent fails to take action within the 45 days, the detained fish shall be seized (Seizure and Forfeiture, Chapter 2, Subject 4) and legal proceedings initiated.

3.8 In certain instances, long term detention of fish can occur (eg. detention for minor can defects which will be re-canned at a later date). In such cases the location and disposition of the detained lot must be verified every 4 weeks.

NOTE: Inspectors are reminded that all Fish Inspection Act violations are summary conviction offences for which the limitation period is 6 months. Therefore, legal action must be initiated within 6 months of the date of the alleged offence.

4. PROCEDURES

4.1 The fish to be detained must be identified as to species, size of lot, type of pack, markings and codings, if applicable, and location.

4.2 Fish should be detained on a lot basis. More than one lot of fish can be detained on the same Notice of Detention (Appendix B, with instructions) provided the lots contain the same species, the same type of pack and the same brand. A single detention notice should not be used to detain a mixture of product consisting of various brands, pack sizes and species.

4.3 A Held Tag (Appendix A, with instructions) must be secured to any fish or containers thereof in a conspicuous place that will be clearly visible to any person examining the lot. It is preferable that one held tag be used. In cases where the lot is very large and is spread over a large area, more than one held tag may be used to ensure that the identity of the lot is maintained. In such cases, the held tags should bear the same number. The location of the held tag should be recorded in the inspector's note book and pointed out to the company official signing the Notice of Detention.

New 31/01/1989

If a lot is broken into two or more portions and stored in several areas of a warehouse or cold storage,the inspector should try to have the entire lot stored in one area prior to detaining.

4.4 The Notice of Detention must be signed by a person with the proper authority (see Definitions). If the owner of the fish or the owner of the premises where the fish is stored is not available, the notice is to be signed by the person responsible for the storage of the product. If the company official refuses to sign, it must be noted on the Notice of Detention. If the company official refuses to accept the Notice of Detention, it is to be mailed to the owner/agent via registered mail.

4.5 The distribution of the Notice of Detention is as follows:

(a) Original - to the owner of the fish
(b) Copy 1 - to the owner of the premises where the fish is stored
(c) Copy 2 - to the district file
(d) Copy 3 - to the inspector's file.

4.6 Where the owner finds it necessary to move fish under detention, he/she shall request authorization by completing the "Request for Permission to Move Fish Under Detention" (Appendix D).

Authorization is granted by the inspector by completing the bottom portion of the form and forwarding a copy to the requesting company.

4.7 When detained product is moved between districts or regions, copies of the Notice of Detention, inspection reports supporting the detention, the Request for Permission to Move Fish Under Detention, the anticipated time of arrival and any other relevant information must be forwarded to the receiving district or regional office.

4.8 When fish under detention has had all deficiencies corrected, has been disposed of, or has been returned to the country of origin, the inspector will prepare a Notice of Release (Appendix C, with instructions).

4.9 When a portion of a lot of fish under detention complies with the regulations, that portion of the lot shall be released as above. The remainder of the lot not complying with the regulations will remain detained under the same Detention Notice.

4.10 The distribution of the copies of the Notice of Release is the same as for the Notice of Detention.

New 31/01/1989

5. FORMS/DOCUMENTS

- Held Tag - Appendix A
- Notice of Detention - Appendix B
- Notice of Release - Appendix C
- Request for Permission to Move Fish Under Detention - Appendix D

New 31/01/1989

HELD TAG

INSTRUCTIONS FOR COMPLETING THE HELD TAG

1. Product Description: species and product form (additional information to be written on the back of tag).

2. Lot Size: weight, number of cartons, number of cans, etc.

3. Marks: markings on cartons/shipping cartons which will identify the lot, such as codes, port marks, brand name, distribution/packer name, registration number.

4. Date-Place: date of detention, place of detention.

2 3 B-1

New 31/01/1989

New 31/01/1989

INSTRUCTIONS FOR COMPLETING
THE NOTICE OF DETENTION

1. The office of the inspector issuing the notice.

2. Date of detention.

3. The owner of the product.

4. Address of the owner of the product.

5. Location of the detained lot.

6. In the case of imported product specify the country of origin and if possible, the foreign producer.

   In the case of fresh water fish products specify the lake or plant.

   In the case of shellfish specify the area of harvest. For all other domestic fish products specify the processor.

7. "for the purpose of preserving the identity"

8. Held tag number.

9. Detailed description of the lot. If samples are taken, the number and weight should be indicated here.

10. Signature of owner or agent.

11. Signature of inspector.

2	3	C-1
New	31/01/1989	

New 31/01/1989

INSTRUCTIONS FOR COMPLETING THE NOTICE OF RELEASE

1. The office of the inspector issuing the notice.
2. Date of release.
3. The owner of the product.
4. Address of the owner of the product.
5. Entire detained shipment (indicated by weight or number).
6. Species & form of detained product.
7. Date of Detention.
8. A detailed description of the fish being released. Should include species, form, weight, number of cartons, codes, port marks, etc. If only a portion of the lot is released, this must be stated indicating how much remains under detention. If any product is destroyed it must be indicated in this section.
9. Held tag number.
10. Signature of inspector.

New 31/01/1989

REQUEST FOR PERMISSION TO MOVE FISH UNDER DETENTION

Date: _____

Request made by: _____

Description of lot of Fish: _____

Date Detained: _____

Held Tag Number: _____

Detaining Inspector: _____

Location of the Fish: _____

I request permission to move the fish noted above: _____

Reason: _____

_____

Location Change: _____

Date of Move: _____

Method of Movement: _____

Signature: _____

TO: _____

_____

Request Granted: _____ Request Denied: _____

Fish under Held Tag Number _____ will be moved on _____

from _____ to _____ subject to the following conditions:

_____

_____

_____

Inspector/Inspecteur

New 31/01/1989

CHAPTER 2, SUBJECT 4

SEIZURE AND FORFEITURE OF FISH PRODUCTS

1. SCOPE

This document outlines the policy and procedures governing the seizure and forfeiture of fish, fish products and containers.

NOTE: This document does not cover the detention of product which is covered under Section 8 of the Fish Inspection Regulations, and outlined in Chapter 2, Subject 3 of this manual.

2. AUTHORITIES

Fish Inspection Act, R.S.C., 1970, C. F-12: Section 7

Section 7

(1) Whenever an inspector believes on reasonable grounds that an offence against this Part or any regulation thereunder has been committed, he may seize all fish and containers by means of or in relation to which he reasonably believes the offence was committed.

(2) All fish and containers seized pursuant to subsection (1) may be detained for a period of two months following the day of seizure, unless during that period proceedings under this Part in respect of those fish and containers are undertaken, in which case the fish and containers may be further detained until such proceedings are finally concluded.

(3) Where a person is convicted of an offence against this Part or any regulation thereunder, the fish and containers by means of or in relation to which the offence was committed, upon such conviction, in addition to any penalty imposed, are forfeited to Her Majesty and may be disposed of as the Minister may direct. R.S., c. 118, s.7.

3. POLICY

3.1 a) Seizure is employed where an Inspector, on reasonable grounds, believes that an offence has been committed against Part 1 of the Act or any regulation thereunder. The fish and containers involved in the offence are seized to prevent their shipment, movement, or disposal.

b) Seizure is only employed as a last resort in those circumstances where an inspector believes that a detention could be, or has been, violated.

3.2 Following seizure action, every effort must be made to remove all seized fish, fish products, and containers to a secure storage location as soon as possible. All costs for removal and storage are to be borne by the Department. The Crown can request that removal and storage costs be considered by the Court when any fine is levied.

3.3 Although the Fish Inspection Act does not provide the authority to sell seized goods and to retain the proceeds of the sale, pending the outcome of the legal proceedings, nothing precludes an understanding between Crown Counsel and Defence Counsel as to the disposal of the seized goods at an agreed upon price. The monies generated from such sales could be placed in escrow.

Inspectors are reminded that a person charged with any offence is considered innocent until proven guilty. Therefore, any product seized must be maintained in the best possible conditions in order to mitigate any losses in product quality. All costs incurred from the point of seizure are borne by the Department.

Seized product determined to be tainted, decomposed or unwholesome by the initial inspection and reinspection procedures will not be further processed and is to be disposed of by the Department. Seized product that can be stored, will be, until the completion of the trial.

3.4 Section 7(3) of the Fish Inspection Act demands the automatic forfeiture of all seized goods where the accused is found guilty. Inspectors must ensure that the Crown Counsel is aware of the forfeiture requirements.

3.5 Only the Minister can decide the eventual disposition of all seized and forfeited fish and containers, as per Section 7(3) of the Act. In cases where decisions on the disposition of forfeited fish, fish products and containers are required, Regional Directors of Inspection are to prepare a Memorandum to the Minister via the Director General, Inspection Services Directorate.

4. PROCEDURES

4.1 Pursuant to Section 7 of the Fish Inspection Act, an inspector shall seize fish, fish products and containers by completing the "DFO Inspection Services Seized Good Receipt" (Appendix A) and advising the owner of the goods or the agent controlling the goods that the inspector has grounds to believe that an offence (specify the offence) has been committed.

A receipt must be issued at the time of seizure for all goods seized.

4.2 If an owner wishes to regain control of the goods following seizure, this may be done through a court hearing. In permitting such an action, the court will require a bond be posted for the value of the goods pending a court decision. Where such an action would not be in the public's interest (ie. health and safety concerns), Crown Counsel can put forth arguments to this effect and request the action be refused.

4.3 Section 7(2) of the Act allows for a two month period of seizure commencing the day following the seizure action during which time legal proceedings must be initiated. If legal proceedings are not initiated within this two month time frame, the seizure becomes null and void and the fish and containers must then be returned to the owner or agent originally having control over the fish and containers.

Once legal proceedings have commenced, the seizure remains in effect until a court decision is reached. If it is determined that legal proceedings will not be undertaken, the seized goods must be released immediately; an inspector must not wait for the two months to lapse.

Legal proceedings begin when the inspector lays an information before the Justice of the Peace outlining the offence that has been committed and for which the fish is seized. This action is completed in conjunction with Crown Counsel and the Department of Justice.

4.4 If the owner or agent having control over the fish being seized obstructs, impedes, or refuses to admit an inspector seizing fish, fish products and containers pursuant to Part 1 of the Fish Inspection Act and any regulation made thereunder, this person is liable to prosecution for obstruction pursuant to section 4(2) of the Fish Inspection Act.

Procedures for the secure storage and transportation for seized fish products is the responsibility of the Regional Director of Inspection.

4.5 To ensure compliance with section 7(3) of the Fish Inspection Act, the inspector must remind Crown Counsel of the forfeiture requirements of the section. During the court proceedings evidence must be produced as to the description, quantity and record of seizure of the seized goods in order for the Court to order forfeiture.

4.6 Upon conviction of the accused and Court ordered forfeiture of the fish and containers, inspectors shall instruct their prosecuting attorneys to complete a DFO Order of Forfeiture Form (Appendix B) for the Provincial Court Judge's signature. In this way, the Department has legal proof that it is now the true owner of all seized and forfeited fish and containers.

4.7 Once the seized goods are forfeited to the Crown, only the Minister of Fisheries and Oceans or a person designated by the Minister may decide the disposition of the goods.

Upon receipt of the completed "Prosecutor's Information and Return Form" at the Regional Office, the Regional Director of Inspection is to prepare, for review by the Director General, Inspection Services Directorate, a Memorandum to the Minister or person designated to handle such matters outlining the following:

- the charge(s) laid;
- history of offence;
- penalties levied;
- quantities of fish forfeited and their value; and-
  recommendations to the Minister regarding disposition of the forfeited lots of fish.

5. FORMS/DOCUMENTS

"DFO Inspection Service Seized Goods Receipt" - Appendix A

"Order of Forfeiture" - Appendix B

New 31/01/1989

The following DFO Inspection Service Seized Goods Receipt can be reproduced locally on departmental letterhead, and is to be given to owners and agents of seized fish at the time of seizure.

DFO INSPECTION SERVICE SEIZED GOODS RECEIPT

Date of Seizure: _____

Place of Seizure: _____

Seized from: _____

_____

_____

Lot Description: Complete description of lot seized

_____

_____

_____

_____

_____

The goods described above have been seized in relation to the following offence: _____

_____

_____

_____

_____

_____

SIGNATURE OF OFFICER MAKING SEIZURE

2	4	B-1
New	31/01/1989	

CHAPTER 2, SUBJECT 5

COMPLIANCE AND ENFORCEMENT STRATEGY

1. SCOPE

The Compliance and Enforcement Strategy provides a framework that outlines the principles and actions that will be followed by the Canadian Food Inspection Agency (CFIA) with the goal that regulated parties operate in full compliance with the *Fish Inspection Act* (FIA), *Fish Inspection Regulations* (FIR) and other applicable legislation. This program specific strategy is consistent with CFIA's Enforcement and Compliance Policy (Revised September 1999) developed and maintained by the Enforcement and Investigation Services (EIS) Division. The CFIA Enforcement and Compliance Policy provides the overarching policy for enforcement and compliance activities across all commodity programs. In addition to the Compliance and Enforcement Strategy being contained within both the Fish Products Inspection Manual and the Facilities Inspection Manual, it will also be issued as an appendix to the CFIA Enforcement and Compliance Policy.

Compliance is normally achieved through a co-operative approach between the regulated party and CFIA in correcting non-conformities through the development of appropriate Corrective Action Plans or other methods. However, when this co-operative approach has ceased, or when the regulated party is incapable of correcting non-conformities, the Compliance and Enforcement Strategy provides CFIA staff with enforcement options that are to be used in responding to infractions of the FIA, FIR and other applicable legislation. This document also defines discretionary parameters for inspectors and establishes principles for fair and consistent enforcement.

2. AUTHORITIES

Fish Inspection Act (FIA), R.S., c. F-12
Fish Inspection Regulations (FIR), C.R.C., c. 802

Food and Drugs Act, R.S., c. F-27
Food and Drug Regulations, C.R.C., c. 870

Consumer Packaging and Labelling Act, R.S., c. 38
Consumer Packaging and Labelling Regulations, C.R.C., c. 417

3. POLICY

3.1 Responsibility for Enforcement Actions

Area Executive Directors are accountable for compliance and enforcement actions undertaken within their respective areas. Regional Directors are responsible for the approval of compliance and enforcement actions including refusal, suspension and revocation of certificates of registration, licenses and permits. They are also responsible for the approval of all recommendations to prosecute. The Regional Director must be consulted and informed when significant enforcement actions are being considered.

3.2 General Enforcement and Compliance Principles

In applying the Fish Inspection Program, the CFIA will promote compliance with the FIA, FIR and other legislation through consultation, education and enforcement. These activities are based on the following guiding principles:

a) Canada's fish processing and import industries must comply with legislation and regulations;

b) application and enforcement of the FIA, FIR and other applicable legislation is to be carried out in a fair, responsible, consistent and uniform manner in accordance with this policy;

c) CFIA inspectors, who are fully conversant with the FIA, FIR and other applicable legislation, are to conduct inspections, regulatory verifications, compliance and enforcement actions and other regulatory activities;

d) CFIA will consider the facts and circumstances of non-compliance incidents and take appropriate corrective action;

e) CFIA will take an active role to promote and monitor compliance and respond to non-compliance;

f) education measures used to promote compliance will include the publication of information and consultation with regulated parties. CFIA inspectors applying and enforcing legislation, and Canada's fish processing and importing industry who must comply with it need to understand why legislation exists, why compliance is necessary, and how enforcement is to be carried out; and

g) CFIA inspectors will be available to explain the requirements of the legislation to regulated parties, maintain open lines of communication and communicate to CFIA management the comments and concerns raised by regulated parties.

3.3 Measures to Promote and Monitor Compliance

3.3.1 Consultation and Education

As consultation and education initiatives promote understanding of legislative and regulatory requirements and thereby generally facilitate compliance, CFIA will strive to:

a) consult with Canada's fish processing and importing industries on legislative and regulatory issues in order to promote awareness of requirements, proposed amendments thereto and to seek involvement, as appropriate, in the development of legislation, regulations and policies; and

b) provide information and conduct education activities on legislative, regulatory, policy and procedural matters of interest to the industry.

3.3.2 CFIA Regulatory Verifications

Inspectors will conduct regulatory verification activities to assess industry's compliance with the FIA, FIR and other applicable legislation, in accordance with established policies and procedures. These activities include:

a) imported and domestic product inspections involving sensory, microbiological, chemical, bioassay, container integrity, weight, labelling evaluations, etc.;

b) systems and compliance verifications of registered establishments;

c) regulatory, systems and compliance verifications of licensed fish importers operating under a Fish Import Licence or a Quality Management Programs for Importers (QMPi) Licence;

d) inspections of conveyances, equipment, unloading, handling, holding and transportation facilities; and

e) verification of protocols, where established.

3.4 Responses to Violations and Non-compliance

When CFIA inspectors have reasonable grounds to believe that an infraction has been committed under the FIA, FIR, or other applicable legislation, they will conduct investigations to determine the facts of the alleged infraction(s) and to gather and preserve evidence. Once it has been determined that an offence has occurred, the inspector may seek advice, guidance and assistance from the Enforcement and Investigation Services (EIS) Division as necessary. The assistance of an investigation specialist should be used particularly in instances involving circumstances of a complex nature that require specialised investigational expertise. For further information, refer to Part 7.0 of the CFIA Enforcement and Compliance Policy developed by the EIS Division.

Instances of non-compliance will be evaluated and the most appropriate action to achieve compliance will be determined. The following factors, along with other applicable information, will be considered:

- the offender's history of compliance with the legislation;
- a demonstrated willingness to achieve compliance;
- evidence of corrective action already taken;
- the intent of the non-compliant party; and
- the seriousness of harm or potential harm.

3.5 Enforcement Actions

One or more of the enforcement actions outlined in this section will be taken to achieve compliance for violations of the FIA, FIR or other applicable legislation.

1. Actions with respect to individuals and companies:
   - warning(s)
   - prosecution(s)

2. Actions with respect to products, equipment or other things:
   - detention
   - seizure
   - refusal of entry of product into Canada
   - removal of imported product
   - refusal to certify product

3. Other Actions:
   - suspension of certificates of registration, licenses or permits
   - revocation of certificates of registration, licenses or permits
   - refusal to issue certificates of registration, licenses or permits
   - issuance of recall orders

3.5.1 Warning

A written warning is appropriate when the non-compliance has not resulted, or is not likely to result, in significant or serious harm and the inspector believes that the letter will have the appropriate deterrent effect. Significant or serious harm would include health or safety risks, or fraud.

A written warning must contain the following information:
- the section(s) of the Act or regulation contravened;
- a summary of the facts and a description of the contravention;
- the time limit within which the regulated party must comply with the warning; and
- a statement that if the warning is not heeded or there are repeat violations, alternate enforcement action will be taken.

A warning letter is not required in the case of QMP or QMPi compliance verifications that have shown non-conformities provided that the regulated party has been given a Non-Conformity Report during the exit meeting (refer to Chapter 3, Subject 3 of the Facilities Manual for QMP; Chapter 3, Subject 4 of the Inspection Manual for QMPi). However, a written warning should still be considered if the regulated party fails to develop an acceptable Corrective Action Plan or fails to meet the terms of a Corrective Action Plan.

3.5.2 Prosecution

For violations of the FIA, FIR or other applicable legislation, a prosecution is appropriate when the offence involves:

a) death of, or injury to, a person and the evidence indicates that the death or injury was directly attributed to failure to comply with the FIA, FIR or other applicable legislation;

b) the willful, reckless, or negligent actions of the regulated party pose a health and safety risk or

constitute fraud;

c) the prohibited sale of fish;

d) forging, altering or tampering with an inspection certificate;

e) obstructing or interfering with an inspector acting in the execution of the FIA, FIR or other applicable legislation;

f) moving or interfering with any thing seized or detained without having received prior permission from an inspector;

g) refusal to comply with a recall order;

h) a conviction for a previous similar offence or a repeat offence; or

i) based on past history of non-compliance, other enforcement actions have not had, nor are they likely to have, the appropriate deterrent effect and more severe action is warranted.

3.5.3 Product Detention

Detention of a product is appropriate when the identity of the product must be maintained until analysis is complete, until non-complying product is brought into compliance, or until disposition is otherwise determined.

Product detention is not necessarily an enforcement action. Detentions can be part of routine inspection activities such as for maintaining the identity of the product pending the results of laboratory analysis. Further information on product detention may be found in the Inspection Manual, Chapter 2, Subject 3.

NOTE: Where non-compliant product is identified during a compliance verification and the registered establishment or QMPi licence holder can demonstrate, to the satisfaction of the inspector, that the problem with the product will be resolved as part of a Corrective Action Plan, product detention is not necessary.

3.5.4 Product Seizure

Seizure of product is generally appropriate when:

a) legal action is being taken for a violation of the FIA, FIR, or other applicable legislation, and the CFIA has reason to believe that detention of the product will not be an effective control measure; or

b) the regulated party demonstrates an unwillingness to comply by failing to remove the product from the market or failing to take corrective action to bring the product into compliance.

Further information on product seizure may be found in the Inspection Manual, Chapter 2, Subject 4.

NOTE: Where non-compliant product is identified during a compliance verification and the registered establishment or QMPi licence holder can demonstrate, to the satisfaction of the inspector, that the problem with the product will be resolved as part of a Corrective Action Plan, product seizure is not necessary.

3.5.5 Refusal of Entry of Product into Canada

Refusal of product entry into Canada may be appropriate when the product is identified prior to importation to pose a health or safety risk to humans or otherwise fails to meet the requirements of the FIA, FIR or other applicable legislation.

3.5.6 Removal of Imported Product

Fish products that do not comply with the FIA, FIR or other applicable legislation must be re-exported back to the country of origin or disposed of. This applies only to product which the regulated party cannot or will not bring into compliance. Further information on removal of imported product may be found in the Inspection Manual.

3.5.7 Issuance of Recall Orders

A recall by any regulated party selling, marketing or distributing a product is appropriate when that product poses a risk to public health and safety. The CFIA will work with regulated parties to ensure that an effective recall takes place. In the event that an individual or company refuses to voluntarily recall a product, a recall may be ordered pursuant to section 19 of the *CFIA Act*. Please refer to the CFIA's recall policy and procedures, maintained by the Office of Food Safety and Recall, for further information.

3.5.8 Refusal to Certify Product

Refusal to certify a product is appropriate when the product fails to meet all pertinent legislative and regulatory requirements, or additional requirements specified by the importing country.

3.5.9 Suspension or Revocation of an Establishment's Certificate of Registration

Suspension or revocation of an establishment's certificate of registration, pursuant to subsection 17(1) of the FIR, is appropriate when:

a) a compliance verification identifies non-conformities and the establishment will not or is unable to address the non-conformities through the development and implementation of an acceptable Corrective Action Plan; or

b) the establishment has a history of non-compliance and the deterrence of other enforcement options have proven ineffective or, in the opinion of the Regional Director, would not be effective.

Other reasons for suspending or revoking a certificate of registration are outlined in subsection 17(1) of the FIR including when false information is provided by the establishment in order to obtain a certificate of registration.

A certificate of registration which has been suspended or revoked will not be reinstated until all deficiencies that resulted in the suspension or revocation have been corrected. To reinstate a certificate of registration which has been suspended or revoked, see the policies and procedures in Chapter 2 of the Facilities Manual.

3.5.10 Suspension or Revocation of a Fish Import or QMPi Licence

Suspension or revocation of an import licence pursuant to subsection 6.2(1) of the FIR is appropriate when:

a) an inspection or compliance verification assesses that the import licence holder is in non-compliance and the importer refuses or is unable to achieve compliance;

b) in the case of a QMPi licence holder, the importer is unable to provide and implement an acceptable Corrective Action Plan; or

c) the importer has a history of non-compliance and the deterrence of other enforcement options has proven ineffective or, in the opinion of the Regional Director, would not be effective.

Other reasons for suspending or revoking an import licence are outlined in subsection 6.2(1) of the FIR including where the importer fails to adequately maintain records in accordance with the FIR and where the importer has provided false information in order to obtain a licence.

Where QMPi privileges have been suspended or revoked, they will not be reinstated until all deficiencies have been corrected including any necessary amendments to the importer's record keeping, documentation, or operational procedures. The importer has the option to apply for a fish import licence if they no longer wish to operate under the provisions of the QMPi licence. Further information on applying for a fish import licence may be found in the Inspection Manual, Chapter 3, Subject 1.

3.6 Formal Hearing

A Formal Hearing involves meeting with the regulated party to discuss issues of non-compliance, and may result in the development of a Corrective Action Plan by the regulated party, if there has been no Corrective Action Plan previously. Such a hearing may be appropriate when previous enforcement options (e.g., Warning letter) have not been effective, but prior to initiating more serious enforcement options (e.g., Licence revocation, prosecution). A hearing may also be appropriate before lost privileges are reinstated. If a formal hearing will be held, the Regional Director (or delegate) will initiate and convene such hearings.

3.7 Removal from Public Lists

The CFIA may remove the name of any regulated party, whose certificate of registration or import licence has been suspended or revoked, from any public list of registered establishments or import licence holders.

3.8 Appeals and Reinspections

In accordance with section 10 of the FIR, any person may appeal an inspector’s decision relating to an inspection, systems verification or compliance verification, grading or marking. An appeal must be made in writing to the Regional Director, stating the reason(s) why a decision should be

given further consideration. The appeal must be received within 30 days of the decision that is being appealed. Pending the outcome of an appeal or a reinspection, the original decision will remain valid.

Where a reinspection is ordered by the Regional Director, the decision of the reinspection will be final. Chapter 2, Subject 2 of the Inspection Manual outlines the policy and procedures governing the reinspection of fish and fish products pursuant to section 10 of the FIR. Chapter 3, Subject 3 of the Facilities Manual outlines the appeal process for compliance verification decisions.

4. COMPLIANCE AND ENFORCEMENT PROCEDURES - QMP

4.1 Assessing a QMP as Unacceptable

A registered establishment's Quality Management Program will be assessed as unacceptable when a compliance verification has identified non-conformities and:

a) the establishment has failed to develop an acceptable Corrective Action Plan;

b) where further to a follow-up compliance verification, the establishment has failed to meet the terms of a Corrective Action Plan and reach closure of the compliance verification; or

c) the establishment has a history of operating without proper controls and, based on the opinion of the Regional Director, is unlikely to initiate an effective Corrective Action Plan.

NOTE: When a critical non-conformity is identified, the registered establishment must be required to immediately develop a Corrective Action Plan and implement corrective actions to bring the system back under control. A thorough investigation across the entire QMP plan may be conducted. Detention and seizure actions must be considered. It may be necessary to suspend and re-schedule the compliance verification if the critical non-conformity is not satisfactorily addressed. When product with a potential consumer health and safety risk has entered commercial channels, the appropriate area/regional recall coordinator must be consulted regarding possible recall action for the implicated product. Further information on the identification of critical

non-conformities may be obtained in Chapter 3, Subject 3 of the Facilities Manual.

4.2 Measures to be Taken for an Unacceptable QMP

4.2.1 The registered establishment has failed to develop an acceptable Corrective Action Plan

Where the establishment is unwilling or unable to develop an acceptable Corrective Action Plan, the following measures will be taken:

a) the inspector will recommend to the Regional Director, through his/her supervisor, that the certificate of registration be suspended until an acceptable Corrective Action Plan is developed;

b) upon acceptance of the recommendation to suspend the certificate of registration, a notice of suspension signed by the Regional Director will be delivered to the operator; and

c) if, after 30 days from receipt of the notice of suspension and pending a determination on any request for reinstatement made pursuant to subsection 17(2) of the FIR, the establishment is still unwilling or unable to develop an acceptable Corrective Action Plan, the inspector will recommend to the Regional Director that the certificate of registration be revoked.

4.2.2 The registered establishment has failed to meet the terms of a Corrective Action Plan and reach closure of the compliance verification

Where the establishment has failed to meet the terms of a Corrective Action Plan, the following measures will be taken:

a) when the establishment can demonstrate that actions have been taken and the terms of the Corrective Action Plan have not been reached through circumstances beyond the establishment's control or time deadlines that have not proven realistic, then the establishment may continue operating with new time frames for completion of the Corrective Action Plan, if the non-conformities are not likely to result in product which fails to meet all requirements of the FIR and other applicable legislation.

A warning letter may accompany this option stating that

failure to meet new time deadlines will result in a recommendation that the establishment's certificate of registration be suspended.

b) when the terms of the Corrective Action Plan have not been reached through negligence, deliberate inaction by the establishment or inability of the establishment, the same steps will be taken to suspend the certificate of registration as outlined in section 4.2.1.

4.2.3 The registered establishment has a history of operating without proper controls and is unlikely to initiate an effective Corrective Action Plan

Where the establishment has a history of non-compliance and operating without the proper controls, the same steps will be taken to suspend the certificate of registration as outlined in section 4.2.1.

4.3 Request for Reinstatement of a Certificate of Registration

Subsection 17(2) of the FIR sets out regulatory provisions for an establishment, whose certificate of registration has been suspended or revoked, to request in writing a review within 30 days after the suspension or revocation to determine whether the certificate should be reinstated.

Any inspection conducted in the course of the determination will be cost recovered in accordance with subsection 17(3) of the FIR.

In order to have the certificate of registration reinstated, the establishment must submit a written Corrective Action Plan. The Corrective Action Plan should describe how they will achieve compliance. The certificate of registration may be reinstated when the Corrective Action Plan is reviewed and verified by an inspector as meeting the QMP requirements.

Where a request has been made by an establishment to reinstate a suspended certificate of registration, the Agency will not initiate cancellation procedures until a determination referred to in subsection 17(2) of the FIR is made.

4.4 Product Action by CFIA

Where the acceptability of product is brought into question through the identification of a deficiency or non-conformity during a compliance verification, and the establishment

cannot resolve the problem as part of a Corrective Action Plan, inspectors are to take appropriate product action. Detention or seizure may be necessary to control fish products that are tainted, decomposed, unwholesome, fraudulently presented or otherwise fail to meet the requirements of the FIA, FIR or other applicable legislation.

5. COMPLIANCE AND ENFORCEMENT PROCEDURES - QMPi

5.1 Assessing a QMPi as Unacceptable

A licence holder's QMPi will be assessed as unacceptable when a compliance verification has identified non-conformities and:

a) the importer has failed to develop an acceptable Corrective Action Plan;

b) where further to a follow-up compliance verification, the importer has failed to meet the terms of a Corrective Action Plan and reach closure of the compliance verification; or

c) the importer has a history of operating without proper controls and, in the opinion of the Regional Director, is unlikely to initiate an effective Corrective Action Plan.

NOTE: When a critical non-conformity is identified during a compliance verification, the importer must be required to immediately develop a Corrective Action Plan and implement corrective actions to bring the system back under control. A thorough investigation across the entire QMPi plan must be conducted. Detention and seizure actions must be considered. It may be necessary to suspend and reschedule the compliance verification if the critical non-conformity is not satisfactorily addressed. When product with a potential consumer health and safety risk has entered commercial channels, the appropriate area/regional recall coordinator must be consulted regarding possible recall action for the implicated product.

5.2 Measures to be Taken for an Unacceptable QMPi

5.2.1 The importer has failed to develop an acceptable Corrective Action Plan

Where the importer is unwilling or unable to develop an acceptable Corrective Action Plan, the following measures will be taken:

a) the inspector will recommend to the Regional Director, through his/her supervisor, that the licence be suspended until an acceptable Corrective Action Plan is developed;

b) upon acceptance of the recommendation to suspend the licence, a notice of suspension signed by the Regional Director will be delivered to the importer; and

c) if, after 60 days from receipt of the notice of suspension and pending a determination on any request for reinstatement made pursuant to subsection 6.2(2) of the FIR, the importer is still unwilling or unable to develop an acceptable Corrective Action Plan, the inspector will recommend to the Regional Director that the licence be revoked.

5.2.2 The importer has failed to meet the terms of a Corrective Action Plan and reach closure of the compliance verification

Where the importer has failed to meet the terms of a Corrective Action Plan, the following measures will be taken:

a) when the importer can demonstrate that actions have been taken and the terms of the Corrective Action Plan have not been reached through circumstances beyond the importer's control or time deadlines that have not proven realistic, then the importer may continue operating with new time frames for completion of the Corrective Action Plan, if the non-conformities are not likely to result in product which fails to meet all requirements of the FIR and other applicable legislation.

A warning letter may accompany this option stating that failure to meet new time deadlines will result in a recommendation that the importer's licence be suspended.

b) when the terms of the Corrective Action Plan have not been reached through negligence, deliberate inaction by

the importer or inability of the importer, the same steps will be taken to suspend the licence as outlined in section 5.2.1.

5.2.3 The importer has a history of operating without proper controls and is unlikely to initiate an effective Corrective Action Plan

Where the importer has a history of non-compliance and operating without the proper controls, the same steps will be taken to suspend the licence as outlined in section 5.2.1.

5.3 Request for Reinstatement of Import Licence Privileges

Subsection 6.2(2) of the FIR sets out regulatory provisions for an importer, whose licence has been suspended or revoked, to request in writing a review within 60 days after the suspension or revocation to determine whether the licence should be reinstated.

Any inspection conducted in the course of the determination will be cost recovered in accordance with subsection 6.2(3) of the FIR.

In order to have QMPi privileges reinstated, the importer must submit a written Corrective Action Plan. The Corrective Action Plan should describe how they will achieve compliance. QMPi privileges may be reinstated when the Corrective Action Plan is reviewed and verified by an inspector as meeting the QMPi requirements.

Where a request has been made by a person to reinstate a suspended licence, the Agency will not initiate cancellation procedures until a determination referred to in subsection 6.2(2) of the FIR is made.

5.4 Product Action by CFIA

Where the acceptability of product is brought into question through the identification of a deficiency or non-conformity during a compliance verification of the QMPi, and the importer cannot resolve the problem as part of a Corrective Action Plan, inspectors are to take appropriate product action. Detention or seizure may be necessary to control fish products that are tainted, decomposed, unwholesome, fraudulently presented or otherwise fail to meet the requirements of the FIA, FIR or other applicable legislation.

6. COMPLIANCE AND ENFORCEMENT PROCEDURES - FISH IMPORT LICENCE

6.1 Non-notification of Imports

Where an importer does not provide the Agency with an import notification in accordance with section 6 of the FIR, the first offence will normally result in a written warning being issued. If the product is available to the inspector, it will be detained until proper notification is received and inspection requirements determined. Subsequent offences will require an investigation for the purpose of determining whether prosecution action should be taken against the importer. In such instances, inspectors may seek advice, guidance and assistance from an investigation specialist within the EIS Division.

6.2 Moving Product Without Permission

Where a fish import licence holder provides import notification but moves the product without permission, the inspector will detain the product to control its distribution. Detention will be maintained until the inspection requirements are determined. Where there is a question that detention is not adequate to ensure control of the product, the product will be seized according to the policies and procedures outlined in the Inspection Manual, Chapter 2, Subject 4.

When product with a potential consumer health and safety risk has entered commercial channels, the appropriate area/regional recall coordinator must be consulted regarding possible recall action for the implicated product.

In addition to the appropriate product action, a warning will be issued for the first offense. Subsequent offences will require an investigation for the purpose of determining whether prosecution action should be taken against the importer. In such instances, inspectors may seek advice, guidance and assistance from an investigation specialist within the EIS Division.

6.3 Unacceptable Record Keeping

Where the importer is unwilling or unable to maintain records in accordance with subsection 6.1(3) of the FIR and the deterrence of other enforcement options have proven ineffective, the following measures will be taken:

a) the inspector will recommend to the Regional Director that the licence be suspended until the importer can

demonstrate adherence to the regulatory requirements;

b) upon acceptance of the recommendation to suspend the licence, a notice of suspension signed by the Regional Director will be delivered to the importer; and

c) if, after 60 days from receipt of the notice of suspension and pending a determination on any request for reinstatement made pursuant to subsection 6.2(2) of the FIR, the importer is still unwilling or unable to maintain records in accordance with subsection 6.1(3) of the FIR, the inspector will recommend to the Regional Director that the licence be revoked.

6.4 Request for Reinstatement of Import Licence Privileges

Subsection 6.2(2) of the FIR sets out regulatory provisions for an importer, whose licence has been suspended or revoked, to request in writing a review within 60 days after the suspension or revocation to determine whether the licence should be reinstated.

Any inspection conducted in the course of the determination will be cost recovered in accordance with subsection 6.2(3) of the FIR.

Where a request has been made by a person to reinstate a suspended licence, the Agency will not initiate cancellation procedures until a determination referred to in subsection 6.2(2) of the FIR is made.

6.5 Product Action by CFIA

Where the acceptability of product is brought into question through the identification of a deficiency or non-conformity during an assessment of the importer’s records or by other means, inspectors are to take appropriate product action. Detention or seizure may be necessary to control fish products that are tainted, decomposed, unwholesome, fraudulently presented or otherwise fail to meet the requirements of the FIA, FIR or other applicable legislation.

7. COMPLIANCE AND ENFORCEMENT PROCEDURES - IMPORTING WITHOUT A LICENCE

Where fish is imported without a valid licence, the fish will be detained and the importer advised that an import licence is required or the fish must be removed from Canada.

The importer should also be provided with an application for a licence to import fish. When the completed application and import notification are received, the process can begin to determine whether an inspection is required.

If an application is not received after 30 days, the importer should be issued a written warning stating that unless the fish is removed from Canada or an application for an import licence is received within the specified time period, appropriate enforcement action including prosecution will be considered. If there is any attempt to move the fish without permission or if an application is still not received within 30 days of the warning, the fish should be seized (refer to Chapter 2, Subject 4 of the Inspection Manual) and consultation initiated with the EIS Division, if not previously done.

NOTE: *Future versions of this chapter may include compliance and enforcement procedures for suspension and revocation of permits and export licenses as well as refusal to issue licenses (import and export), certificates of registration and permits. Until such time, these actions will be taken as deemed appropriate by the Regional Director.*

CHAPTER 2, SUBJECT 6

COST RECOVERY FOR DOMESTIC PRODUCT INSPECTION/CERTIFICATION

1. SCOPE

This document outlines the regulations, policy and procedures governing cost recovery for the certification of domestic fish and fish products and other related Inspection services.

2. AUTHORITIES

Fish Inspection Act, R.S.C. 1985, c. G-12;

Fish Inspection Regulations (F.I.R.) C.R.C., 1978, C.802;

Section 6.5, Section 9, Section 10 (F.I.R.)

3. POLICY

3.1 The provisions of the domestic cost-recovery system apply to fish and fish products destined for human consumption that are processed in a federally registered establishment.

3.1.1 There shall be no fees levied for all or part of any facility or product inspection performed under the audit function of the Quality Management Program.

3.2 **Product Certification**

3.2.1 A fee is to be levied for all certificates issued by the CFIA for products processed by a federally registered establishment. The amount of the fee depends upon:

a) whether a "physical" inspection of the product is conducted; and/or

b) whether a certificate is provided on the basis of an evaluation of the establishment's QMP and a record check of the product.

3.2.2 If a person requests an inspection certificate and an inspection is conducted, the fee will be levied even if the applicant later requests that a certificate not be issued.

3.2.3 All decisions regarding whether an inspection is to be performed shall be in accordance with the Quality Management Program Policy and Procedures, Chapter 3, Subjects 1 and 2 of the Facilities Inspection Manual.

3.2.4 The inspection service fees for certificates are found in Section 9(3) of the FIR.

3.2.5 The maximum amount of inspection service fees for certificates paid by any one person in a calendar year shall not exceed $10,000.

3.2.6 If an inspector needs to issue a new certificate in order to amend or correct a previously issued certificate, as a result of omissions or oversights by the CFIA, there shall not be any additional charges to the applicant.

3.2.7 A Broker/Wholesaler who requests certification of product prior to the product being exported shall be assessed fees in the following manner:

a) when requesting a certificate for one or more lots of fish which have been previously certified (sometimes referred to as a "Master Certificate"), a fee of $25 will be levied provided the original certificate(s) is valid. This is irrespective of which region issued the original certificate(s).

   In accordance with paragraphs 3.1 and 3.6 of Chapter 10 of this manual, an inspector shall inspect the products to be certified if there is reason to believe that the fish/fish products have deteriorated or do not meet the conditions of the original certificate. In this case the products shall be inspected before the master certificate is issued and a fee of $100.00 will be charged;

b) when requesting a certificate for one or more lots of fish which have not previously been certified from one federally registered establishment located in the same region as the broker, the fee will be in accordance with section 3.2.1 (i.e., on the basis of the QMP rating);

c) when requesting a certificate for one or more lots of fish which have not been previously certified from more than one federally registered establishment, a fee of $100 will be levied as an inspection of the product will be mandatory.

3.2.8 Fees shall be assessed in the following manner for non-registered exporters of live fish operating under approved protocols who request certification of product prior to the product being exported:

a) when a "record" check only is necessary, a fee of $25 will be levied;

b) when an inspection of the product is conducted, a fee of $100 will be levied, provided the exporter is in compliance with a signed certification protocol; or

c) when a live fish exporter is not operating under a protocol for certification purposes, the fee levied will be $100 for each certificate.

3.2.9 When one lot of fish requires more than one type of certificate, the fees associated with that lot of fish shall be levied in the following manner:

a) if the particular lot of fish requires an inspection, the fee for the first certificate will be $100 and the subsequent additional certificates will be at a rate of $25 per certificate; or

b) if a particular lot of fish does not require an inspection, the fee for each certificate will be $25.

3.2.10 For all product originating from a non-registered establishment not operating under a live fish protocol, an inspection shall be performed prior to issuing a certificate with the appropriate fee levied ($100).

3.2.11 When chemical and/or microbiological evaluations must be performed on fish to meet the importing country's requirements (as listed in Chapter 10 of this manual), no additional fees will be charged for these inspections.

In cases where the foreign country requirements have changed and the information in Chapter 10 is out-of-date or when the requirements are not found in this manual, the fees for chemical and/or microbiological evaluations will be waived. Exporters should obtain documents from authorities in the importing country that outline these requirements. NHQ should be advised immediately of these changes.

3.2.12 When chemical and/or microbiological evaluations are performed at the request of the exporter for any reasons other than those listed in 3.2.11 above, they will be

considered to be a requested product inspection and will be fully cost recoverable as described in 4.2.

4. PROCEDURES

4.1 Product Certification

4.1.1 Upon written request, industry members may be supplied with adequate product certificates for their use. If corresponding certificate numbers are assigned to the certificates, a system for inventory and verification must be in place to ensure proper use and control of certificates. Whenever a subsequent request for additional certificates is received, a record check is performed to review outstanding certificates under the control of the applicant.

4.1.2 When a written request for product certification is received, all procedures as outlined in Chapter 10 of this manual are to be followed.

4.1.3 When the QMP and record check indicate that no inspection is required, or when the required inspection is completed, the certificate is signed, sealed and issued to the consignor.

4.1.4 All pertinent information including "the results of an inspection", when an inspection has been performed, shall be entered into the appropriate National Database.

4.1.5 Certificates issued for live fish under an approved protocol will be signed and sealed prior to issuance as per the protocol.

4.1.6 When the inspection of the product is complete (if needed) and the certificate issued, a "Record of Transaction" (Appendix A) must be produced.

4.1.7 All processors/exporters who have invoices outstanding for 60 days will be identified by the Regional Financial Officer. All processors/exporters so identified shall be given a written "warning" indicating that fees are outstanding and that if payment in full is not submitted within 30 days, Section 17(1)(e) of the FIR will be invoked (i.e., registration suspended). The Regional Financial Office should be consulted for details.

4.2 Requested Product Inspections

4.2.1 Where a request for a product inspection is received from a QMP Importer for a test listed in Table 6.5(5) of the FIR, the testing should be conducted. Where a request for product inspection of fish and/or fish products is received from a non-QMPI owner/interested party, or for tests which are not listed in Table 6.5(5) of the FIR, the testing will be conducted at the discretion of the laboratory.

4.2.2 The "Request for an Inspection of Fish or for a Fish Processing Facility" (Appendix A) shall be used by anyone requesting a product inspection. The form is to be forwarded to a CFIA office with the samples. The CFIA is not responsible for conducting the sampling for requested product inspection testing.

4.2.3 The minimum fee payable for any requested inspection shall be of the amount stated in Column III of Table 6.5(5). This includes any fish and/or fish products offered for requested inspection containing a sample size less than the amount stated in Column II of Table 6.5(5).

4.2.4 For requested inspections, laboratories assume the role of a third-party service provider and service standards do not apply. Regular inspection work should take priority over requested tests. For QMP or QMPI it is assumed that the company requesting the test is responsible for application of the associated standard, so the test results should be reported in a manner that does not render a Pass/Fail inspection decision. Laboratory inspections should be reported to QMP importers on a Laboratory Inspection Report and not on a Fish Inspection Report.

4.2.5 In circumstances where there is a health and safety concern identified based on the test results, the CFIA should discontinue the third party role and ensure that the products are not distributed or that any necessary recall actions are initiated.

4.2.6 Any requested product inspections shall be performed based upon the presentation of the product for inspection by the applicant. It shall be the applicant's decision on how the lot will be presented.

4.2.7 Once the product has been inspected, fees will be billed on a monthly basis.

4.2.8 Requested inspections will be billed using a "Record of Transaction" form (Appendix B) produced by Accounts

Receivable of CFIA.

5. FORMS/DOCUMENTS

Appendix A - Record of Transaction

Appendix B - Request for an Inspection of Fish or for a Fish Processing Facility

APPENDIX A

APPENDIX B

CHAPTER 2, SUBJECT 7

PERMIT POLICY

1. SCOPE

This document outlines the policy governing the issuance of permits for fish processing establishments and fish and fish products.

2. AUTHORITIES

Fish Inspection Act, R.S.C., 1985, c. F-12; Part I
Fish Inspection Regulations (FIR) C.R.C., Chapter 802

Section 18.(1) (FIR)

Despite anything in these Regulations and subject to subsection (2), the President of the Agency may, on receiving an application, issue a permit to allow, during the period stated in the permit,

(*a*) the production or marketing of experimental or test products;
(*b*) the reworking, reconditioning, processing, culling or salvaging of fish at a registered establishment to enable the fish to meet the applicable requirements of the Act or these Regulations;
(*c*) the construction or utilization of processing and support areas that do not comply with the Act or these Regulations;
(*d*) equipment that is used in a vessel or an establishment constructed before the coming into force of this section that does not comply with the Act or these Regulations to continue to be used or to operate;
(*e*) the marketing, possession, use or disposal of tainted, decomposed or unwholesome fish not intended for human consumption;
(*f*) the re-use of containers or the use of labels that do not meet the applicable requirements of these Regulations;
(*g*) the labelling of products to accommodate particular cultural communities in Canada;
(*h*) the importing, exporting or marketing of fish for charitable purposes, international events or national festivities, if the lot size is less than 1 000 kg;

(*i*) the production and supply of food in a national emergency or for international aid; or
(*j*) the exporting to another country of fish or containers that do not meet the applicable requirements of the Act or these Regulations.

Section 18.(2) (FIR)

The President of the Agency may on reasonable grounds refuse to issue a permit if, in the President's opinion, the issuance of the permit

(*a*) would result in a risk to public health or safety or otherwise diminish consumer protection;
(*b*) may result in the marketing to consumers of fish that does not comply with subsection 6.(1) or section 27 or the requirements of other countries; or
(*c*) may damage the reputation of Canada's fish processing industry.

Section 18.(3) (FIR)

The President of the Agency may revoke or refuse to issue a permit if

(*a*) the President has reasonable grounds to believe that the holder of the permit or the applicant has provided false information to the President for the purpose of obtaining the permit; or
(*b*) the holder of the permit or the applicant has contravened a condition of the permit or a provision of the Act or these Regulations.

Section 18.1 (FIR)

The President of the Agency may, from time to time, attach any conditions to a registration certificate, licence or permit issued under these Regulations if the President is satisfied that those conditions are necessary to ensure that the import or export of fish complies with these Regulations.

3. DEFINITIONS

"experimental product" - a fish product that is subject to scientific or technological experiments, is imported or exported for experimental purposes only, and is not distributed in any form to the public. (Note: if a processor or importer decides to distribute the final

product to the public, the product loses its "experimental product" status and becomes a "test market" product, provided the test market criteria are met.)

"fish for scientific purposes" - fish that is used by research centres, universities, etc., in their experiments and studies, and which is not intended for human consumption.

"permit" - a permit issued under Section 18.(1) of the *Fish Inspection Regulations*. (See Section 4.1 for those instances when permits are not required.)

"product for personal use" - a product that is not sold or traded for items or services of value, and that is not distributed in any form (e.g., samples) to the public (which includes exemptions for demonstration purposes).

"speciality food" - a food for special religious ceremonies, or an imported food that is not widely used by the population as a whole in Canada, and for which there is no substitute food processed in Canada (e.g., ethnic food).

"test product" - a fish product that is new to the Canadian market with respect to its composition, function, state or packaging form and is processed, imported, or exported for evaluation of market access.

4. GUIDELINES FOR ISSUANCE

4.1 Instances for which permits are not required:

- For fish products for "personal use", "experimental products" and "fish for scientific purposes" as defined in Section 3 of this document, as these products are not subject to the *Fish Inspection Regulations*.

- For production of test products at non-federally registered facilities and sold within the province where they were processed as these products are not subject to the *Fish Inspection Regulations* (permits may still be required by Section B.01.012 of the *Food and Drug Regulations* or by provincial regulations).

- For the use of labels that do not fully comply with Canadian requirements due to minor non-compliance(s) (e.g., spelling errors, letters smaller than

required, minor errors in translation, etc.). The conditions and corrective actions required to bring the label into compliance as outlined in a Label Evaluation Report will serve in lieu of a permit.

- To conduct reworking, reconditioning, processing, culling or salvage of fish in a federally registered establishment in conjunction with QMP activities so long as the fish have not been rejected by an Inspector. A corrective action process must be applied as outlined in the plant's Quality Management Program (QMP).

- For the disposal of rejected fish, provided the disposal is carried out in accordance with procedures outlined in a QMP or QMP for Importers (QMPI) plan. In the case of fish import "basic" licence holders, the procedures outlined in Chapter 3, Subject 1 of the Fish Products Inspection Manual must be followed.

- For the sale of rejected fish for use other than for human consumption. The Detention and Release procedures for rejected fish are outlined in Chapter 2, Subject 3 of the Fish Products Inspection Manual.

- For labelling of fish products for cultural/ethnic communities in Canada. These products are defined as "speciality foods" (see Definitions), and the requirements for their labelling are specified in Section B.01.012 of the *Food and Drug Regulations*.

4.2 Instances for which permits may be issued:

- For the production of experimental and test products in a non-registered facility, where the products are exported.

- To conduct reworking, reconditioning, processing, culling or salvage of fish that has been inspected and rejected by an inspector.

- For the construction or utilisation in facilities of processing and support areas that do not comply with the Fish Inspection Act or Regulations.

- For equipment that is used on a vessel or in an establishment that does not comply with the Fish Inspection Act or Regulations, but that was constructed before the coming into force of section 18.(1) of the FIR in 1999.

- For the marketing of test products with unilingual labels (English or French).
- For the re-use of containers that are normally intended for one-time use.
- For the use of labels that do not comply with the labelling requirements of the Fish Inspection Regulations, and that are intended for use on fish products exported outside Canada.
- For the import, export or marketing of fish for charitable purposes, international events or national festivities.
- For the production and supply of food in a national emergency or for international aid.

5. POLICY/PROCEDURES

5.1 General Principals

5.1.1 Any person may apply for a permit provided that they are:

a) a holder of a fish export or import licence;

b) an operator of a registered establishment as defined under the *Fish Inspection Regulations*; or

c) an operator of a non-registered establishment, provided that information is available to prove that foods are processed under sanitary conditions and that final products are safe and wholesome.

5.1.2 Permits may be issued by the President of the CFIA, or the authority may be delegated to the Regional Directors. For all permits related to processing and marketing of test products, and the production and supply of food in a national emergency or for international aid, the National Manager, Product Inspection must approve the issuing of the permit, as per Section 5.3.2 of this policy. The Director, Fish, Seafood and Production Division is to be advised of all permits issued in these instances.

5.1.3 Activities and items that require permits are specified in Section 4.2 of this document. If required, conditions will be attached to the permit and will be the minimum requirements to be met in order to maintain the permit in good standing.

5.1.4 A permit will specify the period of time for which it is valid. This period may vary, and will be decided by the inspection office issuing the permit.

5.1.5 No permit will be issued when it is determined that issuing the permit would:

a) result in a risk to public health or safety or otherwise diminish consumer protection; or

b) result in the marketing of fish that does not comply with the *Fish Inspection Regulations,* Sections 6.(1), or 27;

5.1.6 Where conditions required by a permit are addressed by a QMP or QMPI Plan, a blanket permit may be issued, so that it would not be necessary to obtain an individual permit for each instance a permit is required (e.g., labels). The permit will become invalid if the processor's registration is revoked or suspended, or if the importer loses their QMPI importer status.

5.1.7 The permit must consist of a document with a unique permit number, reference to the appropriate Sub-section under Section 18 of the *Fish Inspection Regulations* and the signature of the issuer. It should also list any of the conditions identified in Sections 5.3.1 to 5.3.6 that are appropriate. A permit format that must be used is in Section 6.

5.2 Revocation of Permits

5.2.1 A permit may be revoked if:

a) there are reasonable grounds to believe that the holder of the permit has given false or misleading information to the CFIA; or

b) the permit holder is not in compliance with the conditions of the permit.

5.2.2 Inspectors shall detain products not in compliance with the conditions of the permit and shall initiate processes that will result in corrective actions or initiate a process to revoke the permit.

5.3 Issuance of permits

5.3.1 Production of test products in non-registered facilities

A permit for production of a test product in a non-registered facility may be issued by a Regional Director subject to the following conditions.

5.3.1.1 If the facility is primarily dedicated to research or product development (e.g., Universities, Technology Development Centres, Research Facilities, etc.).

5.3.1.2 The processing takes place under sanitary conditions and the final product is safe and wholesome.

5.3.1.3 Normally permits issued for test products are a one-time occurrence. However, where more than one experimental facility are developing products using similar processing method(s) and/or resulting in a product showing similar characteristics, a permit may be issued to more than one non-registered facility for the production of these similar products provided that the interval of time between the request from the first establishment and any subsequent requests from other establishments does not exceed 6 months.

5.3.2 Marketing of Test Products

The applicant must submit to the National Manager, Product Inspection, the following information:

- a description of the product form;
- the quantities of product to be marketed;
- a product formulation;
- the area(s) and a list of the stores or other locations where marketing will take place;
- the approximate date when the marketing will commence;
- any other relevant information, as requested by the CFIA.

A permit for marketing a test product provides an exemption only from bilingual labelling and standard container size requirements. It may be issued subject to the following conditions:

5.3.2.1 The requirements of Section B.01.012 of the Food and Drug Regulations are met.

5.3.2.2 The information submitted shows that the product is new to the Canadian market in regards to its composition, function, state or packaging form. (This information will be reviewed by NHQ; the Regional Director will be advised of the decision.)

5.3.3 Permits for non-compliant construction, non-compliant equipment and re-use of containers

To receive a permit for non-compliant construction, non-compliant equipment and re-use of containers, the processor must submit an application to the Regional Director and satisfy the conditions outlined below:

5.3.3.1 To obtain a permit for the use of non-compliant construction, the processor has in place a satisfactory mechanism or system that deals with the intent of the regulations and is documented in an accepted QMP plan. If the requirements of the regulations are not met, and no other satisfactory system is in place, the facility cannot obtain a permit or process for export.

5.3.3.2 To obtain a permit for the use of non-compliant equipment in an establishment, the processor must demonstrate that appropriate measures are in place which will ensure acceptable sanitation and the production of wholesome and safe products. The measures must be documented in an accepted QMP plan.

5.3.3.3 To obtain a permit for the re-use of containers, there is a system to ensure adequate cleaning, disinfection and sanitation and the system is documented in an accepted QMP plan.

5.3.4 Issuance of Permits for the Import, Export or Marketing of Fish for Charitable Purposes, International Events or National Festivities

The organisation applying for the permit must provide the Regional Director with a letter signed by a representative of the organisation containing all required information related to the event (where, when, approximate number of participants, and any other information requested by CFIA). The permit will be for the exemption of import licensing, import record keeping, product labelling and/or payment of fees pursuant to the *CFIA Act* and *Fish Inspection Regulations*. Normally permits for products for charitable purposes will only be issued for lots of less than 1,000 kg, but permits may be issued for larger lots provided the following conditions

are met.

5.3.4.1 Where products are not appropriately labelled, all the mandatory information is available upon request. If intended for cooking and subsequent distribution to consumers, products are accompanied by a manifest which lists all ingredients in an intelligible manner, and adequate information on the proper method of handling, storage and preparation of the product.

5.3.4.2 The importer must provide a written statement verifying that the fish will not be used for personal and/or individual profit, and that any fish remaining from the event will be disposed of in an acceptable manner.

5.3.5 Issuance of Permits for the Production and Supply of Food in a National Emergency or for International Aid

An international emergency relief organisation may apply to the Regional Director for a permit to process, distribute, or export a product in emergency situations.

5.3.5.1 A permit for processing or importing food in a national emergency may be issued with the approval of the President.

5.3.6 Issuance of Permits for Export of Fish and Containers that do not comply with the Requirements of the Fish Inspection Act or Regulations

A permit for the purpose of exporting to another country, fish and containers that do not comply with Canadian requirements but that comply with the requirements of the importing country, may be issued by the Regional Director. These permits apply mostly to labelling; however, they may include other issues, such as the presence of additives in an amount exceeding the maximum levels permitted in Canada, or the use of a type of container unapproved in Canada. If the procedures that are applied to control these instances are included in the establishment's QMP plan, a one-time permit may be issued and will remain valid for an unlimited time, unless a compliance verification finds a lack of control by the processor. In the case of labels, a single permit may be issued for **all** labels subject to the documented controls if the conditions in this section as described below, and further described in the Label Inspection Policy and Procedures for Fish and Fish Products, are met:

5.3.6.1 The label is not false, misleading or deceptive.

5.3.6.2 The manufacturer is able to substantiate any claims or statements included on the label.

5.3.6.3 Labels contain the normal mandatory information such as name, ingredients, net content, manufacturer, and any descriptive terms such as storage instructions and expiry date (when required).

5.3.6.4 The exporter:

a) in cases related to health and safety (e.g., non-permitted additives), submits to the inspection office the appropriate documentation from the competent authorities of the importing country confirmation that the label/product that is the subject of the permit, meets the importing country regulations; and

b) in all other cases (e.g., quality designations, grades), has in their possession and available for audit, the related specification from the importing country authorities **or** from the buyer.

Note: In cases where the inspection office is aware of the requirements of the importing country, the exporter need not acquire the noted documentation.

5.3.6.5 The permit number is identified on the carton with the term "For Export to (name of the importing country)".

6. FORMAT FOR EXEMPTION PERMIT

Permit #

In accordance with Section 18, sub-section __ of the *Fish Inspection Regulations*, this Permit is granted to: (Name, Address and, if applicable, Registration or Import License Number of company which applied for the permit).

This permit is granted subject to the following conditions:

___ Processing in a non-registered facility takes place under sanitary conditions and the product is not tainted, decomposed or unwholesome, in accordance with the *Fish Inspection Regulations*.

___ A maximum (quantity) of (product) is marketed in (test market area).

___ A control system approved by an Inspector is identified in the processor's QMP and is effectively implemented for processing with non-compliant construction, equipment or containers.

___ Product remaining after a charitable event or festival is disposed of in an acceptable manner.

___ Master cartons are labelled with the statement "For export to (name of importing country)".

___ A control system approved by an Inspector is identified in the processor's QMP and is effectively implemented for the development and control of labels which meet the requirements of the *Fish Inspection Regulations* or are in compliance with conditions outlined on the permit.

___ The local Inspection Office is notified in advance of any shipments under the permit.

___ The permit number is shown on the label and on the documentation for the product shipped under the permit.

___ The permit is valid until _____.

Other than the conditions identified on this permit, all other requirements of the *Fish Inspection Regulations* must be met.

Regional Director _____ _____
Name Signature

Inspector _____ _____
(who approved the request or prepared the permit)
Name Signature

Date of Issue _____

CHAPTER 2, SUBJECT 8

CLASSIFICATION OF PRODUCTS CONTAINING MEAT AND FISH

1. SCOPE

This document outlines the regulations, policies and procedures governing the inspection of foods containing both meat and fish ingredients.

2. REGULATIONS

Fish Inspection Regulations, (C.R.C., c. 802)
Meat Inspection Regulations, 1990 (SOR/90-288)

3. POLICY

3.1 A person may send an application to the Canadian Food Inspection Agency (CFIA) requesting exemption from either the *Meat Inspection Regulations* or *Fish Inspection Regulations* for a food containing meat and fish ingredients.

3.2 The application will be evaluated by the Fish, Seafood and Production Division and the Food of Animal Origin Division to classify the food as either a fish product or a meat product.

3.3 Foods containing both meat and fish ingredients that are classified as a fish product will be exempt from the requirements of the *Meat Inspection Regulations*. Factors to classify the food as a fish product include, but are not limited to:

- the proportion of the fish and meat ingredients;
- description of the food;
- common name;
- level of processing applied to the components to manufacture the food; and
- historical (commercial and/or public) recognition of the food as a fish product.

3.4 Foods containing both meat and fish ingredients that are classified as a meat product will be exempt from the requirements of the *Fish Inspection Regulations*. Factors to classify the food as a meat product include, but are not limited to:

- the proportion of the fish and meat ingredients;
- description of the food;
- common name;
- level of processing applied to the components to manufacture the food; and
- historical (commercial and/or public) recognition of the food as a fish product.

3.5 When a fish processing establishment processes a food containing both meat and fish ingredients that is classified as a fish product, the processor will be required to use meat ingredients that are ready to be incorporated into the final product. Processing of the meat ingredients will be limited to trimming or cutting boneless meat products (e.g., sliced bacon, bacon slabs, cooked ham, roast beef, chicken meat, etc.) to allow the processor to incorporate the meat into the product and any actions needed to assemble the final product. Other processes, including actions such as deboning, cooking or curing meat products will not be permitted.

Processes including, but not limited to cooking or breading, may be performed on the food in its final assembled form. Details on accepted processes can be found in the list of exempted products, which is available in the Fish and Seafood section of the CFIA Internet site.

3.6 When a meat processing establishment processes a food containing both meat and fish ingredients that is classified as a meat product, the processor will be required to use fish ingredients that are ready to be incorporated into the final product. Processing of the fish ingredients will be limited to trimming or cutting the fish meat (e.g., fillets, smoked fish fillets, fish pastes, shellfish meats, lobster/crab meat, peeled shrimp, etc.) to allow the processor to incorporate the fish into the product and any actions needed to assemble the final product. Other processes, including actions such as heading and eviscerating, filleting, shucking shellfish or shucking crustaceans will not be permitted.

Processes including but not limited to cooking or breading may be performed on the food in its final assembled form. Details on accepted processes can be found in the list of exempted products.

3.7 A fish establishment can process food containing meat and fish ingredients only if:

- the food is commonly recognised as a fish product and is

exempt from the *Meat Inspection Regulations*; and
- the meat ingredients originate from an establishment registered under the *Meat Inspection Regulations*, or a foreign establishment eligible to export meat products to Canada.

3.8 A meat establishment can process food containing meat and fish ingredients only if:

- the food is commonly recognised as a meat product and is exempt from the *Fish Inspection Regulations*; and
- the fish ingredients originate from an establishment registered under the *Fish Inspection Regulations*, or were imported into Canada in compliance with the Fish Inspection Regulations.

3.9 Foods containing meat and fish ingredients that cannot be classified as either a fish product or a meat product following the conditions described in sections 3.3 and 3.4 above, must be processed and/or imported in accordance with both the *Meat Inspection Regulations* and *Fish Inspection Regulations*.

4. PROCEDURES

4.1 Applications for exemption shall include a label of the product and, on the manufacturer's letterhead, the recipe indicating the percentage of every ingredient used as well as the method of preparation of the product. Detailed composition of any prepared meat or fish product ingredients must also be provided to assess the compatibility of the meat or fish product with the Canadian legislation related to the composition of the food. The request for exemption along with the relevant documents, shall be addressed to both the Director, Food of Animal Origin Division, Canadian Food Inspection Agency, and the Director, Fish Seafood and Production Division, Canadian Food Inspection Agency.

4.2 Each application will be reviewed by a designated officer of the Food of Animal Origin Division and the Fish, Seafood and Production Division to classify the food as either a meat product or a fish product.

4.3 A list of exempted products is available in the Fish and Seafood section of the CFIA Internet site.

4.4 The Regional Director will identify appropriate personnel to verify that a company that processes or imports an

exempted product listed on the CFIA Internet Site is composed of acceptable ingredients as described in sections 4.5 and 4.6 below.

When a company wishes to process or import a food containing meat and fish ingredients that is not listed on the CFIA Internet Site, the representative of the company will be advised of the procedures identified in section 4.1 above.

4.5 A food containing meat and fish that is classified as a fish product will be inspected in accordance with the requirements identified under the *Fish Inspection Regulations*, and must comply with all applicable Canadian regulations, including, but not limited to the *Food and Drug Regulations*.

The importer of a food containing meat and fish recognised as a fish product must hold either a valid Fish Importers Licence or a valid Quality Management Program for Importers Licence. The importer must provide written notification of each shipment to the appropriate CFIA inspection office and each shipment will be subject to inspection in accordance with the policies and procedures described in Chapter 3 of the Fish Products Inspection Manual.

The importer must be able to demonstrate that the meat component of a food containing meat and fish that is recognised as a fish product can be legally imported into Canada. This means that the meat component must comply with the *Meat Inspection Regulations* and other applicable Canadian regulations, including but not limited to, the *Health of Animals Regulations* and the *Food and Drug and Regulations*. For example, the use of a meat ingredient that contains non-approved additives or that originates from a region restricted for animal health diseases will not be permitted.

In order to demonstrate that the meat ingredients comply with Canadian requirements, the importer must include the country and the establishment number where the animal was slaughtered, and the country and establishment number where the meat was processed with their written import notification form.

4.6 A food containing meat and fish that is classified as a meat product will be inspected in accordance with the requirements identified under the *Meat Inspection Regulations*, and must comply with all applicable Canadian regulations, including, but not limited to the *Food and*

Drug Regulations.

The label and recipe of a meat product must be registered with the Food of Animal Origin Division. For more information please consult Chapter 7 of the Meat Hygiene Manual of Procedures. The food will be subject to inspection in accordance with the policies and procedures described in Chapter 4 of the Meat Hygiene Manual of Procedures.

The importer of a food containing meat and fish recognized as a meat product must be able to demonstrate that the fish component can be legally imported into Canada. This means that the fish component must comply with the requirements described in applicable Canadian regulations, including but not limited to the *Fish Inspection Regulations* and the *Food and Drug Regulations*. For example, the use of a fish component such as raw shellfish (e.g., mussels, clams or oysters) that contains non-approved additives or that originates from non-approved sources will not be permitted. Imports will be subject to inspection in accordance with the policies and procedures described in Chapter 10 of the Manual of Procedures.

CHAPTER 3, SUBJECT 1

IMPORTED FISH AND FISH PRODUCTS INSPECTION

1. SCOPE

This document outlines the regulations, policy and procedures governing the inspection of imported fish and fish products.

2. AUTHORITIES

Fish Inspection Act, R.S.C. 1985, c. F-12.
Fish Inspection Regulations (FIR), C.R.C., 1978 c.802

Food and Drugs Act, R.S.C., 1985, c. F-12.

Consumer Packaging and Labelling Regulations, SOR/88-204

3. DEFINITIONS

Canned Products - canned products are those products hermetically sealed in a container that has been sterilized with heat to prevent spoilage and to destroy all pathogenic organisms. These products require can seam specifications and thermal process control documentation prior to importation.

Fish Import Licence - a licence issued in accordance with subsection 6.1(1) of the FIR.

First-Time Import - products new to the Canadian market or which have not been inspected in the last two years.

Fresh/Live Fish - this product category includes fish products in their natural or live state with the exclusion of molluscan bivalves.

Frozen/Salted/Dried Fish Products - this product category includes raw fish products that have undergone additional processing but which are not ready-to-eat.

High-Risk Products - products that may pose a serious risk to human health and safety as a result of improper preparation, handling, or processing, and for bivalve molluscs, as a result of the harvest source. High-risk

product types fall under the categories of low-acid canned products, ready-to-eat products or molluscan shellfish.

Import Alert List (IAL) - a listing of processors and products for which there has been a rejection as a result of product inspection, for which CFIA has received product alerts from other countries, or for which problems have been found during an investigation.

Import Control Tracking System (ICTS) - a computer system to track imported fish products. The system stores and processes the information related to fish imports (product description including scientific name and source, processor, importer, country of origin, lot size, product codes) as well as product inspection results (analyses conducted and the results). The system uses this information to identify and target for inspection products which are first-time imports as well as products which are part of an import alert. The information is also used by the system to maintain the IAL and provide import inspection management reports. The system also assists with tracking cost-recovery fees for imported fish products.

Lot - for import purposes, means a shipment or part of a shipment of fish that is of the same species, is processed in the same manner by the same producer, is packaged in the same size and type of container and bears the same label. An example of the same manner of processing includes but is not limited to canned sardines in different sauces or fish pâtés manufactured with different ingredients.

Molluscan Bivalves - includes all edible species of oysters, clams, mussels and whole and roe-on scallops.

National Sampling Plan - an annual national plan which outlines the targeted number of samples and test requirements for various products.

Process Authority - any person or organisation that has been recognised by the Agency as being competent in developing and evaluating thermal processes.

Product Categories - products are grouped into broad categories in accordance with the means of processing. The product categories are: a) ready-to-eat products; b) canned products; c) molluscan bivalves; d)

frozen/salted/dried products; and e) fresh/live fish. Each product category has specific health risks that affect the testing and verification requirements as well as record-keeping requirements.

Product Monitoring - unbiased sampling of a population of products with the purpose of gathering historical information and assessing global compliance with requirements.

Product Surveillance - sampling of a target population of product during a specific period of time, with the purpose of evaluating the degree of compliance with one or more specific requirements, in response to issues that have been previously identified.

Quality Management Program Import (QMPI) Licence - a licence issued in accordance with subsection 6.1 (1.1) of the FIR.

Random Product Verification - the testing of a lot, selected randomly, in accordance with the frequency identified in Table 4 of Appendix A. Each product verification will be counted as contributing one unit towards the national sampling plan.

Ready-To-Eat Products - any fish, with the exception of canned fish and live shellfish, that does not require preparation other than thawing or re-heating prior to consumption. Examples include cooked shrimp, cooked crustacean meats, smoked salmon, kamaboko, mousse and pâtés. These products require process control documentation prior to importation.

Reason for Inspection - products imported into Canada may be inspected as a first-time import, as part of the random product verification or background verification and as a result of an import alert.

Semi-preserved - fish that has been prepared by salting or pickling in brine, vinegar, sugar, spices or any combination thereof and packed so that it may be kept fit for human consumption for a minimum of six months by means of refrigeration without freezing.

Shipment - for import purposes, is a specific quantity of fish or fish products imported at the same time, by the same importer, on a single transport carrier or vessel, and notified to one inspection office as being available

for inspection at one location.

Standard tests - testing that applies to all fish product types. Standard tests include labelling evaluation, sensory evaluation and net content evaluation.

Specialised tests - testing which is based on the potential microbial and chemical hazards associated with a fish product type. Specialised tests include bacteriological analyses, chemical analyses, natural toxin analyses, safety parameters testing, product composition testing and container integrity evaluation.

Supplier Assessment Program - is a verification of offshore testing, which may consist of offshore test results or agreements to perform standard tests offshore.

Testing Category - test requirements are divided into two categories: 1) standard testing; and 2) specialised testing.

4. POLICY

All imported fish and fish products subject to the FIR shall be inspected as per the policies and procedures outlined in this document. This policy also outlines the general responsibilities of the CFIA and importers.

4.1 Imported Products

Except for imported products described below, imported fish are subject to the requirements of the Fish Inspection Act and Regulations. Products not subject to the Fish Inspection Act and Regulations would include:

- shipments not defined by the Canada Border Services Agency as imports;
- imported fish that are not intended for human consumption such as those declared as bait or pet food;
- imports that are intended for personal consumption;
- imports of fish products such as functional foods or nutraceuticals that are the responsibility of Health Canada;

- foreign products which remain in bond while being trans-shipped via Canada to another country;

- Canadian goods that are produced for export to a foreign market and are subsequently returned to Canada by the initial exporter. However, they will be subject to the requirements of the Import Inspection Program when the exporter of the Canadian goods and the importer of those goods are different;

- fish sold by a foreign vessel which is federally registered with the CFIA;

- products that are imported by foreign embassies or consulates are not normally subject to the FIR. If products are imported for commercial sale or redistribution, they will be subject to inspection and cost recovery;

- products imported as trade samples for the purpose of analysis and evaluation to determine general compliance with government and/or company requirements.

4.2 Importer Licensing

Any person who wishes to import fish or fish products into Canada for sale or distribution for human consumption, must first obtain an import licence from a CFIA office.

The requirements for all fish import licence holders are described in detail in Chapter 3, Subject 2 of this manual.

4.2.1 *QMPI Licence*

The requirements for the issuance of a Quality Management Program for Importers (QMPI) licence are described in detail in Chapter 3, Subject 2 of this manual.

A QMPI licence may be issued to importers who receive systems approval of their QMPI submission. There are two types of QMPI Licences: Shared and Enhanced.

In a Shared QMPI, the importer takes responsibility for determining the inspection requirements for standard tests and for specialised testing for container integrity, ensuring that all products imported are

produced under a documented and acceptable supplier assessment program, obtaining the samples, and conducting the standard tests on their final products as described in their system. The CFIA determines the need for specialised tests, draws the samples for specialised analyses and conducts these analyses as required.

In an Enhanced QMPI, the importer takes responsibility for determining the inspection requirements, ensuring that all products imported are produced under a documented and acceptable supplier assessment program, obtaining the samples, and conducting both the standard and specialised final product tests. All specialised testing must be carried out in accredited third party laboratories. The CFIA will not conduct any routine product testing in the Enhanced QMPI system, but may conduct tests on products imported by QMPI importers as part of an audit process, as part of an investigation, or as a result of requested inspections from the QMPI importer for both standard and specialised tests.

The Quality Management Program prepared by the importer must demonstrate:

a) compliance to the licence requirements;

b) details of the system for record keeping;

c) a supplier assessment program (offshore quality-control systems for standard tests or an alternative program to ensure compliance to Canadian Regulations);

d) a system to inspect cold-storage facilities;

e) the procedure to conduct verification of imported lots for the standard tests and specialised tests (Enhanced QMPI Importers only) at prescribed frequencies at the final product critical control point; and

f) the procedure for self-audit.

4.2.2 *QMPI Importer Inspection Results*

Shared and Enhanced QMPI licence holders must report on product rejections to the CFIA. Where QMPI Importers reject products for non-compliance with regulatory requirements that are health and safety related, they

must notify the CFIA immediately who will become involved in the determination of the actions to be taken. If the product is not rejected for a health and safety related reason then the CFIA must be notified within 5 working days of the product decision. The CFIA will place the product on the IAL with an ALI designation. Note that importer-specific label rejections will not be placed on the Import Alert List.

All inspection results of the tests conducted on imported products must be provided electronically to the CFIA. The inspection results are to be provided in a form acceptable to the CFIA every six months, once for the period of April to September and once for the period of October to March.

4.3 Import Licence Requirements

The requirements for all fish import licence holders are described in detail in Chapter 3, Subject 2 of this manual.

4.3.1 *Complaints*

All importers who receive information that questions the safety of the fish which they have imported shall investigate the information.

4.3.2 *Recall*

All importers who initiate a recall are required to notify the Agency immediately upon the decision being made. It is the responsibility of the Agency to work with the importer to monitor and assist in the recall if necessary.

4.3.3 *Record-Keeping Requirements*

All importers must maintain records for recall, complaints, and process controls in a location in Canada. These records must be retained for 3 years and must be accessible to inspectors for audit and evaluation.

4.4 Shipment Notification

All importers must notify the CFIA upon importation of all fish products into Canada within 48 hours of the arrival of the shipment. A written notification is required for each shipment. Products listed in Section

4.1 are not considered imports and do not require to be notified to the CFIA.

The CFIA has an official notification form available at the following internet address: http://www.inspection.gc.ca/english/anima/fispoi/import/importe.shtml
The use of the CFIA's notification form is voluntary, however all notifications must be accurate and must include all information required under the Fish Inspection Regulations.

4.4.1 *Import Data Requirements*

The importer as declared to the Canada Border Services Agency (CBSA) as the importer of record must be identified on the notification. If the name of the individual or enterprise providing the notification to CFIA is not the importer of record then they must include the name of the CBSA importer of record on the notification.

Products intended for further processing are to be identified on the import notification form.

Notification for shipments including high-risk products (i.e., canned and ready-to-eat fish) must include a list of the production codes that identify the processing establishment and date of processing and the number of containers for each production code. The complete production codes for these products should be entered into the import database.

4.5 Compliance Assessment - Regulatory Verification System

4.5.1 *Compliance assessment - Audit and Inspection activities*

The CFIA will assess the importer's compliance to applicable regulations, agreements, policy and procedures through the following activities:

4.5.1.1 For the Holder of a Fish Import Licence:

Inspection of importers for compliance to documentation requirements on consumer complaint and recall systems and process controls.

Inspection of imported products as part of the import product monitoring system.

4.5.1.2 For the Holder of a QMPI Import Licence:

The CFIA will assess Shared and Enhanced Importer's compliance of their Quality Management Program by the means of audit and inspection activities included in the Regulatory Verification System as detailed in chapter 3, subject 4 of this manual, Regulatory Verification Program for Imports.

4.6 Non-conformities

Please refer to Chapter 3, Subject 4 for details on non-conformities and subsequent procedures to follow with non-compliant importers.

Deficiencies identified during an inspection or evaluation of a licenced importer should be documented and categorised according to:

a) those resulting in the importation and or distribution of product that is fraudulent or unsafe;

b) those that are not in compliance with the agreed upon reference standard but which do not present a health or safety risk:

   I) regulatory non-conformity such as non-conformance with the Fish Inspection Regulations; or

   ii) non-regulatory non-conformity such as violation of applicable policy and procedure requirements;

c) deficiencies which if not addressed could lead to a non-conformity (observations).

4.7 Compliance Strategy - Enforcement

Enforcement actions applied by inspectors of fish products in response to non-compliance must follow the general Compliance Strategy framework, Chapter 2, Subject 5 of this manual. This document outlines enforcement and compliance principles and actions to be followed by inspectors to promote and verify compliance with the Fish Inspection Act and Regulations and all other applicable legislation.

4.8 Inspection Requirements

4.8.1 *Testing Requirements*

4.8.1.1 Standard Tests

Fish products are subject to the following tests to determine compliance with Canadian requirements:

a) Labelling evaluation - examination of the label, packaging and code markings.

b) Net Content evaluation - examination of the product weight to evaluate conformity to all weight declarations (e.g., net and/or drained weight, including fluid measure where applicable).

c) Sensory evaluation - product examination to evaluate sensory and physical compliance to quality standards for taint (rancid or abnormal), decomposition, foreign matter, undesirable parts and parasites, and to evaluate conformity to all other content declarations such as style, count, composition, etc.

4.8.1.2 Specialised Tests

Imports of fish products are subject to specialised testing to determine compliance with Canadian requirements regarding bacteriological and/or chemical hazards and fraudulent practices. Table 3 of Appendix A identifies the bacteriological and/or chemical hazards associated with a product type. Specialised testing includes the following tests:

a) Bacteriological testing - product testing for pathogenic organisms such as *E. coli, Listeria monocytogenes*, *Salmonella* sp., and *Staphylococcus aureus* in fish products.

b) Chemical analyses - product testing for chemical contaminants such as toxic elements, pesticides, industrial chemicals and drug residues in fish products.

c) Composition analyses - product testing regarding ingredients and additives.

d) Natural Toxin analyses - product testing regarding natural toxins such as histamine, paralytic shellfish

poison, domoic acid and other biotoxins such as ciguatoxin, okadaic acid and tetramine.

e) Safety Parameter testing - analyses to determine that fish packed in containers sealed to exclude air and which do not depend solely on heat sterilization, freezing or refrigeration for safety have adequate pH and/or water activity and/or water phase salt to ensure product safety.

f) Container integrity evaluation - examination of the hermetically sealed containers to determine their integrity.

g) Other - Specialised testing done as part of an investigation or special project. For example, swollen cans may undergo testing for sterility, and monitoring of products from countries where commercially harvested fish may be exposed to additional chemical or microbiological contamination which are not normally subject to testing.

4.8.2 *Reason for Inspection*

Imports of fish products are subject to inspection, to determine compliance with Canadian requirements, as follows:

a) First Time Import

Imported fish products for which there is no history of compliance are subjected to inspection. A product is considered to have no history of compliance if no fish of the same species, processed in the same manner (i.e., in the same product category) has been inspected in the previous two years.

b) Import Alert List

Imports of fish products on the Import Alert List (IAL) are subjected to inspection. The IAL is available on the CFIA internet site at: http://active.inspection.gc.ca/script/fispoi/ial/IALFront.asp?lang=e

c) Random Product Verification

Imported fish products are subjected to random inspection.

d) Monitoring or surveillance project

Imported fish products may also be subjected to inspection as part of a monitoring or surveillance project as established in the national sampling plan.

4.9 Products Imported for Further Processing: Inspection Requirements

4.9.1 Products imported for further processing will not be inspected by the CFIA for standard tests under the import inspection program. All products in the shipment that are destined for further processing will be charged a single fee of $30.00 for the entire shipment (see Chapter 3, Subject 3 of this manual, Cost Recovery). The fish products imported for further processing are to be treated as "Incoming Fish" under the plant's QMP. Processors importing fish for further processing will advise the CFIA of any instances of non-compliance with the FIR by providing details on the reason for rejecting the product. This information will be used to place the product on the Import Alert List (IAL) as a general alert (ALA). Depending upon the reason for non-compliance, the plant may be allowed to rework, cull, re-export or destroy the product.

When processing of the product does not remove potential health and safety risks (e.g., chemical contamination or pathogens), the CFIA may conduct specialised testing as required under the Import Inspection Program.

4.9.2 The importer must identify the products on their import notification that will be destined for further processing. They must include information that demonstrates that the fish will be substantially transformed in a registered plant as described below. For the purpose of determining the product’s inspection requirements and appropriate inspection service fee, the inspector will either approve or disallow the application for further processing in accordance with the following criteria:

a) The product must be processed in a CFIA registered plant. The importer must either operate a CFIA registered plant or identify the CFIA registered plant that will do the processing and the type of processing that will be carried out on the imported product.

b) The further processing must involve a significant transformation such as changes to the product as a result of, but not limited to, filleting, trimming, boning, freezing, canning, smoking, salting, cooking, pickling or drying. Products that have been re-packaged without also undergoing any of the previous processes are not considered to have undergone significant transformation. The importer must identify what further processing will be conducted on the imported shipment.

c) The importer must advise the CFIA of any lots imported for further processing which are rejected under the domestic QMP.

4.9.3 The importer should be advised if the lots identified on the import notification do not qualify for further processing. Imported products that do not qualify for further processing status are to be entered into the import database accordingly. These will be inspected following the policies and procedures applied to imported fish products not destined for further processing and will be subject to the flat fee per kilogram.

4.10 Products Imported For Further Processing: Country of Origin Declarations

4.10.1 Under certain conditions, products from fish imported for further processing may be labelled as Product of Canada. The Product of Canada designation is important for market access where certificates are required since certificates can only be issued on products of Canada.

Under the North American Free Trade Agreement (NAFTA) only products of Canada are eligible for the reduced tariff privileges when exported to the United States or Mexico. The rules of origin in NAFTA state that an imported product is substantially transformed when it has changed tariff chapters in the Harmonized Tariff Schedules as a result of processing. Normally this would involve a shift of products classified under Chapter 3 when imported, to a product in Chapters 16 or 21 after processing. Mexico enforces the NAFTA rules of origin without exception, but both Canada and the USA apply some special considerations.

4.10.2 In Canada, in addition to processing that would result in changed tariff chapters, the following processes on imported fish will result in substantial transformation.

A "Product of Canada" designation is allowed as long as the products are sold in Canada or exported to countries other than Mexico or the United States. Special considerations for substantial transformation in Canada must involve more than repackaging, freezing of fresh products, culling, trimming, etc. The processes listed below are examples that can be considered substantial transformation based on the criteria that there is significant value added as a result of the processing and the processing changes the nature of the product:

a) the peeling and then freezing of fresh or frozen uncooked shrimp;

b) the filleting, mincing or steaking of whole or headless and gutted (H&G) fish;

c) the salting and drying of whole or H&G fish, or the drying of green-salted fish, and then conducting further actions such as salting, trimming, de-boning, grading for preparation of dried, salted fish meeting the requirements for heavy-, light- or slack-cured products in the Fish Inspection Regulations (FIR): and

d) shucking molluscan shellfish.

Fish sold in Canada or exported to countries other than the United States or Mexico that is processed on board a foreign vessel that is registered according to Section 15 of the FIR may also be designated as "Product of Canada".

4.10.3 For fish exported to the United States, some products are considered substantially transformed as a result of changing Tariff Headings or Subheadings of the Harmonized Tariffs as opposed to changing of Chapters. For export to the USA, products imported into Canada and processed to affect a shift of tariff categories as listed in the table below may be designated as "Product of Canada".

Tariff-Shift Rules of Fish Imported for Substantial Transformation and Exported to the USA

Codes[1]	Descriptions	Tariff-Shift Rule
03.01-03.03	Live, fresh, or frozen. Whole or H&G	A change from any other chapter.
03.04	Fresh and frozen fillets, fish meat	A change to 03.04 from any other headings such as 03.01, 03.02, 03.03
03.05.10	Flours, meals, pellets of fish for human consumption	A change to 03.05.10 from any other subheading
03.05.30	Fish fillets dried, salted, or in brine, but not smoked	A change to 03.05.30 from any other subheading, except from fillets of heading 03.04
03.05.41-69	- Smoked fish, including fillets; - Dried fish, whether or not salted but not smoked; - Salted but not dried or smoked; and - Fish in brine	A change from any other chapter
03.07	Molluscs	A change from any other chapter or a change to edible meals & flours from within Chapter 3

[1] The first 2 digits in the Harmonized Tariff Schedule codes represent the Chapter, the third and fourth digits represent the heading, and the fifth and sixth digits represent the subheading

1. Examples of imported fish processed in Canada that may be labelled as Product of Canada if exported to the United States:

   a) whole or H&G fish that is filleted or minced (03.02 to 03.04) is considered substantially transformed;

   b) whole or H&G fish which is filleted and then dried or salted (03.02 to 03.05) would be substantially transformed; or

   c) green salted cod (with back bones attached)

which are filleted and dried(03.05.61 to 03.05.30) would be substantially transformed.

2. Imported products which may not be labelled as Product of Canada if exported to the United States:

   a) fish which is smoked (no change in chapters) is not substantially transformed;

   b) whole or H&G imported fish that is split or steaked whether or not the fish is fresh or frozen is not considered substantially transformed;

   c) molluscan shellfish which are shucked (03.07 to 03.07) are not considered substantially transformed;

   d) shell-on shrimp which is peeled (03.06 to 03.06) is not considered substantially transformed; or

   e) fillets in brine which are trimmed and dried (03.05.30 to 03.05.30) are not considered substantially transformed.

4.10.4 For imported fish products exported to Mexico, the processing must change the classification of the product from one chapter to another before the product can be declared as a product of Canada. Examples of further transformation of fish products that would change the classification from one chapter to another include:

a) preparing breaded fish from frozen fillets (03.04 to 16.04);

b) preserving frozen fish fillets in a marinade (03.04 to 16.04);

c) cooking and peeling shell-on shrimp (03.06 to 16.05);

d) preparing clam juice from frozen clam meats (03.07 to 16.03); or

e) canning fresh H&G salmon (03.02 to 16.04).

The following examples of further processing of imported fish would not change the classification from one chapter to another:

a) packing smoked salmon in air tight containers (03.05 to 03.05);

b) cooking but not peeling raw shell-on shrimp (03.06 to 03.06); or

c) cooking and packing whole lobsters (03.06 to 03.06).

4.11 Memoranda of Understanding and Mutual Recognition Agreements

Agreements concerning the inspection of fish have been signed with foreign governments. Memoranda of Understanding (MOU) are agreements that are processor and product specific. The recognised inspection agencies in the exporting country have the authority to inspect specific fish products destined for Canada for compliance to Canadian requirements.

While MOUs are still applicable, Canada is pursuing bilateral or Mutual Recognition Agreements (MRA) that recognise the equivalency of fish inspection and control systems for fish and fish products imported into Canada. These MRA recognise entire inspection systems in the agreement countries as opposed to specific processors and their products. The determination of equivalency is based on an evaluation by Canadian inspectors of the design and implementation of the other country's fish inspection and control system. This includes an evaluation of personnel, inspection and sampling plans, certification systems, history of compliance and enforcement. Once equivalency has been established, the responsible authority in the other country determines those processors in that country that are recognised under the MRA.

Specific information on the agreements (MOU and MRA) and the processors and products covered can be found on the CFIA Internet site at: http://www.inspection.gc.ca/english/anima/fispoi/export/mupd/mupde.shtml

4.12 CFIA Responsibilities for Imported Fish

4.12.1 *CFIA Service Guidelines and Performance Standards*

The CFIA is to adhere to the standards and inspection frequencies identified below:

a) an import licence is to be issued within 5 working

days of the receipt of the fee and the completed application;

b) enforcement action is to be initiated within 10 working days against non-compliant importers in accordance with enforcement policies;

c) importers are to be informed of the decision to inspect within 2 working days of receiving notification that the product is available for inspection;

d) enforcement action is to be taken against firms for non-notification according to enforcement policies;

e) shipments are to be inspected/sampled within 5 working days of decision to inspect;

f) bacteriological and chemical analyses are to be completed within 10 working days of delivery of samples to the laboratory except in special instances where steps in the method, such as confirmation of a presumptive reject, require more time;

g) reporting of the acceptance/rejection decision for the shipment is to be issued within 2 working days of receipt of final analysis/examination results;

h) re-inspections (in the same region) are to be completed within 20 working days of the lot being made available for re-inspection;

I) QMPI submissions are to be evaluated and the results communicated to the importer within 20 working days;

j) Shared/Enhanced QMPI Importers are to be audited every 3 months;

k) holders of a Fish Import Licence are to be evaluated every year based on information provided on the "Application for a License to Import Fish" and also on a problem-driven basis.

5. PROCEDURES

The procedures to monitor and inspect imported products to determine compliance to the Fish Inspection Act and Regulations are covered in this section.

5.1 Importer Licensing

An import licence will be issued to importers who submit an "Application for a License to Import Fish" to CFIA which identifies that they will meet the requirements of the FIR, including those for record keeping, recalls, complaints and records for process controls.

The procedures for issuing a Fish Import Licence are described in Chapter 3, Subject 4, Section 5. Persons wishing to apply for a Shared or Enhanced QMPI Licence shall be provided with a QMPI Submission Guide. The Director of the Fish, Seafood and Production Division or a delegated authority must approve the Shared or Enhanced QMPI Submissions before the importer receives shared or enhanced privileges.

5.2 Shipment Notification

Electronic notification by telex, facsimile, or electronic mail will be considered written notification. The CFIA offices receiving import notifications must have a confirmation system in place to systematically document all notifications received. It is recommended that the system should print reports identifying the sources of notifications received.

The information from each notification must be entered into the import database (ICTS). Only one notification per shipment can be processed by the CFIA.

Canadian goods returned to Canada by the original exporter are not considered imports and are not to be entered into the import database. Canadian products brought back into Canada by an importer who was not the original exporter must be entered into the import database and are subject to the same inspection requirements as imports from other countries.

5.3 Control of Imports

Fish Import Licence - All products must be withheld from distribution subject to receiving a decision to inspect by the CFIA. Products can be distributed if the CFIA advises that testing is not required. Except as outlined below, when testing is required the product must be held from distribution until all testing is completed and the product is found to be in compliance with all pertinent regulations.

Fresh products, except for aquaculture fresh product and unless listed on the IAL, can be sampled for inspection without detention.

Refrigerated ready-to-eat fish (examples include marinated seafood salads, unfrozen kamaboko and unfrozen cooked fish products) require detention pending completion of analytical results if they are First Time Imports or IAL products. They may be sampled without detention if they are inspected as Random Product Verifications.

Shared QMPI - All products must be held subject to receiving a decision to conduct specialised tests by the CFIA. In addition, if testing is required, products must be withheld from distribution until standard tests are conducted by the importer and/or specialised tests are completed by the CFIA and the product is found to be in compliance.

Enhanced QMPI - Importers can sell and distribute their imported products without clearance from the CFIA after conducting their own verification inspections.

5.4 Inspection Requirements

5.4.1 *Inspection Procedures*

5.4.1.1 Imports of fish products will be inspected in accordance with the procedures outlined in Chapter 2 of this Manual in order for an official decision to be made on the lot. All products will undergo initial inspection on a lot basis (as opposed to breaking the lot into sub-lots by code).

Shared QMPI licence holders are required to carry out standard tests on fish imports while the CFIA will perform the specialised tests. Enhanced QMPI licence holders are expected to carry out the standard and specialised tests in place of CFIA.

5.4.2 *Testing Requirements*

The CFIA reserves the right to draw samples and conduct tests beyond minimum frequencies. However, the CFIA will not charge analysis fees for any discretionary testing.

Appendix B outlines the decision process for determining the tests to be conducted.

5.4.2.1 First Time Import Inspection

All fish products new to the Canadian market or which have not been inspected in the last two years will be subject to standard testing and any specialised testing identified for that product type in accordance with Table 3 of Appendix A (as applicable).

5.4.2.2 Random Product Verification

Fish products will be subject to standard testing and any specialised testing identified for that product type as identified in Table 3 of Appendix A (as applicable), and in accordance with the frequencies identified in Table 4 of Appendix A.

Fish products may also be subject to testing as part of monitoring or special surveillance projects in accordance with the annual national sampling plans.

5.4.2.3 Import Alert List (IAL)

Fish products which fall under an Import Alert (IA) will be evaluated for the corresponding analysis on the IAL. Products will be removed from the IAL once the required number of consecutive acceptable shipments has been reached. The number of inspections with acceptable results required to have a product removed from the IAL is dependent on the reason for rejection (see Table 1 of Appendix A).

5.4.3 *Inspection Recommendations* (CFIA's Import control Tracking System)

5.4.3.1 The Import Control Tracking System (ICTS) will generate inspection recommendations and testing requirements based on the information provided on the notifications. If it is determined that the information entered into ICTS is inaccurate, the shipment will need to be reprocessed in ICTS using the accurate information.

The Import Control Tracking System (ICTS) will generate inspection recommendations for:

a) First Time Imports

Inspectors will refer to Table 3 of Appendix A to determine applicable specialised testing.

b) Random Product Verification

These recommendations will not be actioned. Inspectors will refer to the national sampling plan for the target numbers for random product verifications. These target numbers have been determined based on the inspection frequencies for random product verification identified in Table 4 of Appendix A. Inspectors will refer to Table 3 of Appendix A to determine applicable specialised testing. Imports of fish products will be randomly selected from different lots throughout the fiscal year to meet the target numbers for random product verification.

c) Import Alerts

The inspection recommendation will identify the inspection analyses corresponding to the IA.

The data elements that identify products for the Import Alert List (IAL) include the country of origin, the processor, the main method of preservation (i.e., primary treatment), the common name, form and any other processing of the product (i.e., secondary treatment), the brand name (for label evaluations only), and the container design (for container integrity evaluations only). The data from the import notifications must match the criteria in the above fields as described in Table 2 of Appendix A in order for the product to be identified as part of an IA.

5.4.3.2 Imports of fish which are not identified for inspection under section 5.4.2, may be inspected if suspected of being noncompliant with Canadian requirements. These inspections will be identified as discretionary in the import database.

5.4.4 *Inspection Results*

If a lot is rejected on initial inspection, a person has the right to request a suspended inspection, or, under Section 10(1) of the FIR to request a reinspection (see Chapter 2, Subjects 1 and 2 of this manual).

A Fish Inspection Report is completed for all products inspected (this includes Special Inspections and inspections requested by the importer).

In the case of a rejected product, the Fish Inspection Report shall be sent immediately to the importer either by mail, fax or in person.

For rejected imported shellfish, NHQ must be informed immediately of the details. NHQ will then notify the proper authorities in the exporting country.

Shipments of fish rejected by foreign inspection agencies with which Canada has signed an inspection agreement may be refused entry when sampling, analytical procedures and tolerances are the same as those applied by the CFIA. These should be evaluated on a case-by-case basis. NHQ should be notified of these shipments.

5.5 Preferred Status Plants

Under review.

5.6 Disposal

After completion of the initial inspection, the Inspector must take one of the following courses of action:

a) release the product;

b) suspend the inspection pending reworking or culling of the product; or

c) reject the product.

Where a decision has been made to reject a lot of imported fish, that lot of fish must be disposed of within 60 days of the date of notification of the inspection/re-inspection results. Disposition will consist of an action that is appropriate to the reason for rejection and which will either bring the product into compliance or prevent it from being sold in Canada. Examples of disposition are:

a) culling to remove the defect;

b) reworking or reconditioning in a registered plant in a manner that will remove the defect or bring the product into compliance with the FIR;

c) re-labelling;

d) destruction; or

e) removal from Canada.

Verification of export from Canada or destruction of rejected imports must be carried out. For products that are destroyed, the usual verification procedure is to witness the destruction. In the case of products removed from Canada, to ensure proof of exportation the inspector may utilise whatever action deemed necessary, depending on the importer's history of compliance. Such proof of exportation will normally take the form of the following documents:

a) the importer is required to provide certified copies of U.S. Customs form 7501 (for products destined for the USA), or U.S. Customs form 7512 (for product destined for a third country but being shipped through the USA);

b) the importer must provide a file copy (e.g., carbon copy) of the Bill of Lading marked "Non-Negotiable", or where acceptable, Canada Border Services Agency form B13A for countries other than the USA.

The inspector must notify NHQ if product not originating from but destined for the UK is rejected in Canada for Health and Safety reasons (Canada/US/UK Tripartite Agreement on Health Issues). NHQ will then notify the proper authorities in the United Kingdom.

If canned product has been rejected for under-processing or presence of toxins, and the product is not being returned to its country of origin, the inspector must notify NHQ so that the proper authorities can be notified in the destination country.

If Canadian product is imported back into Canada and rejected, the inspector is to notify the office responsible for the original processor, so that follow-up action can be undertaken if necessary.

When product which has been rejected for health and safety reasons is being shipped to the United States, the inspector is to notify the nearest office of the USFDA.

When any shipment of canned, fresh/frozen or processed fish originating from the United States is rejected in Canada, a copy of the Fish Inspection Report is to be mailed directly to:

Director
Centre for Food Safety and Applied Nutrition (HFF-1)
"C" Street, S.W.
Washington, DC, U.S.A.
20204

and

Chief, Seafood Inspection Division (F/TS4)
National Marine Fisheries Service
East West Highway
Silverspring, MD, U.S.A.

5.7 Imported Shellfish

5.7.1 As per section 6(1)(b) of the FIR, fresh and frozen mussels, oysters, clams, and scallops with viscera or roe attached from United States and New Zealand shippers, and shucked frozen oysters from Japanese and Korean shippers, whose names appear on the monthly "Interstate Certified Shellfish Shippers List" (ICSSL) published by the United States Food and Drug Administration (USFDA), may be permitted entry provided that each container is clearly and permanently marked with the name and address of the shipper and the certificate number. The requirements for importing live and raw shellfish can be found at the following internet address:
http://www.inspection.gc.ca/english/anima/fispoi/import/molimpe.shtml

5.7.2 Processed raw molluscan shellfish products such as breaded clams or oysters can be imported on the condition that the importer is able to provide a statement from the processor that the product was produced under a HACCP system and the processor used only product from ICSSL- approved areas as described above.

Establishments from France which have been approved to ship oysters to Canada can be found at the following internet address :
http://www.inspection.gc.ca/english/anima/fispoi/import/oysthuite.shtml

Establishments from Ireland which have been approved to ship oysters to Canada can be found at the following internet address :
http://www.inspection.gc.ca/english/anima/fispoi/import/iroyshuie.shtml

5.7.3 Ready-to eat molluscan bivalve shellfish from non-agreement countries must have acceptable process control documents[2] and be cooked sufficiently to be coagulated[3].

[2] Process control documentation will be considered acceptable if the product, as a minimum, has been subjected to a thermal process that results in a 5 log reduction of Listeria monocytogenes as defined by Health Canada. Note that it is still the responsibility of the manufacturer to design a thermal process which will result in a safe product and which takes all factors into account, including processing conditions and the presence of other food pathogens with greater thermal resistance.

[3] Coagulation in this case is the formation of a structure, which ranges from solid to semi-solid, when the proteins are denatured as the result of exposure to heat and is typically identified by flesh that is dull ivory, opaque, with a firm texture.

5.8 Request for Inspection

When an importer makes a request to the CFIA for an inspection of imported fish products, the written request should clearly indicate which evaluations the importer wishes to have performed on the product. A CFIA form is available for this purpose. The importer should be informed that inspection fees will be charged for all requested evaluations (see Section 4.5, Chapter 3, Subject 3 of this manual).

Importers are responsible for the decision making on a shipment once the results of requested specialised or standard tests are received.

CFIA's Responsibilities

- The CFIA office performing the requested analyses will inform the importer of the numerical laboratory results and whether the product meets Canadian guidelines. The laboratory will not make a decision (pass/fail) on the product's suitability for sale.

- The laboratory will notify inspection staff when a product may be in violation so the inspection staff can monitor the situation and take action when necessary.

5.9 Recall

Recalls will be conducted in accordance with established CFIA policies.

6. FORMS/DOCUMENTS

Appendix A - Tables/Lists

Tables

Table 1	Reasons for Adding and Removing Products from the IAL
Table 2	Matching Matrix For Type of Analysis Listed on Import Alert
Table 3	List of Potential Hazards and Associated Fish Products
Table 4	Summary of Testing Frequencies

Lists (lists are maintained on the CFIA Internet site)

- List of Large Predatory, Freshwater and Bottom Feeder (considered fatty) Fish
- List of Scombroid Fish Species
- List of Fish Species which are, or may be, Aquacultured

Appendix B	Decision Process for Determining Tests to be Conducted
Appendix C	Notification Form
Appendix D	Fish Inspection Report
Appendix E	Request for an Inspection of Fish
Appendix F	Application for a Licence to Import Fish
Appendix G	Canada Border Services Agency Form B13A - Export Declaration
Appendix H	Application for a Quality Management Program for Importers (QMPI) Licence

APPENDIX A
TABLES / LISTS

Tables

Table 1 The following list identifies the reasons for products to be added to, and removed from, the IAL.

Products are added to the IAL with an Alert Mandatory (ALM) designation when:	**Products with an Alert Mandatory (ALM) designation are removed from the IAL when:**
Imports inspected and rejected by CFIA inspector.	The products have been sampled and inspected either by the CFIA or the QMPI importer four consecutive times with acceptable results, except for products listed for label evaluation which are removed after one acceptable result.
Products are added to the IAL with an Alert (ALA) designation when:	**Products with an ALA designation are removed from the IAL when:**
Products imported for further processing and rejected during inspection under the domestic processors QMP;	The product is inspected and passed once by either the CFIA or a QMPI importer; The product is rejected by the CFIA and gets moved to the ALM designation; The product is on the IAL with an ALA designation for one year but there have been no rejections
There is an Alert issued by the USFDA or a Health Canada Stop Sale order for a product which may be imported into Canada and is not already on the IAL with an ALM designation;	The corresponding USFDA Alert has been dropped; The corresponding Stop Sale order is withdrawn;

A region may request a product be listed on the IAL with the designation ALA where there is reason to inspect the next importation; or	The product is inspected and passed once by the CFIA; The product is rejected by the CFIA and gets an ALM designation; The product is on the IAL with an ALA designation for one year but there have been no rejections;
Investigations indicate a problem with an imported product.	The product is inspected and passed once by the CFIA; The product is rejected by the CFIA and gets an ALM designation; The product is on the IAL with an ALA designation for one year but there have been no rejections.
Products are added to the IAL with an Alert Information (ALI) designation when:	**Products with an ALI designation are removed from the IAL when:**
A Shared/Enhanced QMPI importer has notified CFIA fish inspection of a product that was rejected for non-compliance to regulatory requirements.	The products on the IAL with an ALI designation have been passed four consecutive times by the QMPI importer and/or the CFIA.

Table 2 Matrix For Matching Fish Imports with Type of Analysis Listed on the Import Alert List

Product Description Field	Label	FIR Reqmt. (Process Control Documents)	Chemical & Bioassay	Bacterio-logical	Container Integrity	Sensory/ Net Content
Processor	Yes	Yes	Yes	Yes	Yes	Yes
Product Category (Frozen, Fresh, Canned, RTE, Molluscan Shellfish)	No	Yes	No	Yes	Yes	No
Common Name (RTE Aquaculture Shrimp, FSO Scombroid, etc.)	No	No	Yes	No	No	No
HS Code	Yes	No	No	No	No	Yes
Brand Name	Yes	No	No	No	No	No
Container Design (Round, Flat, etc.)	No	No	No	No	Yes	No

Table 3 Potential hazards and associated fish products

Part A. Microbiological hazards

Microbiological agent	**Type of Product**
E coli	All RTE products
	Raw molluscan shellfish
Listeria monocytogenes	All RTE products
Salmonella spp	All RTE products
	Raw molluscan shellfish
Staphylococcus aureus	RTE products
Vibrio spp	Raw molluscan shellfish

Part B. Chemical Hazards

Environmental Contaminants	
Component	**Product Type**
Mercury	Large predatory fish Freshwater fish (not aquaculture) Bottom feeders *(see species list on web site)*
PCBs (Polychlorinated biphenyls)	Fatty fish Freshwater fish *(see species list on web site)*
Dioxins, Furans and Dioxin-Like PCBs	Fatty fish Freshwater fish *(see species list on web site)*
Marine Toxins	
Component	**Product Type**
DSP (Okadaic Acid) PSP (Paralytic Shellfish Poisoning) ASP (Amnesic Shellfish Poisoning)/Domoic acid	All Molluscan Shellfish
Ciguatoxin	Tropical Reef Fish

Aquaculture Drugs	
Component	**Product Type**
Amphenicols: Chloramphenicol Thiamphenicol Florfenicol Florfenicol Amine *Tetracyclines*: Oxytetracycline Tetracycline Chlorotetracycline *Sulfonamides*: Sulfadimethoxine Sulfadiazine Ormethoprim Trimethoprim Sulfanilamide Sulfacetamide Sulfaguanadine Sulfapyridine Sulfadiazine Sulfathiazole Sulfamerizine Ormetoprim Trimethoprim Sulfamethoxazole Sulfamoxole Sulfisoxazole Sulfamethizole Sulfamethazine Sulfamethoxypridazine Sulfamonomethoxine Sulfachloropyridazine Sulfaquinoxaline Oxolinic acid Nitrofurans Malachite green/ leucomalachite green Flumequine Emamectin/Ivermectin	Aquaculture Fish *(see species list on web site)*

Additives	
Component	**Product Type**
Sulphites	Raw/Cooked/Canned crustaceans
	Dried Fish
	Raw/cooked/canned clams
	Canned Abalone
Borates	Caviar/Roe
3-MCPD	Fish Sauce
Nitrites/Nitrates	Smoked fish
	Dried Fish
Decomposition indicator	
Component	**Product Type**
Histamine	Scombroids Enzyme ripened products *(see species list on web site)*

Part C. Additional Testing (Health and Safety/Regulatory)

Component	**Type of Product**
Container integrity	Canned products (commercially sterile, hermetically sealed container e.g., metal, glass, pouch
Phosphates	Raw and cooked crustaceans
	Raw scallops
	Fish fillets
	Raw and cooked clams
Safety Parameters - Water phase salt - Water activity - pH	Non-frozen ready-to-eat
	Semi-preserved

Table 4 Summary of Testing Frequencies

High-risk products		
Product type	**Testing**	**Frequency**
Canned products	▸ Standard testing	5%
	▸ Risk-based chemical and/or microbiological testing (see Table 3) ▸ Container integrity	
RTE products	▸ Standard testing	5%
	▸ Risk-based chemical and/or microbiological testing (see Table 3) ▸ Safety Parameters (non-frozen)	
Molluscan shellfish	▸ Standard testing	5%
	▸ Risk-based chemical and/or microbiological testing (see Table 3)	
Low-risk products		
Product type	**Testing**	**Frequency**
Frozen, salted, dried	▸ Standard testing	2%
	▸ Risk-based chemical testing and/or microbiological testing (see Table 3)	
Fresh	▸ Standard testing	2%
	▸ Risk-based chemical testing and/or microbiological testing (see Table 3)	

Lists

Lists indicated below are available and maintained on the CFIA Internet site (see www.inspection.gc.ca).

- List of Large Predatory, Freshwater and Bottom Feeder (considered fatty) Fish

  This list is available at the following address:

  http://www.inspection.gc.ca/english/anima/fispoi/import/prede.shtml

- List of Scombroid Fish Species

  This list is available at the following address:

  http://www.inspection.gc.ca/english/anima/fispoi/import/scome.shtml

- List of Fish Species which are, are may be, Aquacultured

  This list is available at the following address:

  http://www.inspection.gc.ca/english/anima/fispoi/import/aquae.shtml

APPENDIX B

Decision Process for Determining Tests to be Conducted

Product Type	**Specialised Analysis**
Aquacultured (*see species list on web site*)	Drug Residues
Caviar / Roe	Borates (caviar only) Safety Parameters
Crustaceans - Raw/Cooked/Canned Crustaceans - Raw/Cooked	Sulphites Phosphates
Clams - Raw/Cooked/Canned Clams - Raw/Cooked	Sulphites Phosphates
Dried Fish	Nitrites/Nitrates (currently under review) Sulphites
Fatty Fish Freshwater Fish	PCBs Dioxins, Furans, Dioxin-like PCBs
Fish Oils and Organs	Pesticides
Fish Sauce	3-MCPD Histamine
Fish Fillets	Phosphates
Large Predatory Fish Freshwater Fish Bottom Feeders (*see species list on web site*)	Mercury
Molluscan Bivalve Shellfish	Marine toxins (PSP, ASP, DSP)
Reef Fish	Ciguatera Toxin
Salted Fish	Moisture content
Scallop Meat	Phosphates Moisture
Semi-preserves	Safety Parameters
Smoked Fish Smoked - Refrigerated vacuum-packed RTE Refrigerated product containing smoked	Nitrites/Nitrates (currently under review) % salt (if package permeability < 2000cc/m^2/24H / no heat treatment applied) Safety parameters
Scombroid Enzyme Ripened (*see species list on web site*)	Histamine

APPENDIX C
NOTIFICATION FORM

The Fish Import Notification Form is available on the CFIA Internet at the following address:

- http://www.inspection.gc.ca/english/anima/fispoi/import/importe.shtml

APPENDIX D
FISH INSPECTION REPORT

APPENDIX E
REQUEST FOR AN INSPECTION OF FISH

The Request for an Inspection of Fish is available on the CFIA Internet at the following address:

- http://www.inspection.gc.ca/english/anima/fispoi/import/importe.shtml

APPENDIX F
APPLICATION FOR A LICENCE TO IMPORT FISH

The Application for a Licence to Import Fish is available on the CFIA Internet at the following address:

- http://www.inspection.gc.ca/english/anima/fispoi/import/importe.shtml

APPENDIX G
CANADA BORDER SERVICES AGENCY FORM B13A - EXPORT DECLARATION

The CBSA Form B13A-Export Declaration, is available on the CBSA Internet site at the following address:

- http://www.cbsa-asfc.gc.ca/E/pbg/cf/b13a/README.html

APPENDIX H
APPLICATION FOR A QUALITY MANAGEMENT PROGRAM FOR IMPORTERS (QMPI) LICENCE

The Application for a Quality Management Program for Importers (QMPI) Licence is available on the CFIA Internet at the following address:

- http://www.inspection.gc.ca/english/anima/fispoi/import/importe.shtml

CHAPTER 3, SUBJECT 2

COMPLIANCE GUIDE FOR IMPORTERS OF FISH AND FISH PRODUCTS

1. SCOPE

This document provides compliance guidelines to assist inspectors and importers in understanding and applying regulations for imported fish. These guidelines will be used when determining the compliance of Fish Import Licence holders and those participating in the voluntary Shared or Enhanced Quality Management Program for Importers (QMPI). All importers are subject to audit by CFIA to ensure that these compliance guidelines are met.

2. AUTHORITIES

Fish Inspection Act, R.S.C. 1985, c. F-12.
Fish Inspection Regulations (FIR), C.R.C., c. 802

Food and Drugs Act
Food and Drugs Regulations

Consumer Packaging and Labelling Act
Consumer Packaging and Labelling Regulations

3. POLICY

3.1 REQUIREMENTS FOR ALL IMPORTERS OF FISH AND FISH PRODUCTS - Fish Import Licence Holders, Shared QMPI Import Licence Holders and Enhanced QMPI Import Licence Holders

3.1.1 Import License Requirements

Only imports from licensed importers are permitted entry into Canada (FIR, Section 6(2)(d)).

The importer registered with and declared to the Canada Border Services Agency must be the holder of a Fish Import License or a Quality Management Program Import Licence (FIR, Section 6(2.1)(e)).

To apply for a Fish Import Licence, an importer must complete the "Application for a License to Import Fish" (see Chapter 3, Subject 1, Appendix F). The importer's signature on this application is the importer's

commitment to comply with all requirements for holding a Fish Import Licence (FIR, 6.1(1)).

For those importers participating in the Shared or Enhanced QMPI, the importer must develop a quality management system and provide details of that system through a QMPI submission to the CFIA. Upon CFIA review and approval of the submission, a Shared or Enhanced Quality Management Program Import Licence is issued. The QMPI Submission Guide for a Shared or Enhanced Importer is found in Appendix A of this subject. For additional details about the QMPI Submission, refer to Section 3.2.1 of this document (FIR, 6.1(1.1)).

3.1.2 Import Notification Requirements

Importers must notify CFIA in writing of each shipment of imported fish products within 48 hours of entry (FIR, Section 6(2)(e)).

Import notifications must include a description of each lot in the shipment, including the quantities, the date codes, the offshore processor, the country of origin, the shipment location, and the name, address, telephone number and import license number of the importer (FIR, Section 6(2.1)(a-e)).

In the case of canned and ready-to-eat fish, the lot must be accompanied by a list of codes which identifies the name of the processing establishment and the date(s) of processing (FIR, Section 6(2)(b)).

Raw molluscan bivalve shellfish must originate from plants listed on the Interstate Certified Shellfish Shippers List (ICSSL) or other approved lists. These plants must be located in countries which have signed agreements with Canada concerning the inspection of molluscan shellfish. Processed raw molluscan bivalve shellfish, such as breaded product, can be imported on the condition that the importer is able to provide a statement from the processor that the product was produced under a HACCP regime and the processor used only product from ICSSL approved areas (FIR, Section 6(1)(b)).

3.1.3 Record-Keeping Requirements

The following requirements are mandatory for **all** importers including those participating in the Shared or

Enhanced QMPI. The records described in the following subsections must be maintained in Canada for a period of three years and will be subject to inspection by CFIA.

3.1.3.1 Recall System - FIR, 6.1(3)(a), 6.1(3)(e)(xi)

All importers are required to maintain records to the first point of sale. This includes as a minimum, a record of the name and address of the person to whom the fish is sold and the date on which the fish is shipped from the importer. The importer can choose to track distribution by lot or code. The importer must document an appropriate plan to administer a recall and to dispose of product which is found to be in non-compliance to Canadian requirements. Companies with a Shared or Enhanced QMPI must clearly describe the system to track product distribution in their written submission.

3.1.3.2 Complaints - FIR, 6.1 (3)(b)

The importer will be required to keep a record of all complaints received, evaluations conducted and any actions taken as a result of the complaint. If the information is validated on investigation, the importer must record a description of the information, the date and time it was received, the name, address and telephone number of the informant, the method of the investigation and the results of the investigation. Any corrective actions taken and any measures implemented to prevent it's reoccurrence are also recorded.

The importer must ensure that appropriate notification of legitimate complaints is provided to the CFIA within the proper time frame. Where any health and safety complaints are identified by an importer, regardless of validity, the CFIA must be notified **immediately (within 24 hours)**. Following CFIA notification, the importer will continue to conduct the investigation and implement any necessary corrective actions.

Where importers reject products for non-compliance to regulatory requirements which are not health and safety related, the CFIA must be notified within 5 days of the product decision. CFIA will place all products rejected on the Import Alert List, except importer-specific label rejections. When warranted, CFIA may also complete some additional testing.

3.1.3.3 Documentation of Process Controls - FIR, 6.1(3)(c)(d)

Importers must have available, on request, documentation for each type of canned fish and ready-to-eat fish product that they import, demonstrating that recognised process controls were followed during processing.

The documentation must precede or accompany the first shipment, and a copy must be maintained in Canada by the importer.

For subsequent shipments of the same product such documentation must be available to the importer and to the CFIA on request. The importers must also be able to obtain the thermal processing records for an individual lot from the processor on demand. While this information must be available, it does not have to be kept on file in Canada.

Since there is a requirement of MOU plants to provide evidence of adequate processing to satisfy the ongoing relationship between the establishment and the inspection agency in that country, importers purchasing product from MOU establishments in MOU/MRA countries would not be expected to maintain such evidence in Canada. The importer would only be required to verify that the product was subject to an MOU agreement.

Should concerns be identified through ongoing product inspection by CFIA or QMPI importers, with respect to the safety of a canned or ready-to-eat imported product, additional information regarding the process will be requested from the importer on a priority basis.

3.1.3.3.1 Canned fish

The following processing documentation, with respect to each type of imported canned product, should be obtained:

- The name, address and telephone number of the thermal process authority.
- The container type, size and seam specifications, style of pack, species packed and if the thermal process used has not been described in published scientific literature recognised by the Minister, the sterilising value (F_0) of the thermal process.
- A statement in writing signed by the representative of the process authority that

attests that the thermal process results in the production of commercially sterile and safe fish product

3.1.3.3.2 Ready-to-eat fish

As of December 1998, the following processing documentation, with respect to each type of imported ready-to-eat product should be obtained:

- The name, address and telephone number of the process authority/specialist and their signature verifying that the process, as delivered, yields safe and acceptable product.
- The container type and size, style of pack, the species packed, the type of process, the description of the process which would include parameters such as formulation, pH, water activity, salt levels, expected storage conditions (refrigeration), shelf life, additives/preservatives, labelling information and the pathogen control program (sanitary zones, hygienic practices, and monitoring procedures supporting the control of pathogens in these areas).
- A statement in writing signed by the person or that person's representative that attests that the process results in the production of safe fish products.

3.1.4 Inspection Requirements

The FIR provide for inspection of fish to determine compliance with Canadian requirements. The owner of the fish must make products available for inspection (FIR, Sections 4, 5).

For a Fish Import License Holder not participating in the QMPI Shared or Enhanced, imported product compliance is determined by the CFIA. CFIA monitors imports and conducts all relevant testing to determine compliance to Canadian requirements in the areas of wholesomeness, net quantity, labels, physical testing, and microbiological and chemical standards. All imported product are subject to inspection and products cannot be moved until the CFIA authorises product release.

The CFIA will inspect products imported by a Fish Import License Holder, not participating in QMPI, in accordance with the FIR (Sections 6.5(1), 6.5(2)(a,b), 6.5(3),

6.5(4)) and the Import Inspection Program policies and procedures (Chapter 3, Subject 1).

Companies with a Shared QMPI must inspect their own products for Standard Tests in accordance with FIR (Sections 6.5(1), 6.5(2)(a,b), 6.5(3), 6.5(4)), 6.1(4)(c)) and Import Inspection Program policies and procedures. CFIA will conduct all specialised testing requirements.

Companies with an Enhanced QMPI must inspect their own products for Standard Tests and Specialised Tests in accordance with FIR (Sections 6.5(1), 6.5(2)(a,b), 6.5(3), 6.5(4)), 6.1(4)(b)) and Import Inspection Program policies and procedures.

Additional details of QMPI Importer test requirements are found in Section 3.2.4 of this document.

The following is a description of the requirements for Standard and Specialised tests as found in Chapter 3, Subject 1 of this manual.

3.1.4.1 Standard Tests

Standard tests involve physical examination of the packages, labelling and the fish to determine compliance with Canadian requirements. Standard tests include the following:

3.1.4.1.1 Labelling

Physical examination of the label, packaging and code markings to evaluate compliance to Canadian requirements, including the Fish Inspection Regulations (ref. sections 6(2)a-c, 6(3), 25(1)a-e, 25(2)a-c, 25(3), 26(1)a-f, 26(2), 26(3), 27, 28, 29a-b and 31(1)(2), and 33), the Food and Drug Regulations, and the Consumer Packaging and Labelling Regulations. All products must not be labelled in a manner that is false, misleading or deceptive.

3.1.4.1.2 Net Content

Physical examination to evaluate compliance to all net content declarations (e.g., net and/or drained weight, including fluid measure where applicable).

3.1.4.1.3 Sensory

Sensory and physical examination, to evaluate compliance to minimum acceptable quality standards for taint (rancid or abnormal) and decomposition, to evaluate specific elements of "unwholesome" such as foreign matter, undesirable parts and parasites, and to evaluate conformity to all other content declarations such as style, count, composition, etc.

3.1.4.2 Specialised Tests

Imports of fish products are subject to specialized testing to determine compliance with Canadian requirements regarding bacteriological and/or chemical hazards and fraudulent practices. Table 3 of Appendix A in Chapter 3, Subject 1 of the manual identifies the bacteriological and/or chemical hazards associated with a product type. Specialized tests include the following:

3.1.4.2.1 Composition

To determine that non-permitted or non-declared ingredients or additives are not present, and that declared ingredients/additives do not exceed regulatory guidelines.

3.1.4.2.2 Chemical Contaminants

To determine that chemical contaminants do not exceed regulatory limits. This would include toxic elements, pesticides, industrial chemicals and drug residues.

3.1.4.2.3 Natural Toxins

To determine that natural toxins do not exceed regulatory limits. This would include histamine, paralytic shellfish poison, domoic acid and other biotoxins such as ciguatoxin, okadaic acid and tetramine.

3.1.4.2.4 Bacteria

To determine that indicator organisms do not exceed regulatory guidelines and that products are free from pathogenic organisms. This would include *E. coli, Listeria monocytogenes, Salmonella, and Staphylococcus aureus.*

3.1.4.2.5 Safety Parameters

To determine that foods that do not depend solely on heat sterilisation, freezing or refrigeration for safety and that are packed in containers that exclude air, meet pH and/or water activity and/or salt content requirements to ensure product safety.

3.1.4.2.6 Container Integrity for Low-acid Canned Fish Products

Visual inspection and/or other types of tests to determine compliance to Canadian standards for container integrity.

3.1.4.2.7 Other

To determine that appropriate testing is conducted to deal with special situations. This testing would fall under one of the above categories but would not likely be identified as a general hazard as defined for the product. Examples would involve situations in foreign countries where commercially harvested fish may be exposed to chemical or microbiological contamination.

3.1.5 Inspection Frequencies

The following outlines the minimum frequencies for final product testing. These frequencies may be reviewed and amended as necessary. Note that the CFIA always reserves the right to draw samples and conduct tests beyond minimum prescribed frequencies.

Shared or Enhanced QMPI Import Licence Holders must, at a minimum, meet these same inspection frequencies when conducting standard or specialised testing, in conjunction with a Supplier Assessment Program.

3.1.5.1 First Time Imports

All products new to the Canadian market or which have not been inspected in the last two years will be subject to standard testing and any specialised testing identified for that product type in Table 3 of Appendix A (as applicable) in Chapter 3, Subject 1 of this manual.

3.2.5.2 Random Product Verification

Fish products will be subjected to standard testing and any specialised testing identified for that product type

in Table 3 of Appendix A (as applicable), in accordance with the frequencies identified in Table 4 of Appendix A in Chapter 3, Subject 1 of this manual.

3.1.5.3 Import Alert List

100% of products on the Import Alert List (IAL) will be evaluated for the corresponding analysis on the IAL.

3.1.5.4 Product for Further Processing

Products destined for further processing in a federally registered facility will be treated as incoming raw material under the mandatory domestic QMP system. Imported products destined for further processing in a federally registered establishment will require CFIA inspection for prescribed tests when they are on the Import Alert List or require specialised tests.

3.1.6 Inspection Results/Product Action

Upon completion of all CFIA testing for a Fish Import License Holder and CFIA specialised testing for a Shared QMPI Licence Holder, results are forwarded to the importer, with options given when products are in non-compliance. Product cannot be moved or sold by these importers without a CFIA release.

Where products are found in non-compliance to regulatory requirements, the product is placed on the Import Alert List, and subsequent products are inspected until 4 consecutive lots are found acceptable, or in the case of labelling rejections, that the next lot is found acceptable.

Shared or Enhanced QMPI Import Licence Holders will forward all inspection results to the Canadian Food Inspection Agency on an semi-annual basis. A template will be provided to the QMPI importer when submitting these results. Where QMP Importers reject products for non-compliance to regulatory requirements which are not health and safety related, the CFIA must be notified within 5 working days of the product decision. CFIA will place information about rejected products on the Import Alert List, except importer-specific label rejections. When warranted, CFIA may also complete some additional testing.

Where health and safety problems are identified by an importer, the complaint or problem must be forwarded to

CFIA **immediately (within 24 hours)**. The importer will continue to investigate the complaint and implement any necessary corrective actions.

3.1.7 Regulatory Verification Program

All Fish Import License Holders and Shared or Enhanced QMPI Import Licence Holders, shall be evaluated for compliance to regulatory requirements through a combination of audit and inspection activities, as described in Chapter 3, Subject 4 of this manual.

3.1.8 Enforcement

When instances of non-compliance are found, all importers will be subject to enforcement actions as described in Chapter 2, Subject 5 of this manual.

3.2 ADDITIONAL REQUIREMENTS FOR QUALITY MANAGEMENT PROGRAM IMPORTERS ONLY - Shared or Enhanced

The QMPI, Shared or Enhanced, is a quality management program for importers choosing to take responsibility to determine product compliance. Shared Importers will determined product compliance for all **standard** testing requirements as described in their written QMPI submission, but will have product compliance for chemical and microbiological standards determined by CFIA. Enhanced importers will determine compliance to all **standard, chemical** and **microbiological** test requirements, as described in their QMPI written submission.

3.2.1 Quality Management Program Import License Requirements

In addition to those requirements listed in Section 3.1, an importer must fulfil the following requirements in order to be issued a Shared or Enhanced QMPI Import Licence:

3.2.1.1 QMPI Submission - FIR 6.1(1.1)(a)(b)(c), 6.1(3)(e), 6.1(4)(a)(d)(e)

The importer must develop a quality management system and provide details of that system through a QMPI submission to the CFIA. The complexity and level of information required will depend on the product type(s) to be monitored. Examples include canned, ready-to-eat, molluscan shellfish, and fresh/frozen or semi-preserved

products. It is recognised that the importer only has control over the final product that is presented. Several control points within the final product area must be addressed within the submission to ensure that products meet Canadian regulatory requirements.

The importer must be advised by CFIA that the QMPI has been reviewed and meets the requirements set out in this document before implementation (FIR 6.1(1.1)(c)).

Once accepted by the CFIA, the importer must implement and comply with their written QMPI (FIR, 6.1(4)(a)). The implementation of the program must be reviewed by the importer on at least an annual basis, through a verification of each control point (self-audit) and if necessary, corrective actions must be implemented immediately (FIR, 6.1(4)(e)). The CFIA must be notified of any changes to the QMPI (FIR, 6.1(4)(d)).

With the exception of corrective actions, changes to the written submission must be provided to the CFIA for review and acceptance before implementation (FIR 6.1(4)(d)).

The QMPI Submission Guide is is attached as Appendix A of this document.

3.2.1.1.1 QMPI Submission Definitions

Control Point (CP) - Control Point is an operation (practice, procedure, process, location) at which a preventative or control measure is exercised to achieve compliance or eliminate, prevent or minimise one or several hazards.

Critical Limits - Critical limits indicate whether a CP is under control. Critical limits can be specific regulatory requirements, administrative criteria (i.e., labelling, ingredients), product characteristics of a physical (i.e., time, temperature), chemical (i.e., acidity, salinity), or biological (i.e., microbiological) nature.

Monitoring - Monitoring procedures are established to ensure that critical limits are met and/or that processes operate under control. Monitoring may be accomplished by means such as analytical testing (i.e., micro, chemical), parameter measurement (i.e. time, temperature), information review (i.e., label, process information), or specific activities (i.e.,

notification, complaint investigation).
Corrective Action - Corrective Action may be a correction or modification that is taken with respect to product, procedures, etc., to exercise control on a product (rejection, detention of the product) or correct a non-conformance (re-label, collect information required) These actions are initiated when critical limits are not met or there is deviation from the QMPI program's policies and procedures. Investigation to identify the cause of the non-conformance provides a mechanism to take further corrective action to prevent repetition of this event. These corrective actions may lead to an amendment of the QMPI program.

Record Keeping - Records are maintained to record significant factors which confirm monitoring is being done effectively and that critical limits were met. Pertinent records are monitoring and verification/self-audit results, as well as corrective actions taken and follow-up activities. Descriptions of critical limits and monitoring procedures may also be included in record-keeping.

Verification (Self-Audit) - Verification (Self-Audit) is the use of supplemental tests or a review of each monitoring procedure and records to determine whether the monitoring element is being carried out effectively and efficiently. Self-audit is the review of the importer's entire program through a verification of each control point. This should be done on at least an annual basis and if necessary, any corrective actions should be implemented immediately.

3.2.1.1.2 Control Points

The following control points must be outlined within the QMPI submission :

1. **Licensing and Notification**
2. **Labelling, Ingredients and Packaging Materials**
3. **Process Controls (for canned and ready-to-eat products)**
4. **Storage**
5. **Final Product**
6. **Recall Procedures**
7. **Complaints**

For each of the above control points the importer submission must elaborate on the following points, as defined above, to identify the measures that will be

taken to ensure compliance with the appropriate regulations.

1. **Critical Limits/Regulatory Points**
2. **Monitoring System** (FIR, 6.1(3)(e)(iii)(iv))
3. **Corrective Action System** (FIR, 6.1(3)(e)(vi))
4. **Record Keeping** (FIR, 6.1(3)(e)(v))
5. **Verification System** (FIR, 6.1(4)(e))

Forms utilised by the plant to administer the QMPI program must also be included and updated in the submission when revisions are made.

3.2.2 Import Notification Requirements

QMPI Shared or Enhanced Import Licence Holders must meet all those requirements for import notification listed is Section 3.1.

3.2.3 Record-Keeping Requirements

Shared and Enhanced QMPI Importers must meet all record-keeping requirements listed in Section 3.1.

3.2.4 Testing Requirements

In addition to those compliance guidelines outlined in Section 3.1 for all importers, a QMPI importer must also meet the following standard and specialised testing requirements:

3.2.4.1 Standard Tests

Monitoring of final product compliance by qualified personnel is required for all lots, as described in Section 3.1 (FIR, 6.1(3)(e)(xii), 6.1(4)(b)(c)). The following provides further details on requirements for complying with the applicable regulations:

3.2.4.1.1 Labelling

Physical examination of the label, packaging and code markings to evaluate compliance to Canadian requirements, including the FIR (ref. sections 6(2)a-c, 6(3), 25(1)a-e, 25(2)a-c, 25(3), 26(1)a-f, 26(2), 26(3), 27,28,29a-b and 31(1)(2), and 33), the Food and Drug Regulations, and the Consumer Packaging and Labelling Regulations. All products must be labelled in a manner that is not false, misleading or deceptive. The program should identify the individual responsible for label

evaluation, the location of label files, and evaluation of ingredients and additives to ensure acceptability for use in Canada.

- The labels have been inspected and approved prior to importation;
- the labels on the product are checked to ensure they match the label approved for the product;
- the cartons and containers are inspected to ensure that they are properly coded;
- all inspections and monitoring actions are documented;
- any corrective action is documented; and
- a description of the verification or self-audit of label evaluations.

3.2.4.1.2 Net Content

Physical examination to evaluate conformity to all weight declarations (e.g., net and/or drained weight, including fluid measure where applicable).

- Appropriate procedures must be available in writing;
- documented procedures are adhered to;
- tests are conducted by trained individuals;
- samples selected at random for the audit must be in compliance;
- scales and equipment must be calibrated or certified;
- inspection records for tests completed must be on file; and
- corrective action taken must be documented.

3.2.4.1.3 Sensory

Sensory and physical examination to evaluate compliance to minimum acceptable quality standards for taint (rancid or abnormal) and decomposition, to evaluate specific elements of "unwholesome" such as foreign matter, undesirable parts and parasites, and to evaluate conformity to all other content declarations such as style, count, composition, etc.

- There are appropriate standards and procedures available in writing;
- the tests are carried out using the documented methodology;
- inspectors have adequate training;
- evaluations are carried out in adequate facilities;
- inspection records for tests completed are on file

and contain sufficient detail to identify the sample, the lot, and support the decision;
- appropriate sampling schedules are employed; and
- corrective actions taken are documented.

3.2.4.1.4 Container integrity for low-acid canned fish products

Visual inspection and/or other types of tests to determine compliance to Canadian standards for container integrity.

- Standards and methods are available in writing;
- testing is carried out by trained evaluator(s);
- inspection results are recorded in sufficient detail to support the decision; and
- corrective actions taken are documented.

3.2.4.1.5 Package Integrity

- Product is packed in new clean sound containers;
- inspections carried out are documented; and
- corrective actions taken are documented.

3.2.4.2 Specialised Tests (FIR Section 6.1(3)(e)(xii),6.1(4)(b))

Importers operating with an Enhanced QMPI must perform chemical and microbiological tests (specialised tests) according to the following criteria:

- testing must follow appropriate methods and procedures;
- tests appropriate to requirements specified in Chapter 3, Subject 1 must be conducted;
- samples must be obtained with an adequate sampling plan;
- tests must be carried out in a lab recognised by the President of the CFIA or accredited by Standards Council of Canada;
- inspection results must be documented with enough detail to support the inspection decision; and
- the records from approved labs must indicate pass or fail.

3.2.5 Inspection Frequencies

QMP Importers must determine that all imported products meet Canadian regulatory requirements, prior to marketing, through their company specific inspection system outlined in their approved submission (FIR, 6.1(3)(e)(vii to x)).

Appropriate documentation and inspection records must be maintained and accessible to the CFIA on request.

Shared or Enhanced QMPI Import Licence Holders must, at a minimum, meet the same inspection frequencies when conducting standard or specialised testing, in conjunction with a Supplier Assessment Program.

3.2.5.1 Supplier Assessment Program

QMPI Importers are required to conduct verification for standard analyses for all imported product at the critical control point "Final Product". This may be done through a combination of offshore testing by the processor and testing in Canada by the importer. Offshore testing is verified through the Supplier Assessment Program, outlined in the importer's QMPI submission. The Supplier Assessment Program is a verification of offshore testing, which may consist of offshore test results or agreements to perform standard tests offshore.

A Supplier Assessment Program may consist of one or more of the components listed below:

a) listing of the supplier under a country-to-country MOU or MRA;

b) information concerning a HACCP- or QMP-like processing regime implemented by the supplier;

c) information regarding product testing conducted by the supplier, and typical analytical results generated from such testing;

d) on-site assessments of the supplier by the QMPI importer;

e) product testing conducted by the QMPI importer offshore or in Canada, exceeding the product testing regime listed in Section 3.1;

f) other steps, as appropriate.

Where there is no Supplier Assessment Program available for a processor, all imported product from that processor will be inspected for compliance to standard tests.

Product listed on the Import Alert List must be

inspected by the QMPI as per current procedures. When import alert products have been inspected and four consecutive acceptable results obtained by the QMPI, the importer can provide in writing, with accompanying supporting documentation, a recommendation to the CFIA to remove that product from the Import Alert List.

3.2.6 Inspection Results/ Product Action

3.2.6.1 Release of Product

Upon completion of CFIA specialised testing for a Shared QMPI Import License Holder, results are forwarded to the importer, with options given when products are in non-compliance. Product undergoing specialised testing cannot be moved or sold by Shared importers without a CFIA release. Product which is not subject to CFIA specialised testing can be released by a Shared importer upon the importer's determination of compliance to all standard test requirements.

Enhanced importers may release product when the importer has determined that the product meets all standard and specialised testing requirements.

3.2.6.2 Submission of Inspection Results

Shared or Enhanced QMPI Import Licence Holders will forward all inspection results to the Canadian Food Inspection Agency on an semi-annual basis. A template will be provided to the QMPI importer when submitting these results.

3.2.6.3 Product Rejection

Where health and safety problems are identified by an importer, the complaint or problem must be forwarded to the CFIA **immediately (within 24 hours).** The importer will continue to investigate the complaint and implement any necessary corrective actions.

Where QMP Importers reject products for non-compliance to regulatory requirements which are not health and safety related, the CFIA must be notified within 5 working days of the product decision. The CFIA will place all product rejected on the Import Alert List, except importer-specific label rejections. When warranted, the CFIA may also complete some additional testing.

Where products are found in non-compliance to regulatory requirements, the product is placed on the Import Alert List, and subsequent products are inspected until 4 consecutive lots are found acceptable, or in the case of labelling rejections, that the next lot is found acceptable.

3.2.6.4 CFIA Testing

The CFIA may conduct product testing as part of the Shared QMPI specialised test requirements, the audit process or through special investigations.

3.2.7 Regulatory Verification Program

All Quality Management Program importers, shall be evaluated for compliance to regulatory requirements through a combination of audit and inspection activities, as described in Chapter 3, Subject 4 of this manual.

3.2.7.1 National Background Program

Under the Quality Management Program for Importers (QMPI), industry will be conducting product compliance and establishing a system to ensure the importation of safe and wholesome fish and fish products, and will be responsible for conducting self-verification of these activities. To help measure the effectiveness of industry QMPI application and delivery, the Fish, Seafood and Production Division of the CFIA plans to establish a National Fish Inspection Background Program, as one component of regulatory verification.

The objectives of the Background Program include determination of the effectiveness of QMPI, identification of strengths, weaknesses and need for policy or program change, and the collection of testing and compliance data.

The Background Program may encompass any sector of the fish industry where food safety or quality can be compromised. This includes harvesters, fish farms, processors, importers, storage and distribution facilities, food service and retail levels. National surveys and evaluations will be planned to determine product compliance within these sectors of industry.

3.2.8 Enforcement

When instances of non-compliance are found, all QMPI importers will be subject to enforcement actions as described in Chapter 2, Subject 5, of this manual.

APPENDIX A

QMPI SUBMISSION GUIDE

This guide may be used to assist importers in developing a QMPI submission.

Control Points: The following seven control points will be monitored by the importer to ensure compliance with Canadian regulatory requirements:

A. Licensing And Notification

B. Labelling, Ingredients, Packaging Materials

C. Process Controls For Canned And Ready-To-Eat Products

D. Cold Storage

E. Final Products

F. Recall System

G. Complaints

Key Elements - At each of the seven control points the importer's QMPI program is required to contain these key procedural elements:

1. **Critical Limits**: are the limits which indicate whether the control point is under control. They can be specific regulatory requirements or established criteria of physical (time, temperature...), chemical (salt quantity, acidity...), or biological (e.g., microbiological) parameters.

2. **Monitoring Procedures:** check that critical limits are met and the processes operate under control. This is accomplished by, as an example, product testing, measuring time, temperature, pH, water activity, container/package condition, or obtaining records demonstrating adherence to requirements.

3. **Corrective Action:** must be initiated when critical limits are not met or there is deviation from QMPI program's policies and procedures. Records must be maintained with respect to corrective action taken and follow-up activity.

4. **Record Keeping**: records should be maintained to record significant factors which confirm monitoring is done effectively and that critical limits were met, and that corrective actions were taken.

5. **Verification**: is the use of supplemental tests or a review of each monitoring procedure and records to determine whether the monitoring element is being carried out effectively and efficiently.

Responsible Contacts - The importer's submission must identify an individual and/or specific position that will be responsible for the overall QMPI program. The importer's submission must also identify any other individuals and/or specific positions that will take an active roll in the application of the QMPI.

System Review or Self-Audit: The importer’s QMPI program must be periodically evaluated to ensure the QMPI program consistently meets:

a) the importer’s requirements as set out in their QMPI Submission; and

b) CFIA requirements.

Maintaining an Up-to-Date QMPI - The documented QMPI program must be amended and updated when there are any changes made to procedures or documents.

Record-Keeping System - The QMPI Submission must utilise a record-keeping system that maintains the essential information identified in this guide in a manner that will enable cross reference to the imported product and imported shipments (see below).

IMPORTER'S MANAGEMENT ORGANIZATION

The company must identify in their submission the organisation of the company's management to illustrate how the Quality Management Program for Importers fits into their import activities and how the QMPI principles, directives, and strategies are exercised in the day-to-day operation of the company. The company may use a generic organisation chart to illustrate the QMPI organisation.

The following information is required in your submission:

- Company Name
- Mailing Address
- Location of QMPI Documents, including the street address
- Import License Number
- Type of QMPI (i.e., Shared or Enhanced)
- Principle Contact
- Telephone Number
- Fax Number
- A description of the types of fish that will be imported by your company
- Date of submission
- Signature of responsible manager

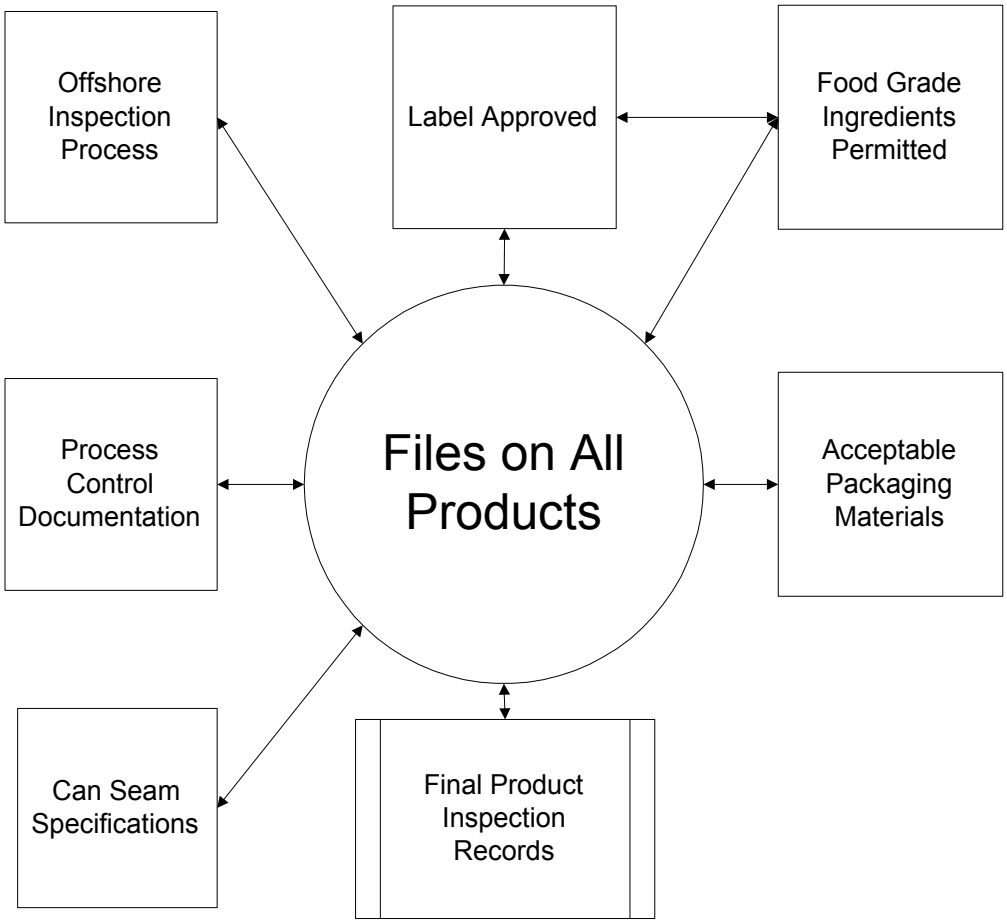


Fig. 1: Records from Processes Associated with QMPI Products

A. LICENSING AND NOTIFICATION

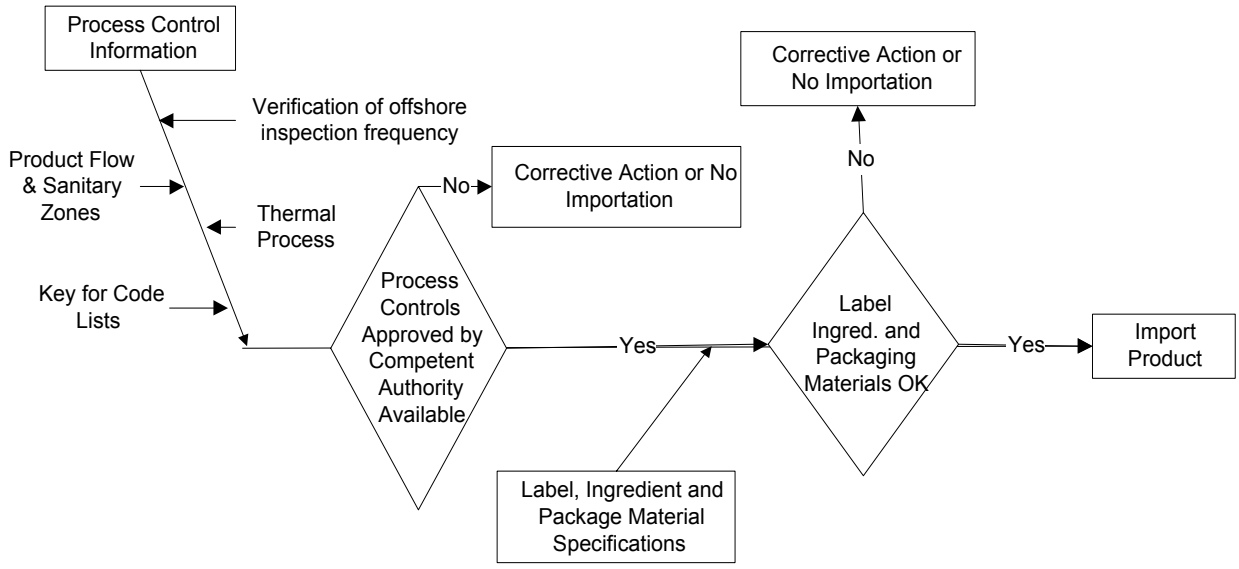


Fig 2: Steps Required Prior to Importation

1. Critical Limits

All products

Only companies holding a valid licence may import fish & fish products. All importers must ensure that notification is provided to the CFIA within 48 hours of importation. Import notification must include a description of the lot, the quantities, the codes, the processor, the country of origin and the shipment location.

In the case of canned and ready-to-eat fish, the lot must be accompanied by a list of codes which identifies the name of the processing establishment and the date(s) of processing.

Canned fish

Documentation must precede or accompany the first shipment from each processor for each type of canned fish and a copy maintained on the importer's file. This documentation must show an adequate thermal process approved by a recognised thermal process authority and process controls to ensure adequate delivery of that process to the product. The documentation must also demonstrate adherence to seam

specifications and container integrity requirements.

Raw Molluscan Bivalve Shellfish

Raw molluscan bivalves and products must originate from plants listed on the Interstate Shellfish Shippers List (ICSSL) or other approved lists. These plants must be located in countries which have signed agreements with Canada concerning the inspection of molluscan shellfish.

Ready-to-eat Fish

Appropriate process documentation must precede or accompany the first shipment from each processor of each type of ready-to-eat product and a copy maintained on the importer's file.

These records must demonstrate the adequacy of the methods and processes employed and their correct application to eliminate, reduce and/or control pathogenic bacteria in order to ensure product safety, such as:

- product formulation parameters such as pH, water activity, salt concentration, and additives in conjunction with storage conditions;
- processes such as heat treatment;
- process flow plus identified critical control points and monitoring procedures;
- pathogen control through the establishment/maintenance of a sanitary zone, environmental monitoring and the reinforcement of sanitation and hygienic practices.

2. Monitoring Procedures

(Describe the procedure that will take place including: the location where it will occur, the standards and methodology which will be applied, who will be performing the procedure, and how the results will be recorded.)

The importer must provide the title and name (if available) of the person who will ensure that:

- the importer holds a valid import licence;
- proper notification is provided within 48 hours of each shipment's arrival in Canada;
- processing records are available as required;
- a list of codes is available for all shipments of canned fish and is provided to the CFIA; and
- raw molluscan shellfish originates from approved sources.

3. Corrective Action

In cases where non-compliance is noted, corrective action must be initiated. The importer must identify the title and/or name of the individual responsible for ensuring the corrective action was carried out and provide examples of report forms to record corrective actions taken.

4. Record Keeping

Notification Form

The importer must provide an example of the notification form that will provide all mandatory information including:

- licence number
- the date of importation
- product(s) description by lot definition
- processor or producer
- code list and key (canned product)
- interpretation of code markings for all products
- shellfish shipper's number, harvesting date and location for raw molluscan shellfish
- number of cartons, number of units per carton, and weight of individual units
- country of origin
- location of each product

Corrective Action Form

The importer must provide an example of the form for recording corrective action that will include the following information:

- description of the deficiency
- identification of the lot
- date deficiency was identified
- description of the corrective action
- final outcome
- signature of the individual responsible

5. Verification System

The importer must identify a system and the title and/or name of the individual responsible to verify that the procedures for this control point are functioning. This system should describe what type of verification will take place, at what location and frequencies, and how it will be recorded.

The importer should provide examples of forms used for monitoring. The form must include the following information:

- date of verification
- identification of the lot(s)
- results of verification
- name, title and signature of individual responsible for verification
- a description of the corrective action for this control point

B. LABELLING/INGREDIENTS/PACKAGING MATERIALS

B.1 LABELLING

1. Critical Limits

All labels used on imported fish and fish products must meet all applicable Canadian requirements, including the Fish Inspection Regulations, the Food and Drug Regulations and the Consumer Packaging and Labelling Regulations. All products must be labelled in a manner that is not false, misleading or deceptive.

2. Monitoring Procedures

(Describe the procedure that will take place including: the location where it will occur, the standards and methodology which will be applied, who will be performing the procedure, and how the results will be recorded.)

The importer must provide the title and/or name (if available) of the person who will ensure that labels are in compliance with Canadian regulations. The importer must provide details of the procedures that will be followed to ensure all labels are in compliance with Canadian regulations. The procedure must show that labels and evaluation reports will be kept on file and will be available for CFIA review.

3. Corrective Action

In cases where non-compliance is noted, corrective action must be initiated. The importer must identify the title and/or name of the individual responsible for ensuring it is carried out.

4. Record Keeping

Label Evaluation Form

The forms used to record the inspections of labels must include the following information:

- the date of inspection
- requirements for all Canadian regulations evaluated
- identification of the label
- results of the inspection

- the signature of the individual responsible for the inspection

Corrective Action Form

The importer must provide examples of report forms to record corrective action that includes the following information:

- description of the deficiency
- identification of the label
- date deficiency was identified
- description of the corrective action
- final outcome
- signature of the individual responsible

5. Verification System

(see "Verification System for Labelling, Ingredients and Packaging" in Section B.3)

B.2 INGREDIENTS AND ADDITIVES

1. Critical Limits

Ingredients and additives must meet the requirements of the Food and Drug Regulations. Ingredients and additives must be permitted for use in the product, must not exceed the levels permitted for the product, and must be acceptable for use in food sold in Canada.

2. Monitoring Procedures

(Describe the procedure that will take place including: the location where it will occur, the standards and methodology which will be applied, who will be performing the procedure, and how the results will be recorded.)

The importer must provide details of the procedures which will be followed to ensure all ingredients and additives are in compliance with the applicable sections of the Canadian Food and Drug regulations. These procedures should demonstrate that the product's formulation only contains permitted ingredients and additives at levels allowed in Canada. The importer must provide the title and name (if available) of the person who will ensure that all ingredients and additives are in compliance with Canadian regulations.

3. Corrective Action

In cases where non-compliance is noted corrective action must be taken. The importer must identify the title and/or name of the person responsible for informing the processor of the appropriate use of additives and ingredients for the specified product and ensuring appropriate corrective actions are taken.

4. Record Keeping

Ingredients and Additives Evaluation Form

Examples of the forms used to record that ingredients and additives are in compliance must be provided and must include the following information:

- the date of inspection
- identification of the processor and product
- identification of the ingredients and additives used

- compliance with all Canadian regulations
- results of the inspection, including all relevant correspondence with the processor
- the signature of the individual responsible for the inspection

Corrective Action Form

The importer must provide examples of report forms to record corrective action that includes the following information:

- description of the deficiency
- identification of the processor and product
- date deficiency was identified
- description of the corrective action
- final outcome, including relevant correspondence with the processor
- signature of the individual responsible

5. Verification System

(see "Verification System for Labelling, Ingredients and Packaging" in section B.3)

B.3 PACKAGING MATERIALS

1. Critical Limits

All packaging materials utilised for fish and fish products must meet the requirements of the Fish Inspection Regulations, (new, clean and sound), all other applicable Canadian regulatory requirements and must be for food packaging.

2. Monitoring Procedures

(Describe the procedure that will take place including: the location where it will occur, the standards and methodology which will be applied, who will be performing the procedure, and how the results will be recorded.)

The importer must provide details of the procedures which will be followed to ensure that all the packaging material in direct contact with the product, or that has potential to directly or indirectly cause contamination of the product, meets the requirements of the Fish Inspection Regulations and the Food and Drugs Act and Regulations, is appropriate for the product type and is acceptable for packaging of food in Canada. The importer should indicate that these procedures will take place prior to importation of the product. The importer must provide the title and/or name of the person who will ensure that all packaging materials are in compliance with Canadian regulations.

3. Corrective Action

In cases where non-compliance is noted, corrective action must be initiated. The importer must identify the title and/or name of the person responsible for informing the processor of the appropriate packaging materials allowed for the specified product.

4. Record Keeping

Packaging Material Evaluation Form

The importer must provide examples of the forms used to evaluate the packaging material and record the results. The form used to record the inspections must include the following basic information:

- the date of inspection
- identification of the processor and product
- type of packaging materials
- the results of the inspection, including relevant correspondence with the processor
- the signature of the individual responsible for the inspection

Corrective Action Form

The importer must provide examples of report forms to record corrective action that includes the following information:

- description of the deficiency
- identification of the processor and product
- date deficiency was identified
- description of the corrective action
- final outcome, including relevant correspondence with the processor
- signature of the individual responsible

5. Verification System for Labelling, Ingredients and Packaging

The importer must identify a system and title and/or name of the individual responsible to verify that the procedures for this control point are functioning. This system should describe what type of verification will take place, at what location and frequencies, and how it will be recorded.

The importer should provide examples of forms used for verification. The form must include the following information:

- date of verification
- identification of the processor(s) and product(s)
- results of verification
- name, title and signature of individual responsible for verification
- a description of the corrective action for this control point

C. PROCESS CONTROLS FOR CANNED AND READY-TO-EAT PRODUCTS

(See Compliance Guide, Section 3.1.3.3 - requirements for the Basic Importer)

1. Critical Limits

This critical control point applies only to canned and ready-to-eat products.

Canned fish and ready-to-eat fish must be adequately processed to ensure product safety and must meet all Canadian regulations. Canned products must also meet all Canadian requirements for container integrity and container closure specifications.

The importer must obtain this information for the first importation from each packer of each product type and keep this information on file. Upon request, the importer must be able to access this information for all shipments within a reasonable amount of time.

2. Monitoring Procedures

(Describe the procedure that will take place including: the location where it will occur, the standards and methodology which will be applied, who will be performing the procedure, and how the results will be recorded.)

The importer must indicate that all canned fish and ready-to-eat products are manufactured following good manufacturing practices. Imports must have monitoring procedures in place that check that critical limits for process control are met. Monitoring results must be recorded.

For canned fish, this will be achieved by records which demonstrate an adequate thermal process approved by a recognised thermal process authority and process controls to ensure adequate delivery of that thermal process to the product. The documents must also demonstrate adherence to seam specifications and container integrity requirements.

For ready-to-eat fish, this will be achieved by records which demonstrate the adequacy of the methods and processes employed and their correct application to eliminate, reduce and/or control pathogenic bacteria in order to ensure product safety, such as:

- product formulation parameters such as pH, water activity, salt concentration, and additives in conjunction with storage conditions;
- processes such as heat treatment;
- process flow plus identified critical control points and monitoring procedures used;
- pathogen control through the establishment/maintenance of a sanitary zone, environmental monitoring and the reinforcement of sanitation and hygienic practices.

The importer must provide the title and name (if available) of the person who will review this information showing that these products are processed in compliance with Canadian regulations.

The monitoring procedures must describe how the importer will ensure that the processor is operating under the conditions outlined in the documentation for process control. These procedures must also describe how the importer will ensure that all products imported from the processor were processed under the conditions outlined in the documentation for process control.

The importer must indicate in their procedures that this documentation will be obtained prior to, or be available with the first importation of each type of fish from each packer. For subsequent shipments of the same product such documentation must be available to the importer upon request. The importer must be kept aware of any changes to this information and must update their QMPI as needed.

3. Corrective Action

Corrective action must be initiated when critical limits are not met or there is deviation from the QMPI policies and procedures. Records must be maintained and made available to the CFIA with respect to corrective action taken and follow-up activity.

. The importer must identify the title and/or name of the person responsible for informing the processor of the Canadian requirements for the specified product and ensuring appropriate measures are taken.

4. Record Keeping

Process Controls Form

Records of monitoring results must be maintained and available to the CFIA upon request.

The importer must provide examples of the forms used to evaluate the process controls and record the results. The form used to record the inspections must include the following basic information:

- the date of inspection
- identification of the processor and product
- the results of the inspection, including relevant correspondence with the processor
- the signature of the individual responsible for the inspection

Corrective Action Form

Records of corrective action and follow-up activity must be maintained and made available to the CFIA upon request. The importer must provide examples of report forms to record corrective action that includes the following information:

- description of the deficiency
- identification of the processor and product
- date deficiency was identified
- description of the corrective action
- final outcome, including relevant correspondence with the processor
- signature of the individual responsible

5. Verification System

The importer must identify a system and the title and/or name of the individual responsible to verify that the procedures for this control point are functioning. This system should describe what type of verification will take place, at what location and frequencies, and how it will be recorded.

Results of the verification system must be recorded and made available to the CFIA upon request.

The importer should provide examples of forms used for verification. The form must include the following information:

- date of verification
- identification of the processor(s) and product(s)
- results of verification
- name, title and signature of individual responsible for verification
- a description of the corrective action for this control point

D. COLD STORAGE

1. Critical Limits

All fish must be stored in a manner to protect it from contamination and deterioration. All frozen fish must be stored at -18 °C.

2. Monitoring Procedures

(Describe the procedure that will take place including: the location where it will occur, the standards and methodology which will be applied, who will be performing the procedure, and how the results will be recorded.)

The importer must provide the title and name (if available) of the person who will ensure that cold storage facilities meet these requirements. The importer must show what procedures will be followed to ensure fish is properly stored.

3. Corrective Action

In cases where non-compliance is noted, corrective action must be taken. The importer must identify the title and/or name of the individual responsible for ensuring corrective action is carried out.

4. Record Keeping

Cold Storage Form

The importer must provide an example of the form that will be used for recording the following information:

- storage temperatures and date
- warehouse location
- signature of person responsible

Corrective Action Form

The importer must provide examples of report forms to describe the corrective action that includes the following information:

- description of the deficiency
- warehouse location
- identification of the lot(s)

- date deficiency was identified
- description of the corrective action
- final outcome
- signature of the individual responsible

5. Verification System

The importer must identify a system and the title and/or name of the individual responsible to verify that the procedures for this control point are functioning. This system should describe what type of verification will take place, at what location and frequencies, and how it will be recorded.

The importer should provide examples of forms used for monitoring. The form must include the following information:

- date of verification
- location of warehouse
- results of verification
- name, title and signature of individual responsible for verification
- a description of the corrective action for this control point

E. FINAL PRODUCT

1. Critical Limits

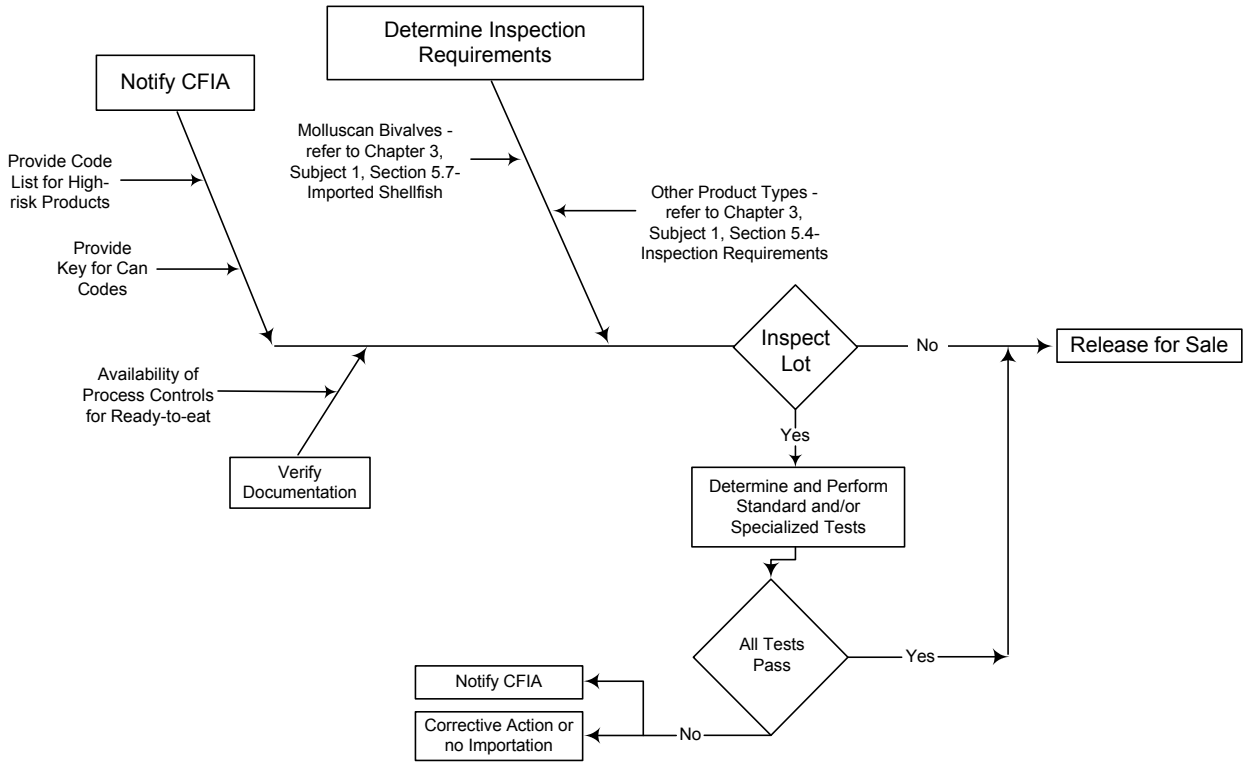


Fig. 3 - Actions and Decisions Required upon Importation

No imported products shall be tainted, decomposed or unwholesome or otherwise fail to meet the requirements as set out in the Fish Inspection Regulations, Food and Drug Regulations and Consumer Packaging & Labelling Regulations. The following are some of the additional relevant requirements of these regulations.

All live oysters, clams, mussels or other bivalve molluscs or raw products derived therefrom (except scallop meats), whether frozen or unfrozen, must be taken from approved waters.

Importation of puffer fish of the family *Tetraodontidae* and live freshwater mitten crab of the genus *Eriocheir* is prohibited.

The master containers and packages for all products must be appropriately coded.

All canned products must be properly sealed, must not have the tops or bottoms distorted outward and must not be otherwise defective.

All containers of canned fish must be permanently marked with a code that identifies the name of the establishment and the day, month and year of processing.

Fish must not be labelled in a manner that is false, misleading or deceptive.

2. Monitoring Procedures

(Describe the procedure that will take place including: the location where it will occur, the standards and methodology which will be applied, who will be performing the procedure, and how the results will be recorded.)

The importer must provide the title and/or name of the person who will ensure that all imported fish meet these requirements. The importer must show what procedures will be followed to ensure fish is properly evaluated.

The procedures must show that 100% of the product will be verified to meet the requirements for standard analyses and, where applicable, that specialised tests will be conducted at the prescribed frequencies. In cases where verification is conducted by offshore facilities, the importer must show that compliance to standard tests will be evaluated in Canada at the minimum required frequencies and that all prescribed specialised tests will be conducted in Canada.

The importer will utilise standards and methodology which are equivalent to those used by the CFIA, as well as an equivalent sampling plan, in evaluating imported fish products for the appropriate criteria. These tests will be conducted by qualified personnel.

Third party laboratory testing will be conducted by qualified personnel in appropriate facilities. The importer must identify the laboratories performing these tests and the standards, methods and sampling plans that they will use.

SHARED QMPI

The Shared QMPI will show the procedure which will be followed to evaluate imported fish products to determine compliance for all the following areas:

- labelling requirements, including evaluation of permitted ingredients/additives
- net weight tolerance and label declarations
- descriptive label declarations, i.e., size, count, packing style, etc.
- minimum acceptable quality utilising sensory evaluation as per CFIA final product standards
- regulatory requirements for container integrity of canned fish
- product coding requirements
- packaging
- process requirements for canned fish products and ready-to-eat products

ENHANCED QMPI

The Enhanced QMPI will evaluate compliance for all areas as indicated above, and conduct laboratory monitoring inspections in Canada utilising CFIA inspection frequencies and equivalent methodology and sampling plans to determine compliance to chemical and microbiological standards.

3. Corrective Action

In cases where non-compliance is noted corrective action must be initiated. The importer must identify the title and/or name of the individual responsible for ensuring corrective action is carried out.

The corrective action procedures must identify the name and/or title of the individual who will notify the CFIA of the importation of products not meeting Canadian regulatory requirements.

The corrective action procedures must identify the name and/or title of the individual responsible for ensuring that non-compliant product is culled, reworked, destroyed or removed from the country.

4. Record Keeping

Final Product Evaluation Form

A copy of the form used to record the inspection of incoming fish must be included and must provide the following information:

- the date the fish was imported and inspected

- lot identity
- lot size
- the species and product description
- sample size
- analyses and verification performed and results
- the overall results of the inspection
- the name, title and signature of the individual responsible for inspection

Corrective Action Form

The importer must provide examples of report forms to describe the corrective action that includes the following information:

- description of the deficiency
- identification of the lot(s)
- date deficiency was identified
- description of the corrective action
- notification of deficiency (except labelling) to the CFIA within the appropriate time frame
- final outcome including disposition of the product
- documents showing that all defective product was destroyed, re-exported or adequately re-conditioned to meet Canadian requirements
- title, name and signature of the individual responsible

5. Verification System

The importer must identify a verification system and the title and/or name of the individual responsible to verify that the procedures for this control point are functioning. This system should describe what type of verification will take place, at what location and frequencies, and how it will be recorded.

The importer should provide examples of forms used for verification. The form must include the following information:

- date of verification
- name and location of facilities where analyses were performed
- type(s) of analyses performed at the facilities
- results of verification
- name, title and signature of individual responsible for verification
- a description of the corrective action for this control point

F. RECALL PROCEDURES

1. Critical Limits

The importer must record the name and address of the person to whom the fish was sold, and the date when the fish was shipped from the importer. The importer must also maintain records to document appropriate disposition of product which is found to be in non-compliance to Canadian requirements.

The importer must be able to provide these records within 4 hours of request.

2. Monitoring Procedures

(Describe the procedure that will take place including: the location where it will occur, the standards and methodology which will be applied, who will be performing the procedure, and how the results will be recorded.)

The importer must provide the title and/or name of the person who will ensure that recall records are being maintained and the person who will be responsible for initiating the recall procedures when non-compliant product is found on the market. The importer must show what procedures will be followed to identify the first point of sale of all imported product and what procedures will be used to remove non-compliant product from the market.

3. Corrective Action

In cases where non-compliance is noted, corrective action must be initiated. The importer must identify the name and/or title of the person responsible for ensuring the corrective action is performed.

4. Record Keeping

Recall Form

The importer must provide an example of the form that will be used for recording the first point of sale. This form should include the following information:

- date of sale and shipping
- product, quantities, production codes

- name and address of consignee
- signature of person responsible

Corrective Action Form

The importer must identify the individual responsible for ensuring that appropriate corrective action is carried out. The importer must provide examples of report forms to describe the corrective action that includes the following information:

- identification of the lot(s)
- description of the deficiency
- date deficiency was identified
- description of the corrective action
- final outcome
- signature of the individual responsible

5. Verification System

The importer must identify a system and individual responsible to verify that the procedures for this control point are functioning. This system should describe what type of verification will take place, at what location and frequencies, and how it will be recorded.

The importer should provide examples of forms used for verification. The form must include the following information:

- date of verification
- identification of lot(s)
- results of verification
- name, title and signature of individual responsible for verification
- a description of the corrective action for this control point.

G. COMPLAINTS

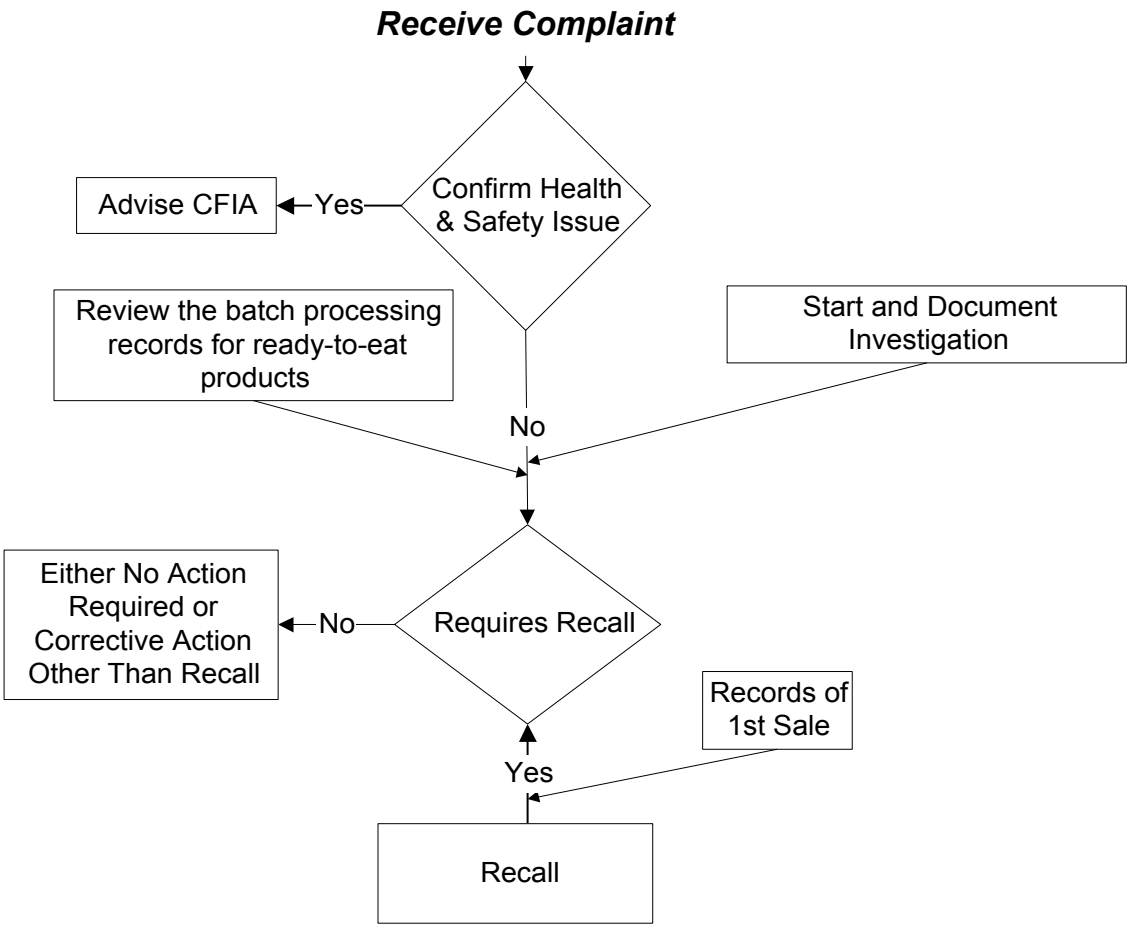


Fig. 4: Actions and Decisions Involved with a complaint

1. Critical Limits

The importer must keep a record of all complaints received relating to regulatory requirements. Examples include, but are not limited to, net contents, quality, composition, labelling, misrepresentation and/or safety of the product. The importer must record all evaluations conducted and actions taken as a result of valid complaints. The importer must ensure that appropriate notification is provided to the CFIA regarding the investigation of legitimate complaints. The CFIA must be immediately advised of all health and safety related complaints.

2. Monitoring Procedures

(Describe the procedure that will take place including: the location where it will occur, the standards and methodology which will be applied, who will be performing the procedure, and how the results will be recorded.)

The importer must provide the title and/or name of the person who will ensure that complaints are recorded and investigated. The importer must show what procedures will be followed to investigate all complaints, and advise the CFIA of legitimate complaints.

The importer must indicate that the CFIA will be advised immediately of all health and safety related complaints.

3. Corrective Action

In cases where non-compliance is noted, corrective action must be initiated. The corrective action must involve a review of the appropriate control point where the deficiency occurred. The importer must identify the individual responsible for ensuring that appropriate corrective action is carried out and that amendments to the QMPI are made as required.

4. Record Keeping

Complaint Evaluation Form

The importer must provide an example of the form that will be used for recording consumer complaint investigations. The form should include the following information.

- complainant
- nature of complaint
- product and processor
- date of complaint
- investigation results
- signature of person responsible for investigating the complaint
- final outcome

If the investigation shows that the complaint was legitimate the importer should record:

- date the CFIA advised (must be immediately for health and safety concerns)
- date of original shipment

- total volume imported
- total volume distributed
- consignee(s)
- original inspection results
- product actions taken
- actions taken to resolve the complaint
- final resolution

Corrective Action Form

The importer must provide examples of report forms used to describe the corrective action that includes the following information:

- description of the deficiency
- identification of the lot(s)
- date deficiency was identified
- description of the corrective action taken on the appropriate control point
- final outcome
- signature of the individual responsible

5. Verification System

The importer must identify a system and individual responsible to verify that the procedures for this control point are functioning. This system should describe what type of verification will take place, at what location and frequencies, and how it will be recorded.

The importer should provide examples of forms used for verification. The form must include the following information:

- date of verification
- consumer complaints involved
- results of verification
- name, title and signature of individual responsible for verification
- a description of the corrective action for this control point.

CHAPTER 3, SUBJECT 3

COST RECOVERY FOR IMPORT INSPECTIONS

1. SCOPE

This document outlines the regulations, policy and procedures governing the cost-recovery program for import inspection of fish and fish products.

2. AUTHORITIES

Fish Inspection Act, R.S.C. 1985, c. F-12.

Fish Inspection Regulations (FIR), C.R.C., 1978, c.802; Part I, General.

3. POLICY

3.1 The provisions of the cost-recovery program for imported fish and fish products apply only to fish and fish products intended for human consumption. Imports that are declared as bait, pet food or that are intended for personal consumption are excluded from the provisions of this policy.

3.2 Import Licence

3.2.1 The importer of record must be the holder of a valid import licence issued by CFIA. The licence is valid for 12 months after the date of issue. The licence will not be renewed if the importer has outstanding fees payable to the CFIA.

The licence will be suspended if the importer has fees outstanding for a period greater than 90 days (see Outstanding Invoices, section 4.9).

3.2.2 A business operating under several company names must have an import licence for each company name, if each company acts as an importer. A broker may obtain a licence if that person/organisation wishes to be the "importer of record" of the goods from a foreign company and accepts all responsibilities and rights associated with the licence.

3.2.3 A company will require only one licence regardless of the number of ports through which product is imported. Companies should be advised that they are to provide their

branch offices with a copy of the licence if imports are to be made through more than one port of entry.

3.2.4 An offshore company may obtain a licence as a non-resident importer in Canada and will have all the responsibilities and rights associated with the licence, including the requirement to keep records for recall, complaints and process controls at an address in Canada.

3.3 Inspection service fee

3.3.1 Importers must provide written notification to the CFIA of all shipments of imported fish and fish products intended for sale for human consumption.

3.3.2 An inspection service fee is to be levied for all imported shipments based on: the declared weight as provided in the import notification form; the category of product; the risks; and the type of licence. The net weight/content is to be the same as declared to Canada Border Services Agency.

3.3.3 An inspection service fee will normally be levied for cancelled shipments when the information concerning this shipment has been entered in CFIA's import database.

3.4 Inspection/Analysis fees

3.4.1 If the inspector decides to divide up the lot, the inspection service fee charged will be the same as if the inspection was done on the undivided lot.

3.4.2 Analyses performed as a result of an importer request or a request for reinspection will be charged in accordance with the fees for requested analysis as found in section 6.5(5) of the FIR or for reinspection in accordance with the fees as found in section 10.1 of the FIR.

3.5 Relabelling

If a product fails for net content or label evaluation and the importer re-labels with the required corrections, only the required inspection service fees are to be charged. Where on-site evaluation is not required, no charges are to be levied. However, the product will be placed or remain on the IAL as an unacceptable shipment. If the importer challenges the rejection and requests a reinspection, then the required reinspection fee is to be charged. If the product fails reinspection, the importer may re-label but no additional label evaluation fee is to be charged.

3.6 Appeal process

When a QMPI licence holder requests a review of the assigned QMPI rating and the regional director initiates such a review, fees will be charged in accordance with section 6(3) of the FIR.

4. PROCEDURES

4.1 Import Licence

4.1.1 Applicants will be issued a licence to import fish products upon receipt at the regional office of a completed "Application for a Licence to Import Fish" and the C$ 500 fee payable by cheque or money order to the Receiver General for Canada. All sections other than "for Departmental use only" must be completed by the applicant. It is important that the legal company name be given. Currently, the customs number is optional. The "For Departmental use only" section is to be completed by the issuing office. The coding is to be completed using the regional collator and cost code.

A shared or enhanced QMPI licence will be issued to importers when their written submission has been accepted and they have submitted the C$ 5,000 fee payable by cheque or money order to the Receiver General for Canada. The shared or enhanced licence fee includes the Fish Importer's Licence fee.

The inspector will update the importer's status in the CFIA's import database from "Fish import licence holders" to either Shared or Enhanced as indicated in their written submission. The effective date will be the date when the submission is accepted and the fee received.

4.1.2 The "Import Licence" will be issued yearly following receipt of the application and fee. The expiration date will be 12 months after the date of issue. NHQ will send importers a licence renewal reminder at least one month before the expiration date for their licence. Regional offices will continue to issue the new licences.

A block of licence numbers have been assigned to each area as follows:

Area	
Atlantic	X0,000 to X0,999
Quebec	X1,000 to X2,999
Ontario	X3,000 to X5,999
Western	X6,000 to X7,999

Where, in the corresponding year, X is:

1998 - 5
1999 - 6
2000 - 7
2001 - 8
2002 - 9
2003 - 1

4.1.3 When an importer renews the import licence in the same area where it was previously issued, the new licence number should be the same as the previous year's licence with only the first digit of the number being changed. However, if the importer sends the licence renewal form to a different area, then the new licence number which is issued should reflect the numbers which have been assigned for that region.

4.1.4 An up-to-date list of importers is available from the national import database.

4.2 Inspection service fee

Charges are to be levied for all imported shipments in accordance with the following table:

	FISH IMPORT LICENCE HOLDERS	**SHARED**	**ENHANCED**	**FURTHER PROCESSING** All Products All Importers*
Type of product	$/kg	$/kg	$/kg	$30/ shipment
READY-TO-EAT	0.15	0.05	0.002	
CANNED	0.02	0.005	0.002	
FRESH	0.01	0.005	0.002	
RAW MOLLUSCAN SHELLFISH	0.01	0.005	0.002	
OTHER PRODUCT (GENERAL)	0.01	0.005	0.002	

* Imported product destined for significant transformation in a federally registered establishment.

4.3 Suspended Inspection

When an inspection of a product selected for inspection has commenced, and the results indicate the lot would be rejected, the owner may have the inspection suspended. (For details on the procedure to be followed, see Chapter 2, Subject 1 of this manual - "Initial Inspection".)

4.4 Reinspection

A charge is to be levied for all reinspections carried out on imported products in accordance with section 10.1 of the FIR. (For procedures and policies governing Reinspections, see Chapter 2, Subject 2 of this manual.)

4.5 Special Inspections

All requested inspections of samples are cost recoverable, as per Section 12(1) of the FIR. Importers should be asked to clearly indicate in writing which inspections they wish carried out. A national form for this purpose is available (see Appendix D). The inspection fees listed in Section 6.5(5) of the FIR will be charged for each completed inspection.

The inspector should verify that no other Special Inspection is being performed or has been performed on the same production code of the product that has been submitted for inspection.

4.6 Cost Recovery With Respect to Special Case Imports

For the applicability of some special case imports, see Chapter 3, Subject 1, of this manual - Imports.

4.7 Appeal process

A fee of $1,000 is to be levied for a review conducted under the appeal process.

4.8 Invoicing

4.8.1 Shipments will be invoiced based on the location where the products were available for inspection. Occasions will arise wherein a shipment will clear customs in one Region but will be destined for another Region. If the importer provides notification to the local CFIA office at the time the goods clear customs, the importer has fulfilled the requirements of Section 6(2.1) of the FIR. The local CFIA

office must then notify the CFIA office in the receiving region of the particulars of the shipment. The CFIA office in the receiving region is responsible for: determining whether the product requires inspection; sampling; conducting the inspection; and preparations for cost recovery of the appropriate inspection service fee, as well as charging for any cost-recoverable inspections that are carried out.

4.8.2 Similarly, where a reinspection is carried out in a region other than that of the original inspection, invoicing is to be completed by the region where the initial inspection took place.

4.8.3 The CFIA's financial office will generate and send the importers the invoices for all fees related to shipments of imported fish.

4.9 Outstanding Invoices

All importers who have invoices outstanding for 60 days will be "listed" by the CFIA's financial office. The importer should be advised in writing and by registered mail that their licence will be suspended in 30 days if their invoices are still outstanding at that time. Subsequent imports from importers on this list will be detained until Finance has indicated that all outstanding fees have been paid. The CFIA financial office is to be consulted for details.

When importers have invoices outstanding for 90 days or more, the licence will be suspended and they will not have their import licences renewed. (Please refer to Chapter 2, Subject 5 of this manual, Compliance and Enforcement Strategy.)

5. FORMS/DOCUMENTS

Appendix A - Fish Inspection Report
Appendix B - Application for a Licence to Import Fish
Appendix C - Import Licence
Appendix D - Request for an Inspection of Fish or for a Fish Processing Facility
Appendix E - Sampling Plans
Appendix F - Import Licence Renewal Letter
Appendix G - Outstanding Invoice Warning Letter
Appendix H - Import Licence Suspension Letter

APPENDIX A
FISH INSPECTION REPORT

APPENDIX B

APPENDIX C

APPENDIX D

APPENDIX E

SAMPLING PLANS

SAMPLING PLAN 1
(Inspection Level I, AQL = 6.5)

Net weight is equal to or less than 1 kg (2.2 lb)

Lot Size (N)	Sample Size (n)	Acceptance No.	Number (c)*
4,800 or less	6	1	(0)
4,801 - 24,000	13	2	(1)
24,001 - 48,000	21	3	(2)
48,001 - 84,000	29	4	(3)
84,001 - 144,000	48	6	(4)
144,001 - 240,000	84	9	(6)
more than 240,000	126	13	(9)

Net weight is greater than 1 kg (2.2 lb) but not more than 4.5 kg (10 lb)

Lot Size (N)	Sample Size (n)	Acceptance No.	Number (c)*
2,400 or less	6	1	(0)
2,401 - 15,000	13	2	(1)
15,001 - 24,000	21	3	(2)
24,001 - 42,000	29	4	(3)
42,001 - 72,000	48	6	(4)
72,001 - 120,000	84	9	(6)
more than 120,000	126	13	(9)

Net weight is greater than 4.5 kg (10 lb)

Lot Size (N)	Sample Size (n)	Acceptance No.	Number (c)*
600 or less	6	1	(0)
601 - 2,000	13	2	(1)
2,001 - 7,200	21	3	(2)
7,201 - 15,000	29	4	(3)
15,001 - 24,000	48	6	(4)
24,001 - 42,000	84	9	(6)
more than 42,000	126	13	(9)

* The figure in brackets under the Acceptance Number (c) indicates the Acceptance Number for decomposition.

SAMPLING PLAN 2
(Inspection Level II, AQL = 6.5)

Net weight is equal to or less than 1 kg (2.2 lb)

Lot Size (N)	Sample Size (n)	Acceptance No.	Number (c)*
4,800 or less	13	2	(1)
4,801 - 24,000	21	3	(2)
24,001 - 48,000	29	4	(3)
48,001 - 84,000	48	6	(4)
84,001 - 144,000	84	9	(6)
144,001 - 240,000	126	13	(9)
more than 240,000	200	19	(13)

Net weight is greater than 1 kg (2.2 lb) but not more than 4.5 kg (10 lb)

Lot Size (N)	Sample Size (n)	Acceptance No.	Number (c)*
2,400 or less	13	2	(1)
2,401 - 15,000	21	3	(2)
15,001 - 24,000	29	4	(3)
24,001 - 42,000	48	6	(4)
42,001 - 72,000	84	9	(6)
72,001 - 120,000	126	13	(9)
more than 120,000	200	19	(13)

Net weight is greater than 4.5 kg (10 lb)

Lot Size (N)	Sample Size (n)	Acceptance No.	Number (c)*
600 or less	13	2	(1)
601 - 2,000	21	3	(2)
2,001 - 7,200	29	4	(3)
7,201 - 15,000	48	6	(4)
15,001 - 24,000	84	9	(6)
24,001 - 42,000	126	13	(9)
more than 42,000	200	19	(13)

* The figure in brackets under the Acceptance Number (c) indicates the Acceptance Number for decomposition.

APPENDIX F

IMPORT LICENCE RENEWAL LETTER

Government of Canada / Gouvernement du Canada
Canadian Food Inspection Agency / Agence canadienne d'inspection des aliments

Ref.: Import Licence Renewal Denied

Licence Number:

Your request to renew your licence to import fish into Canada is denied.

A review of your records shows that the following invoices :

- XXXXX
- XXXXX
- XXXXX

have not been paid.

Section 6.2. of the Fish Inspection Regulations allows the Minister to refuse to renew an import licence when the holder of that licence has outstanding fees payable to the CFIA.

Please contact this office to advise me of your plans to pay your outstanding invoices. This will allow the CFIA to renew your import licence.

Sincerely,

Individual Responsible

c.c.: Supervisor

Canada

APPENDIX G

OUTSTANDING INVOICE WARNING LETTER

Government of Canada / Gouvernement du Canada
Canadian Food Inspection Agency / Agence canadienne d'inspection des aliments

Ref.: Outstanding Invoices

Licence Number:

A review of your account shows that the following invoices :

-XXXXX
-XXXXX
-XXXXX

have not been paid and are past due for 60 days. Please contact this office to advise me of your plans to pay your outstanding invoices. Future shipments may be detained pending the payment of these outstanding invoices.

Section 6.2. of the Fish Inspection Regulations allows the Minister to suspend an import licence when the holder of that licence has outstanding fees payable to the CFIA. Your licence will be suspended if these invoices have not been paid in the next 30 days.

Once your licence has been suspended you will no longer be eligible to import fish into Canada under licence number (#####). The licence will remain suspended until your outstanding invoices have been paid.

Sincerely,

Individual Responsible

c.c.: Supervisor

Canada

APPENDIX H

IMPORT LICENCE SUSPENSION LETTER

Government of Canada / Gouvernement du Canada
Canadian Food Inspection Agency / Agence canadienne d'inspection des aliments

Ref.: Import Licence Suspension
Licence Number:

Section 6.2. of the Fish Inspection Regulations allows the Minister to suspend an import licence when the holder of that licence has outstanding fees payable to CFIA.

A review of your account shows that the following invoices:
- XXXXX

have not been paid and are past due for 90 days. You were advised on (date) that these invoices were past due for 60 days and that your licence would be suspended if the accounts where not settled in the next 30 days.

Since CFIA has not received payment for these invoices, your import licence will be suspended on _____ (*dated 2 weeks from date on letter*). Please contact the closest CFIA office found on the attached list to advise them of your plans to pay your outstanding invoices.

Once your licence has been suspended, you will no longer be eligible to import fish into Canada under licence number (#####) until your outstanding invoices have been paid. Should your licence expire before payment of your outstanding invoices, you will also not be able to renew your import licence until the outstanding fees have been paid.

Sincerely,

(signed at Director level)

Attach.

Canada

CHAPTER 3, SUBJECT 4

REGULATORY VERIFICATION PROGRAM FOR IMPORTS

1. SCOPE

This document outlines the regulations, policy and procedures governing the regulatory verification program for imported fish and fish products.

2. AUTHORITIES

Fish Inspection Act, R.S.C. 1985, c. F-12.
Fish Inspection Regulations (FIR), C.R.C., 1978, c.802; Part I, General.

Consumer Packaging and Labelling Act and Regulations.

Food and Drugs Act and Regulations.

3. DEFINITIONS

Systems Verification

This is a verification of the company's documented quality management system against regulatory standards. This verification is done on the initial submission and on any amendments submitted by the company.

Compliance Verification

This is a verification of the operating quality management system to determine that the importer is implementing the quality management system as designed and that the system is effective in meeting the applicable regulatory and offshore agreement requirements as set out in the regulations.

There are 3 types of compliance verifications as follows:

1. **Full compliance verification**, which entails a complete verification of all aspects of the company's quality management system.

2. **Partial compliance verification**, which focuses on

critical areas of a company’s quality management system.

3. **A follow up compliance verification,** which focuses on ensuring the company has completed corrective actions.

Inspections

Fish Import License Holder

This is an evaluation of a Fish Import License Holder's regulatory compliance to documentation and record keeping systems for consumer complaints, recall and process records for high-risk products.

Products

This is an evaluation of the company's product compliance level and ability to complete product assessments according to regulatory standards.

Background Program

This is a product monitoring program which is in addition to the product inspections conducted as part of the regulatory verification. The Program provides data to indicate the regulatory compliance levels of imported products in the market.

Critical non-conformities

Deficiencies in the quality management system that may result or have resulted in unsafe or fraudulent product. Immediate action will be taken to correct the critical non-conformance.

Major non-conformities

Deficiencies that violate the agreed-upon reference standards (regulatory requirements) but do not present a health or safety risk.

Minor non-conformities

Deficiencies where procedures specific to the quality management system were not followed, but there is no violation against regulations.

Observations

Deficiencies which if not dealt with could lead to a non-conformity. Observations also assist in the final report preparations to generate general comments.

4. POLICY

All importers that are subject to the FIR shall be evaluated for compliance to regulatory requirements through a combination of verification and inspection activities as prescribed by the regulatory verification policy and procedures.

4.1 Importer Inspection for Record Keeping Requirements/Product Inspection

4.1.1 All licensed importers are subject to inspection and verification to ensure that all record-keeping requirements (as outlined in Chapter 3, Subject 1 of this manual) for recall, consumer complaint, and process controls are satisfied.

4.1.2 The Fish Import License Holder will be inspected once every three years for record-keeping requirements or more often if required to address problems identified by routine inspection activities.

4.1.3 The Shared/Enhanced Importer will be inspected for record-keeping requirements as part of the compliance audit (see section 4.2 for more details).

4.1.4 Where importers fail to meet the record-keeping requirements as set out in Chapter 3, Subject 1, they may be subject to enforcement related to product or license actions. (See Chapter 2 of this manual for more details regarding enforcement actions [to be issued at a later date].)

4.2 Shared/Enhanced QMPI Regulatory Verification

4.2.1 The importer that holds a Shared or Enhanced Importer license is subject to regulatory verification on a once/quarter basis until a compliance history is established. The frequency of subsequent verifications will be based on the degree of regulatory compliance and on the level of risks, associated with importation of the products, from both a health and trade perspective.

4.2.2 The regulatory verification process entails a system verification, including a review of the QMPI submission; a compliance verification; an inspection of basic record-keeping requirements; enforcement actions as necessary to ensure regulatory compliance; and product surveillance as required by the National Import Inspection program.

4.2.3 The regulatory verification process will follow general audit principles and as such will require prior importer notification; a pre- and post-verification plan; a verification schedule; team leaders and team members; completion of verification reports and forms (see Appendices); data analyses; importer specific checklists; and a final verification report with appropriate follow-up corrective actions as required.

4.2.4 Regulatory verifications can be complete or full verifications in which a complete evaluation of the importers' QMPI system is conducted; or they can be a partial evaluation focusing in on specific areas of the QMPI system. In both cases a follow-up compliance verification is performed to document completion of corrective actions.

4.2.5 Importers will be required to provide a corrective action plan where the inspector identifies non-conformities.

4.2.6 The CFIA will conduct a follow-up verification to close the evaluation and verify corrective actions have occurred.

4.2.7 Importers that do not implement corrective actions will be subject to enforcement actions.

5. PROCEDURES

5.1 Importer Inspection for Basic Record-Keeping Requirements

All importers will be evaluated to determine whether they have in place a recall and consumer complaint system and have on file by type of product, all appropriate process control information on canned and ready-to-eat fish products.

5.2 Recall System Evaluation

5.2.1 Documentation from the importer will be obtained which explains the company's recall system. These will be reviewed to determine whether the system has been and is effective. Examples of questions to be asked include the following:

- What procedures are in place to record recalls and initiate them? Which position in the company is responsible? Do you as the responsible company designate for recall, understand the process?

5.2.2 Any previous recall actions taken by the company, which are obtained in advance by the CFIA, will be evaluated for their effectiveness.

5.2.3 The inspector will choose a lot or code from a list of known imported products and will require that the importer provide a list of distributors to first point of sale within 4 hours.

5.2.4 Examples of non-compliant lots taken from CFIA files and company reports will be matched to documents on file with the importer to ensure appropriate follow-up actions, such as destruction, shipment out of Canada or CFIA approved reconditioning have occurred.

5.3 Consumer Complaint System Evaluation

5.3.1 Documentation from the Importer will be obtained to explain the company's complaint system and to determine whether the system utilised by the company has been and is effective. Examples of questions to be asked include the following:

- What procedures are in place to action and investigate consumer complaints? Which position in the company is responsible? Do you as the responsible company designate for complaints, understand the process?

5.3.2 Any previous complaints on record by the CFIA and/or the importer will be obtained in advance by the CFIA. These will be reviewed to determine the effectiveness of the importer's complaint system.

5.3.3 The inspector will choose complaint files from the company and evaluate the procedure and its

effectiveness.

5.4 Process Information Inspection

5.4.1 Documentation from the importer will be obtained to explain their process control filing system and to determine whether the information is accurate, up-to-date and includes all regulatory requirements. The documents will also be assessed to evaluate how the product formulation and heat-processing determinations (where applicable) were completed by the company to ensure they are appropriate. Questions will be asked to determine how the company maintains these records, ensures they are updated, and evaluates them utilising appropriately qualified personnel. Examples of questions could include:

- What procedures are in place to action and obtain process information on each product type? How do you know when the packers make changes to their processes? Which position in the company is responsible? Do you as the responsible company designate for process information, understand the process? Which individuals or companies are you utilising to evaluate the process information and what are their qualifications?

5.4.2 The inspector will choose process control information from the company files and evaluate the contents to determine completeness.

5.4.3 The inspector will note the recognised authorities listed in the documents and the qualifications of the individuals/companies being utilised to evaluate the process information.

5.5 Evaluation of Inspection Results for Record-Keeping Requirements

5.5.1 Where any deficiencies are noted during the inspection of recall, consumer complaint and process control information, which are not of a critical nature, as noted below, the importer will be given the opportunity to correct these deficiencies by a negotiated time frame utilising corrective actions agreed to by the CFIA and the importer.

5.5.2 Where corrective actions are to be taken by the importer, following a record-keeping inspection, the

CFIA will verify that these corrective actions have been completed during a follow-up inspection.

5.5.3 Where deficiencies of a critical nature are identified during a record-keeping inspection, enforcement actions may be initiated. Deficiencies that are regulatory or policy violations may also warrant enforcement action. The following are examples of areas that would be considered critical or regulatory or policy violations:

- provision of false information for the purpose of obtaining a license;
- failure to maintain any records for a recall system; of valid complaints; or provide adequate process information for canned or ready-to-eat fish after warnings have been issued and negotiated corrective actions have not been implemented;
- repeat violations of specific FIR requirements, such as failure to notify the CFIA within 48 hours of importation;
- actions such as obstruction or refusal to provide assistance, moving product under detention;
- outstanding fees as indicated in Chapter 3, Subject 3 of this manual;
- refusal to recall or remove products that are under the control of the importer, that have been identified as having health and safety problems;
- intentional and reckless distribution or sale of known non-compliant (regulatory non-compliance) products; e.g., sale of products inspected and found to be decomposed.
- failure to notify CFIA of valid health and safety problems.

5.6 Shared/Enhanced QMPI Regulatory Verification Process

All Shared or Enhanced QMPI will be evaluated to determine if:

a) the plan is being followed;

b) the plan meets regulatory requirements; and

c) implementation of the plan meets regulatory requirements.

An inspection of the Shared/Enhanced record-keeping requirements will be undertaken as part of the process (refer to Sections 5.1 to 5.5 for procedures).

5.7 Shared/Enhanced QMPI Compliance Verification Process

5.7.1 The Shared/Enhanced QMPI submission or QMP plan will be evaluated to determine compliance to regulations and the QMPI program elements.

5.7.2 Each area or control point of the QMPI plan or submission will be evaluated to determine whether it addresses the regulatory and/or QMPI program requirements, by providing the procedures to be utilised by the company, the monitoring that will occur at each control point; the corrective action systems and controls in place; the verification that will take place; and the record keeping that occurs to capture regulatory compliance. Specific requirements of the QMPI Plan or QMPI Submission are outlined in Chapter 3, Subject 2, Appendix A.

5.7.3 Initial QMPI submission compliance verifications will be undertaken at the Regional level, and upon acceptance will be recommended and forwarded to NHQ for final approval and designation at the Shared or Enhanced QMPI level.

5.7.4 Subsequent QMPI submission compliance verifications will be undertaken during the regulatory verification process and as part of the systems verification to determine the effectiveness of the QMPI plan and ongoing adherence to regulatory and compliance requirements.

5.7.5 Where QMPI submission updates or revisions are undertaken by the company, these must be forwarded to the CFIA for review and approval.

5.8 Shared/Enhanced QMPI Systems Verification Process

5.8.1 All Shared or Enhanced QMPI importers will be evaluated to determine regulatory and program requirements through a verification of the systems application of the QMPI

plan and its associated control points. The monitoring programs in place at each control point, the forms utilised, the procedures in place to ensure compliance, the corrective actions systems, the self-verification system, and the qualifications of personnel will be evaluated during the course of the evaluation.

5.9 Regulatory Verification Preparations

5.9.1 The scope of the verification will be defined based on the extent of the evaluation, i.e., full or partial and the past history of compliance, including the current full and partial regulatory verification schedule.

5.9.2 A team of inspectors will be assembled, including a lead inspector or evaluator. Team participants will be chosen based on past experience and expertise.

5.9.3 The lead evaluator will be responsible for coordination of the regulatory verification, compiling the final report, providing guidance to inspectors during the on-site evaluation, and leading the discussions with the importer. Normally the Shared/Enhanced regulatory verification will be conducted in the Region where the submission has been made; that is where the company has indicated it will conduct its inspection procedures and ongoing activities. Where the Shared/Enhanced QMPI Importer has indicated that inspection processes occur in more than one Region of the country, and where verification of activities and inspection processes cannot be completed in the Region where the submission has been made, the lead evaluator may seek assistance from other Regions to complete the regulatory verification. The inspector acting as lead auditor will direct the regulatory verification process through designated Regional contacts and will compile the final report at the primary Regional site where the submission has been made.

5.9.4 The inspectors will be responsible for conducting the verification utilising their own checklist questions, specific to the control point being evaluated, and the company plan, and completing their portion of the regulatory verification report.

5.9.5 All relevant CFIA and Customs documentation related to the importer and imported products declared during the evaluation period will be available and studied by the evaluation team prior to the verification plan being

finalised. Import alert listings, recalls, complaints, company product rejection notices are examples of other documentation that should be available prior to the evaluation.

5.9.6 A current QMPI Submission or Plan will be available and where updates have occurred, will be studied to familiarise the evaluator with the current company procedures.

5.9.7 The evaluation team will divide the regulatory verification into sections which will be evaluated by each inspector. Where overlap may occur, the team will assign specific portions of the assessment as part of the evaluation plan. The verification schedule will be finalised based on the number of evaluators and the type of evaluation (i.e., full, partial or follow-up verification).

5.10 Regulatory Verification Plan

5.10.1 The company will be notified of the timing of the evaluation and the proposed schedule, along with a list of inspectors that will be conducting the plan. Mutually agreed upon times and witnesses from the company will be outlined prior to audit start up.

5.10.2 Verification forms as outlined in the Appendices will be utilised in completing a systems evaluation.

5.10.3 Reference documents, including the FIR regulations, Shared/Enhanced QMPI Compliance Guide, and the Fish Import License Holder Compliance Guide and QMPI Submission Guide must be utilised by the inspector during the regulatory verification to cite the standards applicable where non-conformance items and observations are noted. These reference documents can be found in Chapter 3, Subject 2.

5.11 On-Site Regulatory Verification

5.11.1 Each inspector will conduct their assessment of the control point and adherence to the QMPI utilising their checklist questions. Questions should be open ended. Where possible, inspection procedures, including sampling should be observed. Any company reference materials that are not already included in the QMPI plan should also be examined.

5.11.2 Where a deficiency is identified, the inspector must determine whether it is a non-conformance (major or minor) or an observation (as per the definitions) and record the findings on the appropriate verification form (see Appendices). In completing the non-conformance or observation report, the inspector must indicate the regulation or policy reference number and outline the description of the requirements in the form. *Note that wherever a critical non-conformance is identified, the verification is suspended and the importer is required to correct the non-conformance immediately.*

5.11.3 Where a non-conformance is found, the evidence to support the inspector's finding must be collected and attached to the verification report. Photocopies of forms, or written observations are examples of evidence that might be available as part of the regulatory verification report.

5.11.4 Where a non-conformance is identified, the company is notified, if not already present during the assessment, and the company representative is asked to acknowledge the finding by signing in the appropriate section of the verification form. Refer to Appendices for an example of the verification form.

5.12 Evaluation of Regulatory Verification Findings

5.12.1 Where non-compliance occurs, evaluate and record as either major or minor. Major non-compliance items have regulatory implications and relate to systems; while minor non-compliance items relate to operational problems. *Where a critical non-conformance is identified, the verification is suspended and the importer must take immediate action.*

5.12.2 Observations are made where appropriate. Corrective actions are not required by the company, but observations are recorded and provided in the verification report.

5.12.3 All major and minor non-conformance items must be addressed through a company action plan within the time frames negotiated between the inspector and company. The verification is not completed until the action plan is developed and verified through a follow-up site visit.

5.13 Verification of company qualifications

5.13.1 Verification of company competence in sensory evaluation

In order to determine whether the company is appropriately assessing the minimum acceptability of the imported fish products to Canadian regulatory standards, an assessment of the qualified company personnel performing sensory evaluations is completed, as part of the regulatory verification process.

5.13.1.1 A total of 50 samples for each group of product imported and inspected by the company will be evaluated. Product groups are: ready-to-eat fish products; canned fish; fresh/frozen fish; molluscan bivalves; and other products. The 50 samples shall encompass a range of quality from acceptable to unacceptable. The company and the CFIA should provide the range of samples. Where applicable, chemical quality indicators will have been completed and the history of the samples known prior to evaluation.

5.13.1.2 The samples will be blind coded by the CFIA and presented to the CFIA and company analysts and evaluated for acceptability to regulatory product standards.

5.13.1.3 The results will be evaluated and where 75% to 80% agreement is reached between the CFIA and company sensory analysts, the company will be deemed to be appropriately applying regulatory product standards.

5.13.1.4 Where results indicate 70% to 75% agreement between the CFIA and company sensory analysts, an additional 50 samples will be evaluated.

5.13.1.5 Where, after 100 samples, results indicate that there is less than 70% agreement between the CFIA and company sensory analysts, further investigation of sensory analyst’s training and expertise will be completed. The company will need to evaluate the use of their current analysts and provide a corrective action plan where applicable.

5.13.2 Verification of company competence in other analyses

Observe the inspection procedures utilised by the company, including tests such as net content, container integrity evaluation, etc. to determine if it matches their company procedures, and whether they are utilising

Canadian government standards which are equivalent to methods recognised and/or utilised by the CFIA.

Record the private laboratories utilised by the company for microbiological and chemical testing where this testing is not conducted by the CFIA. Note that only private laboratories (chemical and microbiological testing) accredited by the Standards Board of Canada are recognised by the CFIA.

5.14 Regulatory Verification Report

5.14.1 Each inspector will complete the answers to their checklist questions and file any non-conformance or observation reports with the lead evaluator. Generic comments by the inspector on the QMPI submission, the QMPI plan procedures or any aspect of the company plan are submitted to the lead evaluator to incorporate into the final summary report.

5.14.2 The lead evaluator will compile the final verification report and present it to the company upon completion of the on-site evaluation. The final verification report will include the scope of the verification; the verification schedule and team members list, as well as the company witnesses (if any); the non-conformance and observation reports; the checklist questions and answers; any evidence supporting the non-conformance reports; and a final summary report of the verification findings.

5.14.3 The company will be expected to utilise the non-conformance reports to indicate their proposed corrective actions and return this to the CFIA for evaluation and approval.

5.15 Regulatory Verification Closure

5.15.1 Where non-conformance items have been identified, the company is required to submit a corrective action plan for review and acceptance by the CFIA. Associated time frames to implement the corrective action must also be included by the company. The company should utilise the verification non-conformance report for this purpose.

5.15.2 The CFIA and company must agree to the corrective action plan. Where there are no agreements, the corrective plan must be revised to satisfy both parties.

5.15.3 In order to close the regulatory verification process, the inspector must review the implementation of the corrective action(s) to ensure completion. The lead evaluator will return the confirmation and audit sign-off utilising the verification non-conformance report.

5.15.4 Where companies do not implement corrective action for the non-conformities as per the action plan; or where companies have deliberately and intentionally marketed products that are fraudulent or are a health and safety risk; or have falsified records, appropriate enforcement action will be taken.

5.16 Product Background Surveillance

5.16.1 Fish Import License Holders

The Product surveillance program for Fish Import License Holders is described in Chapter 3, Subject 1.

5.16.2 Shared/Enhanced QMPI

The product surveillance program for Shared and Enhanced QMPI is based on past history of compliance and a risk-based testing regime and is therefore subject to change as required.

5.17 Evaluation of Product Compliance Findings

5.17.1 Where non-compliant products are identified, notify the company and initiate a partial verification of the final product testing regime as required. For details as to product action to be taken in the case of non-compliance, see Chapter 3, Subject 1.

5.17.2 Product non-compliance may lead to a QMPI regulatory verification which will include a verification of company personnel competence to conduct product inspections, as outlined in Section 5.6.

Note: The CFIA will be providing standardisation sessions to Industry for specific product groups on a problem-driven basis. Where company personnel who are designated and functioning as analysts in the Shared/Enhanced QMPI are identified as unable to, or applying product standards inappropriately, this information will be noted in their regulatory verification results and the company will be offered the

option to utilise CFIA services or other recognised third-party personnel.

6. FORMS/DOCUMENTS

Appendix A - Regulatory Verification Summary Report

Appendix B - QMPI Audit Workplan/Schedule

Appendix C - Regulatory Verification Activity Summary

Appendix D - Non-Conformance/Observation Report

APPENDIX A

REGULATORY VERIFICATION SUMMARY REPORT

Regulatory Verification Summary Report	Page ____ of ____

Company Name:	Date:
Location:	

The contents of this report are confidential to the Company as named above. As such, distribution to persons not under the employ of either party must be agreed upon by both parties prior to circulation.

The non-conformance items and observations contained within this report are the result of limited sampling and therefore it cannot be assumed that others do not exist.

The signature(s) below of the Company's representative(s) indicates their acknowledgment and understanding of the non-conformance items and observations found and that are the subject of this report.

Scope:

Comments, Conclusions and Follow-up Action:

CFIA Inspectors	**Company Representatives**
Signed:_____	Signed:_____
Signed:_____	Signed:_____
Signed:_____	Signed:_____
Signed:_____	Signed:_____

APPENDIX B

QMPI AUDIT WORKPLAN/SCHEDULE

Date: (Day 1)

TIME	Member 1 Location\Department\Function	Member 2 Location\Department\Function
09:00		
10:00		
11:00		
12:00		
13:00		
14:00		
15:00		
15:30		
16:00		

TIME	Member 3 Location\Department\Function	Member 4 Location\Department\Function
09:00		
10:00		
11:00		
12:00		
13:00		
14:00		
15:00		
15:30		
16:00		

Form No.: QMPI96-2

APPENDIX C

REGULATORY VERIFICATION ACTIVITY SUMMARY

Page ____ of ____

	REGULATORY VERIFICATION ACTIVITY SUMMARY	SUMMARY NC	Observation
FIR Section Ref	**Description**		
	Licencing and Notification		
6(1)(b); 6(2)(b), (d), (e); 6(2.1)(a-e); 6.5(2)(ii)	- valid licence - 48 hr notification - CFIA notification re: rejected shipments - import alert info. to CFIA - code list provided for canned/ RTE products - ICSSL info. provided for bivalve products		
Monitoring	- procedures as per submission		
Corrective Action	- review of control point, and initiation of corrective action where non-compliance		
Record Keeping	- forms utilised		
Verification System	- company system verification (can be part of total verification system, see last Section of this form)		
	QMPI Submission		
6.1(1.1)(b), (c); 6.1(4)(a), (d); 6.2(1)(g); 6.1 (3)(e)(i-iii),(xii); 6.1(3.2); 6.1(4)(d)	- approved by CFIA - up-to-date and on file - appropriate procedures to meet regulations - amendments forwarded to CFIA - notify inspection summary results to CFIA twice/year		
	Labelling		
6(2)(a-c); 6(3); 6.1(3)(e)(x)	- meets Canadian requirements, not false or misleading		
Monitoring	- procedures as per submission		
Corrective Action	- review of control point and initiation of corrective action where non-compliance		
Record Keeping	- forms to record compliance		
Verification System	- company system verification (can be part of total verification system - see last Section of this form)		
	Ingredients		
6.1(3)(e)(viii)(A), (B)	- additives/ingredients approved in Canada and at acceptable levels		
Monitoring	- procedures as per submission		
Corrective Action	- review of control point and initiation of corrective action where non-compliance		
Record Keeping	- forms to record compliance		
Verification System	- company system verification (can be part of total verification system, see last Section of this form)		
	Packaging Materials		
6.1(3)(e)(ix)(A), (B)	- approved for food use - clean and sound		
Monitoring	- procedures as per submission		
Corrective Action	- review of control point and initiation of corrective action where non-compliance		
Record Keeping	- forms to record compliance		
Verification System	- company system verification (can be part of total verification system, see last Section of this form)		

Page ____ of ____

	REGULATORY VERIFICATION ACTIVITY SUMMARY	SUMMARY NC	Observation
FIR Section Ref	**Description**		
	Cold Storage		
22.(1-3)	- protect fish from contamination and deterioration - store at -18 degrees C		
Monitoring	- procedures as per submission		
Corrective Action	- review of control point and initiation of corrective action where non-compliance		
Record Keeping	- forms to record compliance		
Verification System	- company system verification (can be part of total verification system - see last Section of this form)		
	QMP Importer Test Requirements/Final Product		
6.1(3)(e)(iv-vii)(A-C); 6.1(3.1)(b); 6.1(4)(b), (c)	- minimum acceptable quality, not TDU, regulatory standards - acceptable supplier assessment program - standard tests at 15%, labelling, net content, container integrity, composition, coding, "A" list 10% - import alert 100% - specialised tests at 2%, 5%, 15% , microbiological, chemical, marine toxins - randomly sampled - appropriate sampling plans and methodology - appropriately qualified people conducting tests		
Monitoring	- procedures as per submission		
Corrective Action	- review of control point and initiation of corrective action where non-compliance		
Record Keeping	- forms to record compliance		
Verification System	- company system verification (can be part of total verification system - see last Section of this form)		
	Recall System		
6.1(3)(a), (b); 6.1(e)(x)	- name, address, quantities, product description to first point of sale - rework, recondition, destroy or remove from Canada non-compliant products - CFIA notification for Health and Safety		
Monitoring	- procedures as per submission		
Corrective Action	- review of control point and initiation of corrective action where non-compliance		
Record Keeping	- forms to record compliance		
Verification System	- company system verification (can be part of total verification system - see last Section of this form)		
	Complaints		
6.01(1), (2); 6.1(3)(b.1)	- immediate notification for health and safety related complaints		
Monitoring	- procedures as per submission		
Corrective Action	- review of control point and initiation of corrective action where non-compliance		
Record Keeping	- forms used to record compliance		
Verification System	- company system verification (can be part of total verification system - see last Section of this form)		

Page ____ of ____

	REGULATORY VERIFICATION ACTIVITY SUMMARY	SUMMARY NC	Observation
FIR Section Ref	**Description**		
	Process Controls for Canned and RTE Products		
6.1(3)(c)(i-iii), (d)(i-ii)(A-C)	Canned Fish - adherence to seam specs and CI requirements - approved thermal process info. on file - process deviations RTE Fish - safety parameters, pH, salt, water activity, etc. - process flow - heat treatment - product formulation		
Monitoring	- procedures as per submission		
Corrective Action	- review of control point and initiation of corrective action where non-compliance		
Record Keeping	- forms used to record compliance		
Verification System	- company system verification (can be part of total verification system - see last Section of this form)		
	Verification/Self Audit -		
6.1(4)(e)	- once per year of system and each control point (to be assessed in total, if not already covered at each control point)		
	Total Non - Conformances		
	Total Observations		
	Comments		
Note: Activity Summary Report is utilised by inspectors to formulate individual checklists.			

QMPI Form 98-09

APPENDIX D

NON-CONFORMANCE/OBSERVATION REPORT

NON-CONFORMANCE/OBSERVATION REPORT	
REGULATORY VERIFICATION REPORT **Non-Conformity Report** __ **Observation Report** __ **(check one)**	**Page** _____ **of** _____
Company Name	Fish Inspection Regulation Reference __ Section _____ __ Section _____
Inspector: _____ Inspector Report #: _____	Category **CRITICAL** __ **(requires immediate corrective and appropriate enforcement action)** **MAJOR*** __ **MINOR*** __ **OBSERVATION*** __ *** (check one)**
Findings:	
Actual: Required: Inspector Signature: _____ Acknowledged by: _____ Date: _____ Date: _____	
Corrective Action (to be completed by company):	
Follow- up Review as required:	
_____ Date _____ Lead Evaluator	

QMPI Form 98 11

5 1 1

New 25/02/1994

CHAPTER 5, SUBJECT 1

INSPECTION OF LIVE CRAB AND LOBSTER

1. SCOPE

This document outlines the regulation, policy and procedures governing the inspection of live crab and lobster before butchering and/or cooking.

2. AUTHORITIES

Fish Inspection Act, R.S.C., 1970, c.F-12; Section 3
Fish Inspection Regulations, C.R.C., 1978, c.802; (FIR) Part I, General

Section 23 (FIR):

No person shall:

a) process crabs, lobsters, clams, oysters, mussels or whelks that are not alive.

3. POLICY

3.1 Crab or lobsters which are defective (see section 4 - Definitions) must not be further processed.

3.2 Processors will be in violation of this policy if the percentage of defective crab or lobster entering into butchering and/or cooking lines exceeds 10%.

3.3 Lots of raw product which meet the 10% or less criterion may be processed; however, defective crab or lobster is to be culled from the line during processing.

3.4 Lots of raw product which contain greater than 10% defective crab or lobster must be culled before butchering and/or cooking.

4. DEFINITIONS

Defective - for the purposes of this document, crab or lobsters will be considered defective if:

- there is an odour of decomposition or there is black discolouration; or
- there is no response to stimulation by a Crab Life Detector; or
- there is no noticeable heart action when the carapace is removed; or
- there is any other indication that the sample unit is tainted, decomposed or unwholesome.

5. PROCEDURES

5.1 During the QMP inspection of the critical control point "incoming fish", in plants which butcher and/or cook raw lobster or crab, the inspector will verify that the plant's QMP is determining the condition of each incoming lot and that appropriate action is being taken to cull any lot found to contain 10% or more of defective crab or lobster.

5.2 The inspector will assess the QMP verification and/or culling procedure by inspecting any lot held for butchering and/or cooking after the lot has been inspected by the plant's QMP personnel. The inspector will determine sample size by using Sampling Plan 1 in the Fish Products Standards and Methods Manual. Sample size is based on the number of sample units in the lot. Minimum sample size shall be 13 crab or lobster.

5.3 The inspector shall calculate the percentage of defective crab or lobster in the lot.

5.4 If the lot held for butchering and/or cooking fails to meet the 10% tolerance before processing, in addition to a QMP deficiency, enforcement action will be initiated in accordance with the National Fish Inspection Enforcement Policy and the QMP Enforcement Policy.

5.5 Lots of incoming raw crab or lobster that have been culled must be processed within 8 hours of culling. If more than 8 hours have passed since the previous culling, the lot must be inspected again to ensure that defective crab or lobster are removed from the lot.

CHAPTER 10

CERTIFICATION OF FISH AND FISH PRODUCTS

1. SCOPE

This document outlines the policies, procedures and regulations governing the certification of fish and fish products.

2. AUTHORITY

Fish Inspection Act, R.S.C., 1970, c.F-12; Sections 9(1) and (2), 14(1), (2) and (3)

Fish Inspection Regulations (FIR), C.R.C., 1978, c. 802; Part I, General.

Section 9 (FIR)

9.(1) Where a person requests an inspection certificate for fish, an inspector shall

(a) where the person operates the establishment in which the fish was processed, inspect the processing record of the establishment to determine whether an inspection of the fish is required and, if it is required, inspect the fish; and

(b) in any other case, inspect the fish.

(2) An inspector shall issue an inspection certificate for fish where

(a) the inspector determines that an inspection of the fish is not required; or

(b) the inspector determines, following an inspection of the fish, that the fish meets the requirements of the Act and these Regulations.

(3) A person who requests an inspection certificate for fish shall pay an inspection service fee of

(a) $100, where an inspection of the fish is performed; and

(b) $25, where an inspection of the fish is not performed.

(4) The amount payable by a person under subsection (3) shall not exceed $10,000 in a calendar year. SOR/96-364, s.4

Section 12 (FIR)

Where an inspector has reasonable grounds to believe that fish has deteriorated after the date on which it was inspected or that it otherwise fails to meet the requirements of these Regulations, he may again inspect such fish.

Section 13 (FIR)

(1) Where an inspection is made under Section 12 and the fish is found not to be of the grade marked on the container, any inspection marks and quality designations on the container shall be removed or obliterated and any inspection certificate that may have been issued for the fish is void.

(2) No person shall use an inspection certificate if he knows that the certificate is void.

2.1 DEFINITIONS

Certification is the procedure by which official certification bodies or officially recognised certification bodies provide written or equivalent assurance that foods or food control systems conform to requirements. Certification of food may be, as appropriate, based on a range of inspection activities which may include continuous on-line inspection, auditing of quality assurance systems, or examination of finished products (Codex - Principles for Food Import and Export).

Inspection is the examination of food or systems for control of food, raw materials, processing, and distribution including in-process and finished product testing, in order to verify that they conform to requirements (Codex - Principles for Food Import and Export).

Lot, with respect to fish other than fresh fish, means a shipment or part of a shipment of fish that is of the same species, is processed in the same manner by the same producer, is packaged in the same size of container and bears the same label (FIR - Section 2).

Quality Management Program means a fish inspection and control system, that includes procedures, inspections and records, for the purpose of verifying and documenting the processing of fish and the safety and quality of fish processed in, exported from, or imported into Canada (FIR - Section 2).

3. POLICY

3.1 When a registered establishment or an export licence holder requests a specific certificate for his/her product, one must be issued, except where:

- the fish or fish products or the fish processing establishment do not meet the requirements of the Fish Inspection Regulations;
- the conditions of the certificate are not met at the time of production; and
- products contain additives, chemical contaminants or bacteriological organisms at levels prohibited by the importing country, even if the levels are in compliance with Canadian requirements.

3.2 Although the CFIA will attempt to assist in providing information on the certification requirements of the destination country, if they are not known it is the primary responsibility of the exporter to identify foreign country requirements and obtain documents that can be verified with officials from the destination country. Known country requirements can be found in the Appendices to this Chapter.

3.3 Fish or fish products that exceed contaminant standards or guidelines established by Health Canada shall not be exported unless the product is in compliance with established standards, tolerances or guidelines of the receiving country, or the foreign regulatory agency has indicated in writing that the products are acceptable in their country. Where these fish are certified, the certificate cannot state that the fish meet the requirements of the Fish Inspection Regulations.

3.4 The details on each certificate or To Whom It May Concern Letter issued must be entered into the Export Certification System. The Product Inspection section at NHQ should be contacted to develop new or amended certificate templates as required.

3.5 Certificates may be issued for imported lots which are "processed" and subject to QMP controls in a registered establishment if the fish meets the requirements of the foreign country stated on the certificate, even if the product does not undergo substantial transformation according to domestic shift rules. (These products cannot be certified as product of Canada.)

3.6 For registered establishments with a QMP system in compliance with the FIR, it is required that 10% of lots intended for certification be inspected.

3.7 Subject to Section 3.8, for export license holders requesting certification of fish that were not processed in a registered plant (e.g., fisher-packers) it is required that 100% of the lots be inspected prior to certification.

3.8 Certificates may be granted without inspection to exporters who have a voluntary protocol between the establishment and the CFIA (e.g., Live Lobster Protocol). The voluntary protocol shall outline the required procedures and resulting privileges for the exporter, and must be signed by both the exporter and the CFIA in order to be in effect. Exporters operating with a voluntary protocol must meet all the requirements of the FIR and the protocol in order to receive an export certificate.

3.9 An inspector may sign a certificate based on an official inspection by another inspector.

3.10 In instances where inspectors are asked to supply certificate(s) for a re-consignment or sub-lot, they must ensure that the product still meets the requirements of the original certificate(s) and that all pertinent product information on the original certificate(s) is incorporated on the certificate(s) for the re-consignment or sub-lot(s). Certificates for re-consigned lots or sub-lots shall not be issued without an inspection of the lot if the interval between the original certificate and the certificate request exceeds:

- 7 days for fresh product
- 30 days for salted fish
- 180 days for frozen products
- 365 days for canned products
- the best before date for any product.

3.11 Where an Inspector has reason to believe that the condition of the fish/fish products has deteriorated since the inspection, another inspection shall be conducted.

3.12 Only one original certificate per lot is to be issued for each type of certificate, but two or more different types of certificates can be issued on one lot. The inspector or exporter can make copies of the certificate. If certificates are issued to replace lost or damaged certificates, then a statement is required on the replacement certificate to cancel the first certificate.

3.13 Where lots are not accessible to an inspector for inspection, or the company's records of inspection pertaining to the lot(s) are not available for verification, then the inspection cannot be carried out and a certificate cannot be issued.

3.13.1 Exporters may request replacement certificates for fish products which have been exported from Canada and are therefore no longer available for inspection. Replacement certificates may be issued in legitimate cases if the integrity of the shipment has not been compromised. Such legitimate cases would include, but are not limited to:

- administrative errors;
- lost or damaged certificates;
- changes to the consignee; and/or
- last minute changes to the quantity shipped.

3.13.2 Replacement certificates will not be issued for a shipment that has been imported into another country.

3.14 In instances where historical data is available for chemical contaminants, e.g., mercury in some species of fish, laboratory analysis is not required to issue a certificate. Inspectors who receive a request for a certificate concerning chemical content are to contact the appropriate CFIA personnel to reference the data base to ensure compliance before issuing the certificate.

3.15 The appropriate fees will be charged for all requests for certification and all inspections for certification, even where a certificate was refused after a review of records or a lot failed inspection.

4. PROCEDURES

4.1 A company requesting a certificate should complete the certificate in advance and provide it to a CFIA office for signature. The information on the certificate or the certification request should identify:

a) certificate type(s)

b) lot location
c) date available for inspection
d) date certificate required
e) lot size
f) product description (size, grade, type)
g) consignee
h) consignor
I) identification marks (production code)
j) mode of transportation (if known).

4.2 In order to determine if the lot requires inspection, the inspector is required by regulation to review the processing record of the establishment, which would consist of the following actions where appropriate:

- ensure the establishment had a valid registration and met all certification requirements for the dates the product was processed;
- ensure that there are no confirmed complaints for the product or that the product was never recalled; and
- ensure that the product does not require 100% inspection prior to certification.

4.3 In order to issue a Certificate for a European Union (EU) country, the inspector must also be satisfied that in addition to meeting the requirements of the FIR:

a) the processor is on the EU List; and

b) that if the product was harvested by a foreign vessel, it had been inspected within the past 12 months and met the requirements of Schedule III or EU Directive EU/48/EEC. (In addition to Canada, the USA, and New Zealand also have Veterinarian agreements with the EU that include fish products. Processors of shipments originating from these countries are not required to provide proof the harvesting vessels met the requirements of EU/48/EEC.)

4.4 When a certification request is received from a processor with a voluntary protocol, the inspector should review the specific requirements of the protocol to determine if an inspection is required prior to making a decision to certify the product.

4.5 If an inspection of a lot is required prior to issuing a certificate, the lot will be inspected as specified in Chapter 2 of this manual. The samples should pass inspection for the requirements for sensory evaluation, labelling claims and ingredient declarations, net content evaluation if the product is pre-packaged, and visual

container integrity for hermetically sealed metal containers.

4.6 If the product is found to be in compliance with the FIR, the requesting company is to complete the certificate and the inspector will review the certificate before signing. Any changes on the certificate must be initialled by the inspector. When a certificate is issued, any space remaining in the product description section is to be marked out by a Z.

4.7 Requests for replacement certificates for consignments that are no longer available for inspection in Canada should be accompanied by a letter from the exporter that sets out the reasons for the request, including an explanation of what happened, where it happened, and who was involved. This letter should be kept in CFIA's files.

4.8 When a replacement certificate is issued, or a certificate is voided or cancelled, the certificate and all copies of the certificate should be returned to the Agency before a new certificate can be issued. If the originals cannot be returned, then the exporter should provide a letter to the CFIA that describes the reasons why the original certificate was not returned.

4.9 A replacement certificate should have the following statement added just above the Inspector's seal: "This cancels and supersedes certificate no. ____ dated ____."

4.10 All stocks of obsolete export certificates or computerized templates of obsolete certificates must be destroyed.

4.11 A fee of $25 per certificate where no inspection was performed or $100 per certificate where an inspection was performed is to be charged unless the establishment has reached the $10,000 cap for certification fees.

4.12 The Canadian Inspection Certificates are to be completed as follows:

a) Product Description - A full and accurate description must be provided. In the case of graded product, the class, grade, size and/or moisture content is to be indicated if specified by regulations.

b) Lot Size - The number of boxes, cartons, packages, etc. in the lot, the number of individual containers in a box, etc., and the weight of the individual container. The weight of the individual container is not required if the product is to be weighed at time of sale.

c) Consignor - The name and address of the person or company that is marketing the merchandise.

d) Consignee - The name and address of the person or company to whom the merchandise is being sold.

e) Marks - The identification marks such as port marks, shipping marks, date codes, name of plant, registration number or any other marks that specifically identify the lot covered by the certificate.

f) Via - The mode of transportation and the name of the transporting company. If the information is not known, complete this section as follows: "Not known at time of inspection".

g) Place - The location where the certificate was issued.

h) Date - The date when the certificate was issued.

I) Inspector - The name of the inspector signing the certificate. Inspectors issuing certificates are to print their name above or below their signatures.

4.13 Instructions for completing foreign country certificates are provided in the specific appendices. For imported products that are processed in registered establishments but which do not undergo substantial transformation, the country of origin must be identified on the certificate.

4.14 All certificates should be signed and stamped using ink that is a different colour from the other text on the certificate. Inspectors should then crimp the certificate over their signature. If the certificate is formatted on more than one page, each page of the certificate should be signed and stamped in a different colour ink with a crimp over the inspector’s signature. The stamp and crimp should be placed so that they do not obliterate the identity and title of the signing officer.

Any copies of the original certificate must be identified as a copy and should be readily distinguishable from the original document.

The seal and crimp used for the certificate must be in the following format:

5. FORMS/DOCUMENTS

NOTE: Copies of all current forms and certificates may be found on the Agency Intranet site.

APPENDIX A

LIVE LOBSTER CERTIFICATION PROTOCOL (LLCP)

1. SCOPE

This document outlines the policies and procedures governing the inspection and certification of live lobster for export carried out by personnel of the Canadian Food Inspection Agency (CFIA), in both registered and non-registered establishments, excluding fishing vessels.

These policies and procedures reflect the low level of risk to public health and safety associated with the handling and packaging of live lobsters.

2. AUTHORITY

Fish Inspection Act, R.S.C., 1970, C.F-12; Sections 6, 9(1) and (2)

Fish Inspection Regulations, C.R.C., 1978, c.802; (FIR) Part I, General: Sections 9, 12, 13 (1), 13 (2)

Section 9

(1) Where a person requests an inspection certificate for fish, an inspector shall

a) where the person operates the establishment in which the fish was processed, inspect the processing record of the establishment to determine whether an inspection of the fish is required and, if it is required, inspect the fish; and

b) in any other case, inspect the fish.

(2) An inspector shall issue an inspection certificate for fish where

a) the inspector determines that an inspection of the fish is not required; or

b) the inspector determines, following an inspection of the fish, that the fish meets the requirements of the Act and these Regulations.

(3) A person who requests an inspection certificate for fish shall pay an inspection service fee of

a) $100, where an inspection of the fish is performed; and

b) $25, where an inspection of the fish is not performed.

(4) The amount payable by a person under subsection (3) shall not exceed $10,000 in a calendar year. SOR/96-364, s.4

Section 12

Where an Inspector has reasonable grounds to believe that fish has deteriorated after the date on which it was inspected or that it otherwise fails to meet the requirements of these Regulations, he may again inspect such fish.

Section 13

(1) Where an Inspection is made under Section 12 and the fish is found not to be of the grade marked on the container, any inspection marks and quality designations on the container shall be removed or obliterated and any inspection certificate that may have been issued for the fish is void.

(2) No person shall use an inspection certificate if he knows that the certificate is void.

3. POLICY

Live lobster exported from Canada to any country in the world shall be certified when the live lobster has been processed in accordance with the requirements of the ***Fish Inspection Regulations***. Inspection and certification of the live lobsters shall be conducted in accordance with the requirements of this protocol and other relevant requirements contained in this manual.

Registered Establishments

The processing and exportation of live lobster shall be subject to all the requirements of the establishment's Quality Management Program. This includes conducting a hazard analysis on any live fish operations as per section 3.1 b) and c) below. Should a registered establishment choose to develop and implement a Live Lobster Certification Protocol (LLCP) to facilitate the certification of live lobster exports, the

audit/verification frequencies and the certificate control requirements of this document shall apply.

Non-registered Establishments

In order to facilitate the export of live lobster from Canada, non-registered live lobster exporters may develop and submit a LLCP submission to the CFIA for evaluation and approval. A Live Lobster Certification Protocol signed by both the exporter and the CFIA is required for non-registered exporters of live lobster who wish to ship to the European Union (EU), and exporters to other markets who require pre-signed certificates. Once the submission is evaluated, accepted and signed, the exporter is then assigned a LLCP number and the exporter name and number is added to the "Canadian List of Exporters Approved for the US" and the "Canadian List of Exporters Approved for the EU".

3.1 Each submission for a LLCP shall contain:

a) appropriate background information (exporter name, mailing address), location of the establishment used for the processing and export of the lobster, including methods of handling and description of the packaging and labelling to be utilised;

b) a hazard analysis which identifies every hazard that is likely to occur for the live lobster operation;

c) where the hazard analysis has identified hazards, a HACCP plan in which all critical control points, critical limits, monitoring procedures used at critical control points, the frequencies of monitoring procedures and corrective action plans are specified;

d) the names of personnel responsible for the development and implementation of the LLCP;

e) a written sanitation program; and

f) a description of the system used to trace lots of live lobster to their first shipping destination.

3.2.1 **Non-registered LLCP Exporters, Excluding Exporters of Crated Lobster Shipped Directly**

Non-registered lobster exporters, operating under a LLCP,

including shippers who further package crated lobster into cardboard or polystyrene foam containers, shall have enclosed facilities. Facilities shall meet the following construction and equipment requirements:

a) Floors - new construction shall be concrete or equivalent (i.e., nonporous). Existing wood will be tolerated provided it can be kept in good repair and clean. No earth or gravel floors permitted.

b) Drains - shall be properly covered to prevent entrance of rodents. Where effluent drains, it must not create an unsanitary condition where flies and unacceptable odours are prevalent.

c) Walls and Ceilings - open studding shall be tolerated provided it can be kept in good repair and reasonably clean. Facilities must have tight doors and windows and be constructed so as to prevent the entrance of rodents.

d) Toilet facilities - must be available in the immediate area.

e) Hand-washing facilities -

   I) in existing establishments, hand-washing facilities with running water are required; pressurised water is recommended, but not required;

   ii) in new construction, the facility must be located adjacent to the toilet facilities, and must be equipped with hot and cold running water, soap and single-service towels.

f) Water - an adequate supply of water derived from:

   I) an approved potable fresh water source; or

   ii) a supply of clean sea water derived from a source which meets the overlay water standard, shall be available for employee hygiene and establishment clean-up.

g) Tables - new construction must be of approved material. Wood is permitted for existing equipment.

h) Offal Receptacles - must be marked "For Offal Only", and be constructed of approved material.

I) Lighting - minimum lighting for live fish holding operations must be available in the processing areas.

3.2.2 **Non-registered LLCP Exporters of Crated Lobster Shipped Directly**

Non-registered shippers of crated lobster from tidal lobster pounds or cars, who hold lobster in crates in tidal lobster pounds, and place loaded crates on transport vehicles for shipment, are not subject to the facility requirements outlined in Section 3.2.1.

3.3 Live lobster exporters operating under LLCPs shall ensure they meet all requirements of the policy as outlined in their HACCP submission.

3.4 Inspectors shall conduct audits and verification of LLCP establishments to ensure compliance with the requirements of the LLCP.

3.5 Individual CFIA offices will outline requirements for notification of shipments to be exported, in order that audit/verification can be conducted.

3.6 Inspectors shall conduct audit/verification activities in accordance with the frequency guidelines provided below:

a) 1 per month for high volume facilities (>20 certification requests/month);

b) once every three operating months for low volume facilities (<20 certification requests/month).

3.7 Where live lobster shippers have implemented and meet the requirements of a LLCP they shall be included on the plant list to be exchanged with the United States for the purposes of meeting the US Seafood HACCP Regulations.

3.8 Since live fish exporters to the United States do not require product certification, the LLCP may be audited approximately every 3 months of operation.

3.9 The CFIA may make additional arrangements to facilitate the export of live lobster to foreign markets as required.

3.10 Inspectors may take samples for any reason, including therapeutant and biotoxin analysis, and make results available to the industry, where appropriate.

3.11 The LLCP may be suspended or revoked by the CFIA if the requirements of the protocol are not met.

3.12 Live lobster shippers operating non-registered facilities without a LLCP may still have product certified provided the lobsters were processed in accordance with the Fish Inspection Regulations. Each lot must be inspected prior to certification.

Live lobster shippers operating non-registered facilities without a LLCP will not have shipments certified for export to the EU as they are required to be included on the list of establishments approved to export fish to the EU, which cannot be done without a LLCP.

4. PROCEDURES

4.1 LLCP submissions, containing the information in 3.1, shall be submitted to the nearest CFIA office for review and approval.

4.2 Where CFIA inspectors determine that shipments of live lobster require the issuance of pre-signed certificates (i.e., European Union), the LLCP exporter shall be granted the privilege of these certificates provided the following measures are implemented:

a) CFIA shall maintain detailed controls of all certificates issued including copies of the certificates issued, names of exporters receiving certificates and serial numbers;

b) designated CFIA inspectors, knowledgeable in the requirements of the Fish Inspection Act and Regulations, shall sign, crimp and stamp, with the CFIA logo, previously prepared certificates that have written or typed on the certificate "Live Lobster (homarus americanus)", the name and address of the consignor, and the certificate serial number;

c) CFIA shall only issue inventories of certificates once they account for all previously issued certificates (including certificates voided by the exporter);

d) CFIA shall only issue certificates to exporters who have not previously received pre-signed certificates on a case-by-case basis, until such time as an acceptable compliance history has been established;

e) exporters shall maintain all stocks of pre-signed certificates under strictly controlled conditions. All pre-signed certificates are legal documents and must be handled as such;

f) exporters shall provide to the CFIA inspector responsible for inspecting their operations - within a reasonable period of time prior to export - a record of their inspection of the product lot to be certified. This record shall include the name of the consignor and consignee, number of containers and weight, the results of inspection, the shipping date, the plant name if different from consignor, the signature of company official and the serial number of the certificate to be used. These records shall be maintained by the exporter and shall be made available to the CFIA inspector upon request;

g) exporters are to complete the remaining sections of the pre-signed certificate to accurately reflect the information provided for each "record" referred to in f). They are to advise CFIA immediately of any changes to information on records previously provided to CFIA;

h) each exporter shall maintain a ledger of the certificates received from the CFIA including a copy of all certificates issued. This ledger shall include certificate type, serial numbers, date received from CFIA and date issued;

I) exporters shall provide CFIA with adequate lead time for replenishing standing inventories of certificates;

j) exporters shall provide the CFIA with copies of all issued certificates within two days following shipment of the certified lots.

4.3 Under LLCPs the following documents may be issued:

a) For registered facilities:

- All Canadian certificates
- EU/Canada certificates, where the processor is on the EU Approved List
- Foreign country certificates

b) For non-registered facilities:

- Statement of Inspection
- FP-1408, Certificate of Inspection _____ Content
- EU/Canada certificates, where the processor is on the EU Approved List
- Export Certificate for Mexico

4.4 Should a non-registered exporter require a statement that

the product is Canadian, it is permissible to change the Statement of Inspection to become a "Statement of Origin and Inspection" and to reword the text to read "This is to certify that the fish described below is a Product of Canada and has been found.....".

4.5 Inspectors conducting audit/verification activities shall complete an audit report as per Chapter 3, Subject 3 of the Facilities Inspection Manual - Compliance Verification Policies and Procedures for Registered Establishments.

4.6 CFIA offices shall enter audit/verification and certificate information into the appropriate national database.

Amend no.3 25/02/1994

CHAPTER 11

CONSUMER AND TRADE COMPLAINTS

1. SCOPE

This document outlines the policy and procedures governing the investigation of consumer and trade complaints with respect to fish and fish products. A consumer complaint originates from a member of the general public and a trade complaint originates from a company, buyer or distributor. There are two classifications of consumer or trade complaints:

1) health complaints, which concern real or potential threats to human health or safety; and

2) other product related complaints, which do not present a threat to human health or safety.

2. AUTHORITIES

The Fish Inspection Regulations do not specifically address consumer or trade complaint investigations; however, during a consumer or trade complaint investigation, any number of the Fish Inspection Regulations or other Acts and Regulations may apply.

3. POLICY

3.1 The Regional Director of Inspection is responsible for all consumer and trade complaints received in his/her region.

3.2 All consumer and trade complaints will be investigated in a timely manner and all health complaints will receive immediate action.

3.3 Inspectors will investigate complaints in accordance with the procedures outlined in this document and with the relevant policies and procedures outlined in the Department of Fisheries and Oceans'(DFO) Inspection manuals.

3.4 The Health Protection Branch (HPB) of Health Canada will be advised of all health complaints in accordance with the procedures outlined in the Memorandum of Understanding (MOU)

between DFO and HPB.

3.5 The Regional Director of Inspection will coordinate all communications between the Inspection Branch and other parties (eg. HPB, industry, the media) for complaints received in that region.

3.6 The Regional Director of Inspection will immediately advise the Director of Inspection Branch, NHQ of all complaints involving health or safety issues or when the complaints become contentious.

3.7 All consumer or trade complaints are to be treated in a confidential manner. The complainant's identity will not be released without his or her consent.

4. PROCEDURES

Following are the duties of personnel responsible during the course of an investigation of a consumer or trade complaint.

4.1 INSPECTOR

The Inspector must determine as soon as possible whether the complaint is a health or safety issue or if the complaint is an other product related issue, and then proceed as follows:

a) completes, without delay, the Consumer Complaint Record Form (Appendix A) and, if applicable, the Supplementary Form for Suspected Food Poisoning (Appendix B) ;

b) if possible, obtains a sample of the product that is in the possession of the complainant;

c) immediately notifies the Regional Director of Inspection, through normal supervisory channels, of all complaints involving health or safety or contentious issues;

d) obtains instructions, through normal supervisory channels, regarding:

- the handling of the investigation; and
- whether to obtain an additional sample of the suspected product;

Note: When sampling lots implicated in a consumer or

trade complaint, every effort should be made to follow established sampling procedures.

e) arranges for the inspection of the obtained sample(s) and if necessary forwards the sample to the appropriate Inspection laboratory for analysis; and

f) through normal supervisory channels, forwards copies of all relevant documents to the Regional Director of Inspection.

4.2 **REGIONAL INSPECTION LABORATORY**

The Regional laboratory analyzes the sample on a priority basis and forwards the results and accompanying forms to the Regional Director of Inspection.

4.3 **REGIONAL DIRECTOR OF INSPECTION WHERE COMPLAINT ORIGINATED**

The Regional Director:

a) determines where the product was processed or imported;

b) forwards all complaints concerning products processed in or imported into another region directly to the appropriate Regional Director of Inspection for action;

c) immediately informs the Director of Inspection Branch, NHQ, of all complaints involving health or safety or contentious issues and provides updates during the course of the investigation;

d) contacts HPB and other federal, provincial and municipal authorities as necessary;

e) upon completion of any consumer or trade complaint investigation, forwards all documentation outlining the action taken to the Director of Inspection, NHQ and to the Regional Director of Inspection where the product was processed or imported; and

f) ensures the complainant is notified of the results of the investigation.

4.4 **REGIONAL DIRECTOR OF INSPECTION WHERE PRODUCT WAS PROCESSED OR IMPORTED**

The Regional Director:

a) determines if the product was previously inspected and forwards all related information to the region where the complaint originated;

b) informs the processor/importer/owner or legal agent of the product of the investigation and establishes procedures for follow-up as the investigation continues towards resolution;

c) ensures that the investigation is followed up via the QMP where valid complaints involve product from a registered facility.

4.5 **DIRECTOR, INSPECTION BRANCH, NHQ**

The Director:

a) advises the Director General of Inspection and Enforcement of all confirmed health or safety complaints and all complaints of a contentious nature;

b) refers the complaint to the appropriate NHQ chief for information and follow up with the Regions as necessary;

c) ensures that monthly and annual national reports of consumer complaints by region are produced; and

d) ensures that personnel administering the Offshore Inspection program are notified, and that they receive all relevant information, where complaints involve imported product from plants covered by a MOU.

5. FORMS/DOCUMENTS

- Consumer Complaint Record (FP1580) - Appendix A

- Supplementary Form for Suspected Food Poisoning (FP1580) - Appendix B

Amend no.3 25/02/1994

APPENDIX A

Amend no.3 25/02/1994

INSTRUCTIONS FOR COMPLETING THE CONSUMER COMPLAINT RECORD

PLEASE PRINT ALL INFORMATION. WHEN NO INFORMATION IS AVAILABLE ENTER "N/A" (NOT AVAILABLE) IN THE BOX.

1. Enter the name of the Fisheries and Oceans laboratory or Inspection office and the region where the complaint was received.

2. Enter the date the complaint was received (e.g. Y/A 93 (1993); M 06 (June); D/J 15).

3. Enter the laboratory identification number. The ten-digit number is generated as follows:

   i) the first two digits identify the region and district where the complaint originated. The first digit is to indicate the region. The second digit should be zero (0) if the complaint was received at the Regional Office or the correct digit if the complaint was received in one of the area offices in the region.

i.e. Headquarters	NHQ	70
Newfoundland	NFLD	10
Scotia-Fundy	SCFU	20
Gulf	GULF	30
Central and Arctic	C+A	50
Pacific	PAC	60
Quebec	QUE	80

   ii) the third to eighth digits identify the date the complaint was recorded:

   - third and fourth digits - the year (e.g. 93)
   - fifth and sixth digits - the month (01 (January) to 12 (December))
   - seventh and eighth - the day of the month (01 to 31)

   iii) the ninth and tenth digits are used to indicate the number of the complaints in consecutive order as they are received each day (e.g. 50-930615-01 would mean the first complaint received by Central and Arctic regional office on the fifteenth of June, 1993).

   iv) trade complaints are to be identified by the addition of the letter T to the end of the consumer complaint

number, (e.g. 50-930615-01T)

If other than Canada, enter the country of origin in the second part of box #3.

4. Check the box which indicates how the complaint was received. Did the consumer contact the department directly or was the complaint received through another department such as the Health Protection Branch (HPB) of Health Canada (HC), Industry Canada, a provincial ministry/department of health, etc.

5. If the complaint was received from another agency, enter the name and address.

6. Check if the complainant reported illness as a result of eating fish or fish products. If yes, complete the Supplementary Form for Suspected Food Poisoning (FP1580, reverse).

7. Print the complainant's name.

8. Print the complainant's home telephone number.

9. Print the complainant's home address.

10. Print the complainant's business telephone number.

11. Print the product brand name as printed on the product label.

12. Print the common name of the product including descriptive terms, noting the species name first (e.g. tuna chunk light, or shrimp peeled, deveined). Note packing medium (e.g. tuna chunk light vegetable broth).

13. Enter the net weight of the product package unit.

14. Enter the unit price of the item, or the retail price paid by the consumer.

15. Enter the manufacturer's container code placed on the packing carton or individual product package.

16. Identify the container pack type (e.g. canned, packaged, bulk).

17. Print the name and address of the manufacturer/distributor of the product as it appears on the product label. (If the

manufacturer or distributor is also the responsible agent, enter "the same" on the form.)

18. Print the name and address of the dealer/vendor where the item was purchased.

19. Enter the date of purchase (e.g. Y/A 93 M 06 D/J 15).

20. Briefly describe the nature of the complaint, providing all pertinent details. If possible, the following terms should be used in the description:

    a) illness;
    b) odour/flavour;
    c) appearance;
    d) foreign material;
    e) extraneous matter;
    f) parasites;
    g) label;
    h) other.

21. Check if the original complaint sample was examined by Fisheries and Oceans personnel. Note under what conditions the sample was stored, e.g. unopened, frozen, refrigerated, etc.

22. Enter the date the sample was inspected or examined.

23. Check if additional sample units were taken for investigation from any of the locations listed. Note the number of additional samples taken and from where.

24. Record the results of the inspection of the original product and the additional sample units, providing observations, action and comments.

25. Check the method of communication used to advise the complainant of the inspection results.

26. The Inspector is to print his/her name and sign the form.

27. Record if the complaint was referred to the Regional Office, the distributor, the manufacturer, HPB, etc.

28. Enter the date the report was completed.

29. If illness was involved, complete the supplementary form for suspected food poisoning.

Amend no.3 25/02/1994

APPENDIX B

Amend no.3 25/02/1994

INSTRUCTIONS FOR COMPLETING THE SUPPLEMENTARY FORM FOR SUSPECTED FOOD POISONING

PLEASE PRINT ALL INFORMATION. WHEN NO INFORMATION IS AVAILABLE ENTER "N/A" (NOT AVAILABLE) IN THE BOX.

1. Enter the name of the Fisheries and Oceans laboratory or Inspection office and the region where the complaint was received.

2. Enter the date the complaint was received (e.g. Y/A 93 (1993); M 06 (June); D/J 15).

3. Enter the ten digit laboratory identification number (see Section 3, Appendix A of this chapter).

4. Enter the date the illness occurred (e.g. Y/A 93; M 06; D/J 15).

5. Enter the date the illness was reported (e.g. Y/A 93; M 06; D/J 15).

6. Record the number of people affected.

7. Record the total number of people that consumed the food containing fish or fish products.

8. Check the symptoms reported by the complainant. Print any other symptoms not listed but experienced by the complainant.

9. Indicate the length of time which elapsed from the time of eating to the time the symptoms occurred.

10. Indicate the length of time the illness lasted.

11. Check if a doctor was consulted.

12. Print the doctor's diagnosis.

13. Print the doctor's name, business address and business telephone.

14. Check where the food was eaten. If applicable, provide the name of the public establishment.

15. Check if the meal was catered.

16. Print: "see attached". On a separate page(s) list the complainant's 24-hour food recall noting all foods and beverages, including the food suspected of causing food poisoning, and all meals and snacks consumed immediately prior to the illness.

    Note: Items 17 to 32 inclusive deal primarily with fish or fish products purchased and prepared at home or in a private residence.

17. Check the form in which the fish or fish product was purchased.

18. Indicate the period of time which elapsed from purchase to consumption (generally in hours for fresh product and in months for canned or frozen product).

19. Indicate the amount of time that elapsed following opening of the package until consumption.

20. Enter the cooking time in hours or minutes.

21. Enter the cooking temperature or microwave power level.

22. If frozen, indicate if the product was thawed prior to cooking.

23. Indicate how the product was thawed.

24. Describe how the product looked prior to cooking.

25. Record the size or approximate weight of the portions consumed.

26. Check if there was a noticeable "off" odour prior to cooking.

27. Record the method used for cooking, e.g. baking, broiling, frying, sautéeing, steaming.

28. Record the product odour when the food was served. The following examples may serve as a guide:

    Taint - rancid, abnormal, contaminated;
    Decomposition - fruity, vegetable, sour, yeasty fermented, ammonia, putrid or faecal.

29. Record in minutes, hours or days the time delay between cooking and serving.

30. Check if the product was refrigerated between cooking and serving.

31. Record in minutes, hours, days, etc., how long the product was refrigerated.

32. Check which ingredients were used in the food preparation. Note any special ingredients.

33. Check if a sample of the suspect product was collected for bacteriological or chemical testing.

34. Record the date the analysis was completed. (e.g. Y/A 93 M 06 D/J 15)

35. Summarise the results of the analyses indicating possible causative agents. Attach bacteriological and/or chemical work sheets, if available.

36. Evaluate the validity of the complaint and record action taken.

37. Enter the date of the report. (e.g. Y/A 93 M 06 D/J 06)

38. The officer finalizing the investigation is to print his/her name and sign the report.

CHAPTER 12, SUBJECT 2

PACKAGE INTEGRITY EVALUATION

1. SCOPE

This document outlines a new evaluation category, "package integrity evaluation" which will be used to represent those products which are evaluated against Section 7 of the FIR but which are not packaged in a hermetically sealed container and subjected to a heat treatment for sterilization or pasteurization.

Products which are represented by the above criteria include, but are not limited to:

- fish sauces in glass or plastic bottles; and
- semi-preserved products in metal containers (fried dace, anchovies).

2. AUTHORITIES

Fish Inspection Regulations (FIR), C.R.C., 1978, c.802, Part I, General.

Section 7

Unless otherwise permitted by the Minister, fish shall be packed in new, clean, sound containers.

3. POLICY/PROCEDURES

3.1 Products which are evaluated for package integrity may be destructively sampled and the sample size used will follow the Codex Sampling Plan #1, Inspection Level I, AQL 6.5 for initial inspection and the Codex Sampling Plan #2, Inspection Level II, AQL 6.5 for reinspection.

3.2 A sample unit will be rejected if the container is damaged sufficiently to cause leaking or if the product is exposed to the environment. The lot will be considered reject if the number of sample units rejected is greater than the higher acceptance level for tainted or unwholesome. Please note, if glass chips are found in one sample unit, then the lot is automatically rejected for critical foreign material.

12	2	2
New		24/05/96

3.3 Cost-recovery fees will not be applied until the fee schedule has been amended to include this evaluation.

3.4 The INIM database and the Mandatory Inspection List (MIL) will be amended accordingly and package integrity evaluation will be treated on the MIL in the same manner as the container integrity evaluation.

CHAPTER 13, SUBJECT 1

PRODUCT STANDARDS WORKSHOPS - GENERAL

1. SCOPE

This document outlines the policies and procedures to be used in the execution of workshops that are held to develop and revise product standards and to train and evaluate Inspectors in the application of product standards.

2. AUTHORITIES

Fish Inspection Act. R.S.C., 1985, c. F-12, as amended by R.S.C., 1985, c. 31 (1st supp.)

Fish Inspection Regulations (FIR), C.R.C. 1978, c.802.

The Fish Inspection Act and Regulations do not specifically refer to product standards workshops; however, the Act provides the authority to designate Inspectors and to make regulations to prescribe standards. In addition, the Act prohibits the import or export of fish intended for human consumption that is tainted, decomposed or unwholesome. The Regulations provide definitions for "tainted", "decomposed" and "unwholesome" and prescribe certain product standards. In addition, the Regulations state that all fish are subject to inspection and that fish that are tainted, decomposed or unwholesome or otherwise fail to meet the requirements of the Regulations may not be imported or exported. Specific standards, not included in the Regulations, provide more precise interpretations and definitions of the terms "tainted", decomposed" and "unwholesome" as well as the phrase "fails to meet the requirements of the Regulations".

NOTE: The authorities listed above apply to all Subjects in this chapter.

3. DEFINITIONS

Analyst - a product inspector who:

a) has demonstrated ability in the application of a specific product standard by attaining a score of at

least 80% overall, with a minimum score of 75% for both reject samples and acceptable samples at their most recent evaluation;

b) inspects the product on a regular basis;

c) has completed a recognized course in sensory evaluation techniques.

Check samples - samples of specific products or product groups of known sensory, physical or chemical characteristics presented to inspectors or prospective inspectors in order to monitor/evaluate their performance.

Coordinator - an inspector responsible for the planning, organization, execution, data analysis and reporting of results of product standards workshops. If qualified, the inspector may also serve as a trainer at the workshops.

Expert Analyst - a product inspector who is recognized as a sensory analyst and:

a) has demonstrated expertise in the application of a specific product standard by attaining a score of at least an 85% overall, with a minimum score of 80% for both the reject samples and acceptable samples at their most recent evaluation for that product or product type (this score must be attained at two consecutive workshops conducted over a period of not less than two months; this accreditation is valid for a period of two years);

b) inspects the product on a regular basis and has at least two years experience inspecting the product or product type; and

c) has completed a recognized course in sensory evaluation techniques.

Expert panel - a group of three "expert analysts" who render expert sensory decisions on samples presented at Assessment/Accreditation and other workshops and who are able to justify the decisions based on sensory attributes.

Product standard - a document which defines the minimum acceptable physical and sensory quality of a product with respect to taint, decomposition and unwholesomeness, and other applicable requirements (including grade standards)

as defined in the Fish Inspection Regulations, and provides methods for determining that acceptability.

Reference standard - a sample that is used to define an attribute or a specified level of a given attribute.

Sample - a unit of product presented at a workshop for which an individual result is expected. Such a sample could consist of a single piece of fish or fish product, several pieces of fish or fish product, an entire fish or more than one fish.

4. POLICY

4.1 General

4.1.1 Product inspections must be conducted by qualified inspectors.

4.1.2 Samples will be collected in order to evaluate the application of the standards.

4.1.3 Workshops will be conducted according to the policies and procedures outlined in this document.

4.1.4 Workshops may be conducted to meet the following objectives:

a) to train inspectors in the application of product standards;

b) to develop new standards or revise existing standards;

c) to evaluate the ability of inspectors to interpret and apply product standards; or

d) to evaluate if the interpretation of product standards is done uniformly and consistently.

4.1.5 Workshops will be conducted at either the National or Regional level. National workshops should be coordinated by, or under the direction of, a representative of National Headquarters. Regional workshops should be coordinated by inspectors identified or approved as Coordinators by the Regional Director of Inspection and National Headquarters. These workshops may be coordinated within one Region, or two or more Regions may together plan and execute Regional

workshops.

4.1.6 Regional Workshop Technical Coordinators will provide National Headquarters with basic details of all Regional workshops at least one month in advance of the workshop.

4.1.7 Inspectors who have extensive experience with respect to specific fish and fish products are deemed to be qualified in the inspection of these products pending verification through official assessment. All new inspectors must be evaluated before they qualify as analysts of specified products or product groups.

4.1.8 All product inspectors should be evaluated at least once every three years in each product class applicable to their duties to demonstrate that they continue to have the ability to interpret and apply the standards for those products. Three years will be the normal period for re-evaluation, but the period may be extended in specific circumstances. Any extension of the three-year time frame must be approved by NHQ.

4.1.9 The evaluation of inspectors may be accomplished at either National or Regional Workshops. Regional workshops must follow a format similar to that used for National workshops. Procedures followed during Regional workshops are subject to approval by National Headquarters.

4.1.10 National Headquarters is responsible for coordinating and conducting assessments to evaluate the interpretation and application of product standards, for designating which inspectors are qualified to be on Expert Panels at assessment workshops, and for liaising with Regional representatives for Regional workshops.

4.2 Selection of Expert Analysts

Expert analysts are appointed after demonstrating during assessment workshops that they are able to consistently and accurately determine the quality of a product. This will be determined through one or a combination of:

a) agreement between their decisions and the decisions of a panel of expert analysts each of whom have previously proven their ability with the specific product type; or

b) in the absence of established expert analysts for

that product, their ability to consistently and correctly identify the acceptability of, and rank by quality level, sample units which have been specially prepared under uniform spoilage conditions for known periods of time; and

c) agreement between their results and the results of chemical analysis of the same samples, where useful chemical indicators of quality exist.

4.3 Participants

4.3.1 For National workshops, at least one inspector from each Region in which the product is normally inspected, or could be inspected, should participate. Where products are specific to only one or two Regions, at least three inspectors from this (these) Region(s) should participate.

4.3.2 The number of inspectors participating in a workshop should be limited so that products can be effectively evaluated. Wherever possible, the number of participants should not exceed 10 per trainer or expert panel, if the product is tasted. **The number of participants should never exceed 12 in any instance.**

4.3.3 Participants at workshops should be inspectors who routinely inspect the product(s) in question, and/or inspectors who will be inspecting this(these) product(s).

4.3.4 Administrative personnel, managers, and others who would not normally be inspecting the product may attend the workshop as organizers or observers as required, but should not normally participate as inspectors.

4.4 Samples

4.4.1 The type and numbers of samples required will depend on the goals of the workshop. In general, samples should represent a complete range from best to worst possible quality and should include "borderline" quality product. Each of the defects generally encountered should be represented. Depending on the goals of the workshop, samples from lots which have previously been inspected may be included. Relevant reference samples may also be presented to inspectors as appropriate.

4.4.2 The previous history of samples used for each workshop should be well-documented. Samples of commercial product

will be used but samples from controlled-spoilage runs will also be included whenever possible. (Appendix A provides procedures for the preparation of controlled-spoilage samples for frozen product.)

4.4.3 Appropriate microbiological, chemical and physical tests should be conducted on workshop samples whenever possible before the workshop. All chemical analysis on workshop samples will be be conducted by the National Centre for Quality Indicators. Regional laboratories, when directed by National Headquarters, will collaborate on the collection and analysis of samples for this purpose.

4.5 Facilities

All workshops should be conducted at appropriate inspection facilities.

4.6 Support

Regional personnel will, upon request from National Headquarters, contribute to the collection and preparation of samples for workshops and will assist with workshop execution, the analysis of both samples and data and the preparation of reports.

4.7 Reports

4.7.1 National Headquarters will provide a report to Regional Directors summarizing the results of each National workshop.

4.7.2 A report on the results of each Regional training or assessment workshop will be prepared by the workshop coordinator and forwarded to the Regional Director or designate for information and review. The report will then be forwarded to NHQ.

4.8 Inventory of Workshop Results

4.8.1 The Regional Training Coordinators will be responsible for tracking inspector attendance at training and assessment workshops. The Regional Training Coordinators are to provide the Regional Directors of Inspection with reports indicating required training and the accreditation expiry dates, as required.

4.8.2 NHQ will maintain an inventory of expert analysts for each product.

5. PROCEDURES

5.1 Normally, workshops will include a number of sessions which involve the presentation of sample units to the participants for independent assessment. Following are guidelines for these sessions.

5.1.1 The number of samples presented at each session, the amount of time between sessions and the total number of samples examined per day will be controlled to prevent sensory fatigue. Such factors as, whether the samples are to be assessed for odour and/or flavour, the overall quality of the samples, the size of the samples and the level of experience of the candidates will be considered in making these decisions.

5.1.2 As a general guideline, the number of units presented at each session will be limited to 15 where both flavour and odour are to be assessed and 20 where only odour is to be assessed. A break of at least 15 minutes should be provided between each session.

5.2 The procedures for assessing samples will be followed for each workshop session. (See Appendix B for the procedures to be followed.)

6. FORMS/DOCUMENTS

Appendix A - Procedures for the Preparation of Controlled-Spoilage Samples of Frozen Product for Workshops

Appendix B - Procedures for the Assessment of Samples in Workshop Sessions

New 05/05/95

APPENDIX A

Procedures for the Preparation of Controlled-Spoilage Samples of Frozen Product for Workshops

1. Determine the purpose and scope of the workshop.

2. Determine the species and product type to be used for the workshop (e.g. cod fillets). Determine the form of presentation, the unit size, the number of units to be presented to inspectors and the overall number of units required. Calculate the amount of raw material required.

3. Analyses for appropriate chemical indicators should be conducted on workshop samples to give additional information on their quality and build an information base; however, not all workshop samples need to be analyzed. Determine the sample preparation, preservation and identification requirements for chemistry samples.

4. Obtain the required amount of fish of very fresh quality of the desired species. If fish are procured from a local fisherman, the inspector should be present to monitor the catch and subsequent handling of the fish. Where this is not possible, specific instructions should be provided to ensure that the fish are carefully handled (e.g. no forking or gaffing), bled, and very well-iced to ensure that quality changes are minimized prior to receipt by DFO.

5. Day-zero samples should be prepared, packaged, identified and frozen immediately upon receipt of the fish. In instances where fillets are being frozen, they are to be frozen in a flat position. All frozen product should be vacuum packaged in individual packages of adequate quality to protect the samples from further deterioration during frozen storage. The remaining fish should be well-iced in insulated boxes (using good commercial practice) and maintained at 0 to 4°C throughout the course of the spoilage run. Melt water should be allowed to drain and fresh ice should be added as required.

6. Fish should be withdrawn and workshop samples prepared at regular intervals to provide a complete range of samples of both acceptable and unacceptable quality. The number and timing of sample withdrawals will depend on the rate of spoilage, and may have to be adjusted as the spoilage run continues. An initial guideline for sample withdrawals of well-iced fresh cod is at 0, 3, 6, 9, 12, 14, 16, and 18

days. All prepared samples should be contact-frozen using equipment capable of reducing the temperature at the centre of a 25 mm thick block of unpackaged fillets to -21°C in two hours or less.

7. A representative sample of raw fish (and fillets, where appropriate) should be graded by one or more expert analysts at the time of preparation of each treatment group. Representative chemistry samples should also be collected for each treatment group.

8. Spoilage workshop samples should simulate commercial samples. For example, for a workshop concerned primarily with the identification of decomposition and taint in cod fillets, the fillets should be trimmed, boned, and candled.

9. If the primary purpose of the workshop is to assess the ability to recognize odours or flavours of decomposition or taint, an effort should be made to maintain homogeneity within each sample unit. Only after the ability to consistently identify these odours/flavours has been demonstrated, should samples illustrating variability within the sample units be presented.

10. Package each sample unit separately, withdrawing as much air as possible from the package before it is sealed. Vacuum packaging should be used where such equipment is available. Permanently mark each sample unit with the species and treatment group. Maintain samples at -26°C or below to minimize changes during storage.

11. The above guidelines are appropriate for preparation of samples which follow a typical pattern of decomposition prior to freezing. However, as a variety of types of spoilage are found during routine inspections, other treatments (e.g. holding at room temperature or abuse during frozen storage) may also be appropriate, depending on the specific product type and the goals of the workshop.

APPENDIX B

Procedures for the Assessment of Samples in Workshop Sessions

The following is a description of the general procedures used to examine product samples in sensory-workshop sessions.

1. All Inspectors attending the assessment session must not have any health-related problems which would interfere with their ability to assess product based on odour characteristics. Any Inspector having any upper-respiratory tract problems such as a cold, allergies, etc. must notify the Workshop Coordinator prior to or during the workshop if symptoms should become evident.

2. Inspectors must refrain from using perfume or scented lotions while they are attending the sessions.

3. Inspectors will wear clean white lab coats or other appropriate protective garments which should be removed when leaving the evaluation area.

4. To ensure good sanitation during assessment sessions, Inspectors must wash and adequately rinse their hands before examining the product.

5. Odourless/tasteless water and unsalted crackers will be provided as rinsing materials.

6. All samples to be tasted are to be handled in a sanitary manner.

7. Samples will consist of individual samples of fish or fish product. No information regarding the origin of the individual samples or previous inspection results will be provided; however, other necessary information may be given as appropriate.

8. The samples are to be assessed only on the basis of odour and flavour and should be rejected if they contain indicators of taint and/or decomposition that are distinct and persistent.

9. A worksheet will be provided for each session on which Inspectors and Experts will record whether each of the samples is, in their opinion, of acceptable or reject quality.

10. The Inspectors and the Expert Panel will examine the product at the same time, moving from sample to sample in random sequence as positions are available.

11. There must be no communication among Inspectors while they are examining the product.

12. Although the surface of the samples may be broken in order to aid in reaching a decision, samples should generally be handled in a non-destructive manner.

13. All assessors will examine each sample and decide, solely on the basis of odour or flavour, whether it is tainted and/or decomposed. Any persistent and distinct odours or flavours indicative of taint or decomposition, regardless of the amount of the sample affected, will result in the sample being failed.

14. For each sample the assessor will indicate their decision by placing a mark in the appropriate space. To indicate that the sample is of acceptable quality, a mark is to be placed in the "A" column. To indicate that the sample is of reject quality, a mark is to be placed in the "R" column.

15. For those samples that are failed, the assessors will also record the reason for failing the sample (i.e. "T" for taint and/or "D" for decomposition) next to the mark in the "R" column. Additional information may be noted in the "Comments" column.

16. A description of the odour or flavour that resulted in the decision indicated should also be written in the appropriate space in the "Comments" column.

17. Inspectors will also indicate their opinion of the quality of the sample by recording the "intensity" or "degree" of the pass/fail decision by placing a vertical mark on the 10-centimetre line scale provided on the worksheet. Positions from the extreme left end of the line to the midpoint indicate that the sample is of acceptable quality (i.e. pass) whereas those to the right of the midpoint indicate that the sample has been failed. As one moves from the left to the right of the line, the quality of the sample becomes worse. The midpoint of the line must not be used in this exercise.

18. After all samples have been evaluated in a session, the

worksheets are to be handed to the Workshop Coordinator. The Inspectors will then leave the room until they are asked to return for the next session. If data collection and discussion are part of the session, worksheets will be retained by each assessor until the completion of that portion of the exercise, then given to the Workshop Coordinator for data entry. Original worksheets will be returned to the participants at the end of the session. Unless agreed upon prior to the session, there should be no discussion of the samples between sessions by the assessors.

19. A break of at least 15 minutes will be provided between sessions.

20. The number of samples to be assessed will be limited to a maximum of 150 per day.

CHAPTER 13, SUBJECT 2

PRODUCT STANDARDS WORKSHOPS - TRAINING WORKSHOPS

1. SCOPE

This document outlines the policy and procedures to be used in conducting workshops that are held to train inspectors in the correct interpretation and application of product standards.

2. POLICY

2.1 General

All training workshops in product standards will be conducted in accordance with the policies and procedures of the National Inspection Training Program.

2.2 Participants

See Subject 1 of this chapter, Section 4.3.

2.3 Trainers

2.3.1 Trainers must be expert analysts for the specific product or product type and should have successfully completed a recognized course in sensory evaluation techniques.

2.3.2 Training sessions should utilize three expert analysts to provide sensory decisions but may use one or two depending on the availability of personnel, the nature of the product and the participants' needs.

2.3.3 Where two expert analysts conduct a training workshop, the decision on each sample will be based on their independent decisions. In case of a "split decision", the decision on a sample should be reached through consensus.

2.3.4 Where three expert analysts conduct a training workshop, the decision on each sample will be based on their independent decisions. In cases of disagreement between the analysts, the majority decision will be observed.

2.4 Samples

See also Subject 1 of this Chapter, Section 4.4.

2.4.1 The primary source of samples for product standard and training workshops should be from the controlled spoilage of the very best quality fish of the desired species. (Appendix A, Subject 1 of this Chapter outlines guidelines for the preparation of samples.)

2.4.2 Good examples of specific attributes, where found, should be set aside following routine inspections of domestic and imported product. These samples should be retained in the Region; however, an inventory, identifying the product and describing attributes, should be forwarded to the Regional Workshop Technical Coordinator and the National Workshop Coordinator.

2.4.3 Ideally, samples which demonstrate each of the attributes listed in the product standard should be available for discussion at a training workshop.

2.4.4 Where available, reference standards should be used to aid in defining an attribute or a specified level of a given attribute.

2.5 Facilities

See Subject 1 of this Chapter, Section 4.5.

3. PROCEDURES

3.1 General

The steps which follow will be included in all Regional and National training workshops.

3.1.1 The procedures used in sensory evaluation should be reviewed with all participants prior to the session.

This includes the procedures for assessing appearance, odour, taste and texture characteristics, methods of sample handling, rinsing procedures and general and special conditions needed for evaluation.

3.1.2 Trainers will familiarize participants with the characteristics of the fish or fish product.

This may be accomplished using photographs, slides, overheads, literature or textbooks, by observing establishments processing/packing the product, by pilot-scale processing, and/or by demonstrating a variety of samples of product.

3.1.3 Coordinators/trainers will introduce the standard which applies to the fish or fish product of interest.

Each requirement of the standard will be defined and explained through discussion, in conjunction with the requirements of 3.1.2 (describing/demonstrating the characteristics of the product) and 3.1.4 (demonstrating the range of qualities). Other appropriate information, such as any special sampling or examination requirements, should be included.

3.1.4 Trainers will demonstrate to the participants, and discuss the attributes of, a range of acceptable and unacceptable product.

Where possible, the variation in quality found under normal circumstances will be represented. Samples of known quality should be used. These may be derived from previously inspected lots, previous workshops, controlled-spoilage exercises, reference standards or offshore projects.

3.1.5 Trainers will examine individual samples at the same time as the participants. The objective is to give the participants the opportunity to independently examine and render a decision on the samples and compare their results with those of the trainers and the other participants.

This part of the workshop should include at least three sets of samples with a complete evaluation of one set before the next set is begun.

The samples should be blind-coded and presented in random order. The trainers and participants should individually examine the samples during the same period of time. A decision should be rendered on each sample and the observations recorded on the appropriate worksheet. There should be no communication whatsoever among the trainers or participants until all samples in a set have been examined and all worksheets have been passed to the coordinator.

The decisions of both the trainers and participants should be tabulated and presented to everyone. The worksheets should be photocopied and the originals returned to the participants. A copy of each worksheet should be retained by the coordinator. Open discussion of the results should be encouraged during which the trainers should review and justify their decisions. Samples that exhibit characteristics of particular relevance to the exercise should be pointed out. These samples should be discussed and re-examined. Any information pertaining to the samples, including previous inspection results or the results of chemical analysis, should be provided to the trainers and participants.

A decision to include additional sample sets should depend on the overall results of those receiving the training.

3.1.6 In order to assess the success of the training and determine if additional training is warranted, new sets of samples will be evaluated. Trainers will again examine individual samples at the same time as the participants.

As in part 3.1.5, this should include at least three sets of samples with a complete evaluation of one set before the next set is begun.

The samples should be blind-coded and presented in random order. The trainers and participants should individually examine the samples during the same period of time. They should render a decision on each sample and record their observations on the appropriate worksheet. There should be no communication whatsoever among the trainers or participants until all samples in all sample sets have been examined and all worksheets have been passed to the coordinator.

The coordinator should examine the individual results with the trainers to determine the performance of each participant. This is calculated from the number of correct responses to the samples presented. A correct response is one that is in agreement with the decision of the trainers (consensus decision if there are two trainers or a majority decision if there are three trainers). When determining each participant's result, the number of individual correct accept and correct reject decisions must be considered as well as the overall number of correct decisions.

Trainers will discuss the results of the training

individually with each participant, and where appropriate recommend further training (e.g. working with a qualified inspector of the product in question).

3.1.7 Participants should be encouraged to provide comments on any and all aspects of the workshop, both during and at the end of the workshop. Additional comments may be submitted (either written or verbally) to the workshop coordinator after the workshop. Any additional comments should be provided as soon as possible after completion of the workshop since a summary of the comments will be included in the workshop report.

3.1.8 The coordinator will provide a written report to NHQ outlining the results of the workshop (if a National Training Workshop) or to the Regional Director of Inspection (if a Regional Training Workshop).

For National Training Workshops, NHQ will forward a copy of the report on the workshop, as well as a copy of a report on each inspector's performance, to the appropriate Regional Directors of Inspection.

In addition to the results, workshop reports should include recommendations for additional training and/or formal evaluation. Workshop results should be retained for future reference.

3.2 Comments

The steps in the training process may or may not occur as a continuous series. Each step may range in duration from several hours to a series of sessions occurring over weeks or months. The time taken by the trainer(s) to complete each step of the process is dependent on the participants' progress and the results of evaluation workshops.

When a participant has successfully completed all steps of the training process for a particular product or product type, the coordinator will recommend the individual concerned for an official evaluation to qualify him/her as an analyst for that product.

CHAPTER 13, SUBJECT 3

PRODUCT STANDARDS WORKSHOPS - DEVELOPMENT/REVISION WORKSHOPS

1. SCOPE

This document outlines the policy and procedures to be used in conducting workshops that are held to develop sensory or physical assessment criteria for new product standards and to review these criteria for existing standards.

2. POLICY

2.1 General

The Fish Inspection Regulations prohibit the import or export of fish that is tainted, decomposed, unwholesome or otherwise fails to meet the requirements of the Regulations. The Regulations provide definitions for "tainted", "decomposed" and "unwholesome". Standards provide a description of defects and the level of each that would result in sample unit being considered tainted, decomposed, unwholesome or that would result in it not meeting other requirements of the Regulations. Standards also provide the methods used to evaluate the product and the acceptance criteria used to determine if a lot is acceptable.

Existing standards will be reviewed periodically to ensure that they are current and new standards will be developed to update "scoring guidelines" and to define requirements for new products.

2.2 Participants

See also Subject 1 of this Chapter, Section 4.3.

The participants at development/revision workshops will include at least one representative from National Headquarters or a designate and at least one representative from each Region in which the product in question is produced or into which it is imported. Inspectors involved in these workshops should be thoroughly familiar with the product in question or similar products, should routinely inspect the product and should have a good understanding of the standards development process.

2.3 Reference Documents

Reference documents will be available for use during the workshop. Examples of these documents should include scoring guides and/or draft standards previously used by the Inspection Directorate, other Canadian standards, product standards used by Codex and/or in other countries, and relevant standards for other product types.

2.4 Samples

See also Subject 1 of this chapter, Section 4.4.

2.4.1 Product samples will be available for demonstration, inspection and discussion. The samples should represent a complete range of product types and quality from the best available through borderline to fully unacceptable. All appropriate product presentations should be available for discussion.

2.4.2 Samples should be available which demonstrate each attribute for the product.

2.5 Facilities

See Subject 1 of this chapter, Section 4.5.

3. PROCEDURES

3.1 General

3.1.1 Depending on the goals of the workshop, the development or revision of a product standard may be accomplished by a review of existing documents, through discussion and/or through product examination.

3.1.2 Several sessions involving the examination of the product, standard revision, and standard testing (by means of independent assessment followed by discussion of results) should take place until a consensus is reached that the standard adequately describes the criteria for assessing the product. Proven chemical indices of spoilage should be used where applicable and feasible.

3.2 Testing new or revised standards

3.2.1 After agreement has been reached by the participants that the new or revised standard accurately describes the minimum acceptable quality for the product, samples should be examined independently by all participants and the results should be recorded and examined. Chemical analysis should be conducted where applicable and feasible and the results should be compared with the results of sensory analysis. Inconsistencies should be identified and addressed.

3.2.2 The description of the cutoff between product of acceptable and reject quality is fine-tuned as further workshops are conducted, as the results of sensory analyses are compared with applicable chemical indicators of spoilage, as check samples are evaluated and as experience is gained with the application of new or revised product standards.

3.3 Comments

The steps in the standards development and revision process may or may not occur as a continuous series. Each step of the process may range in duration from several hours, to a series of sessions occurring over weeks or months.

CHAPTER 13, SUBJECT 4

PRODUCT STANDARDS WORKSHOPS - ASSESSMENT WORKSHOPS

1. SCOPE

This document outlines the policy and procedures to be used in conducting workshops that are held in order to determine the ability of inspectors to interpret and apply product standards uniformly and consistently.

2. POLICY

2.1 Expert Panel

An expert panel of three expert analysts, preferably from different Regions, will render expert sensory decisions on sample units presented at National Assessment Workshops. For Regional Assessment Workshops, at least one of the three expert analysts should be from a Region other than the Region where the workshop is being held.

2.2 Candidates at Assessment Workshops

2.2.1 Priority for participation in assessment workshops will be given to inspectors whose qualification period is about to expire and whose duties involve the inspection of the product in question.

2.2.2 An inspector should not be assessed when he/she is affected by a cold, allergies or other condition which would prevent an objective evaluation of his/her performance. It is the inspector's responsibility to advise the workshop coordinator of any such condition before the assessment begins. When an inspector is unable to participate in an assessment due to a specific condition, the inspector should be assessed at the next earliest opportunity. Regional organizers should ensure that prospective participants at workshops are aware of these situations so that unnecessary travel costs can be avoided. Regions should also advise the workshop coordinator if a prospective participant will be unable to take part in the workshop because of illness or for any other reason so that his/her place on the workshop can be reassigned.

2.3 Analyst Status

2.3.1 An inspector will be considered an analyst qualified to inspect a specific product when he/she has:

a) had at least six months experience assisting another inspector with the inspection of the product;

b) scored at least an 80 % average on an official assessment for that product or product type based on the results of a National or Regional Expert Panel consisting of three expert analysts, or in the absence of established expert analysts, by correctly identifying and ranking by quality level 80 % of the samples from a controlled-spoilage run. (In both situations, proven chemical indices of spoilage should be used where applicable and feasible.); and

c) correctly identified at least 75 % of both the acceptable and reject samples presented at the official assessment referred to in b) above. As in b), this could be based on the results of an Expert Panel, or in the absence of established expert analysts, on the inspector's ability to correctly identify and rank samples by quality level from a controlled-spoilage run. (Again, proven chemical indices of spoilage should be used where applicable and feasible.)

2.3.2 An inspector not meeting the criteria specified in 2.3.1 may be reassessed after gaining additional experience through on-the-job training in the inspection of the product or product type . Regions are responsible for ensuring that these inspectors receive additional training, if the inspection of the product in question is to still be one of the inspector's responsibilities.

2.3.3 Regions are responsible for ensuring that inspectors are assessed regularly. Inspectors who have not been assessed during the previous three years will lose their status for the specific product or product type and will not be able to conduct inspections of that product. Coordinators shall provide as much advance notice as possible of scheduled assessment workshops.

2.3.4 If an analyst fails an assessment, steps will be taken to determine the cause for the failure. The inspector is not permitted to inspect the product in question until having

received additional training and been reassessed. The results and accompanying information will be reviewed by National Headquarters.

2.4 Application of Product Standards/Check Samples

National Headquarters has the ultimate responsibility for determining if product standards have been correctly applied. In order to assess the application of standards, NHQ will:

a) request that the Regions procure and maintain additional sample units from lots inspected and forward these samples, on request, with a copy of the results of the inspection;

b) arrange for the evaluation of these sample units by an Expert Panel at a National Workshop (this evaluation may include chemical analysis); and

c) prepare a report on the results of the evaluation and forward a copy to the appropriate Regional Director(s) of Inspection.

2.5 Samples

See also Subject 1 of this Chapter, Section 4.4.

2.5.1 Samples from controlled-spoilage runs should be used during assessments where feasible and when available. Samples from lots previously inspected should be used to determine if standards have been correctly applied.

2.5.2 The original results for samples retained from previous inspections must be available to the workshop coordinator, but not to the experts and not to those being assessed. A special effort should be made to include samples previously examined by the inspectors who are to be assessed.

2.6 Facilities

See also Subject 1 of this Chapter, Section 4.5.

2.6.1 Where available, panel booths will be used to isolate sample units.

2.6.2 Only one inspector will examine a sample or be at a booth at one time.

2.7 Examination of Procedures and Methods

A representative of National Headquarters will review procedures and methods used during product inspections. Laboratory report forms, summary reports and sampling procedures will also be reviewed to determine if the standards have been correctly applied.

3. PROCEDURES

3.1 General

See Procedures in Subject 1 of this Chapter.

3.2 Samples

3.2.1 Individuals being assessed should examine a minimum of 100 samples at each assessment workshop; however, a minimum of 150 samples should be used where the product (such as canned tuna) consists of several species, styles of pack or packing media. The samples will be examined over several sessions as indicated in the procedures described in Subject 1, Section 5.

3.2.2 Participants and the expert panel should have no prior knowledge of the source of any of the samples used. Samples should be blind-coded using a series of three-digit random numbers and they should be presented in standard containers appropriate to the product and not in the original packaging.

3.3 Explanation of Procedures

3.3.1 Before the assessment begins, the coordinator should explain how the workshop is to be conducted including:

a) the number of samples that are to be evaluated;

b) the amount of time that will be provided for the evaluation;

c) the attributes of the product that are to be evaluated;

d) the method of recording the results;

e) the method that will be used to determine the

participants' scores; and

f) when the participants will be provided with their results.

The examination of the samples should not commence until all participants have indicated that they understand the above procedures.

3.4 Sample Examination

3.4.1 At each session, the three members of the expert panel and all participants will independently examine each sample and determine, based on the attributes that are to be evaluated, whether they would pass or reject the samples. Results will be recorded on worksheets provided by the coordinator. When all samples have been examined for a particular session, these worksheets will be passed to the coordinator who will transfer the results to a master form.

3.4.2 There must be no communication between the members of the Expert Panel and the participants or amongst the participants regarding the results, until all sessions for a particular product have been completed. Communication among the members of the expert panel regarding any results must be limited to specific items identified by the Workshop Coordinator. In this regard the Coordinator will identify samples of questionable quality or for which the results among the expert panellists, or between the expert panel and the participants, are not in agreement, for the purpose of identifying specific problems in the results and for identifying samples which should not be used in the assessment session. Immediately after each sample set the Coordinator will communicate any such results to the expert panel and the implicated samples will be re-examined by the expert panel along with adequate discussion to provide the Coordinator with sufficient information to reach a final decision in each sample (in some instances it may be necessary to discard the particular sample from the session).

3.5 Chemical Analysis

The coordinator will review the results of sensory analysis. Where there are contradictory results within the Expert Panel for a particular sample, or between the Expert Panel and the participants, and where there are proven

chemical indices of quality for that product, that sample may be analyzed as appropriate and the results compared with the results of sensory analysis. If the results for a proven chemical indicator show that a sample unit is of reject quality, that will normally be the final decision. Otherwise any such chemical results can only be classed as inconclusive and the expert panel results will be final.

3.6 Determination of Results

3.6.1 An inspector's overall results will be determined:

a) by comparing his/her individual results with the results of an Expert Panel; or

b) where only controlled-spoilage samples were used, by comparing the inspector's results with the known history of the sample.

In either case, the results of chemical analysis should be used to assist in the interpretation of the results of sensory analysis where there are proven chemical indices of spoilage.

3.6.2 Where the results will be determined by the decisions of an Expert Panel:

a) the participants will be scored against the majority decision of the expert panel except in instances where a conclusive result of a proven chemical indicator showed the expert panel to be incorrect or for any samples which were to be discarded from the session. When tallying the scores, the coordinator will keep a separate record of the number of correct accept and reject decisions for each of the participants;

b) a participant's score is determined by calculating the total number of times their individual decisions agree with the correct decisions on individual sample units. This score should be expressed as a percentage and should be determined for the participant's score on "accept" and "reject" sample units as well as on the average of the two scores.

3.6.3 Where controlled-spoilage samples are used, the results will be determined by calculating how well the participant is able to identify and/or rank samples in terms of whether each sample was accepted or rejected. This assumes that a

clear cutoff between acceptable and reject product has previously been established for samples from the same sample set at a certain level of spoilage. This cutoff may have been confirmed by an expert panel and/or the results of chemical analysis.

3.7 Feedback from Participants

At the end of the workshop, the participants will be given an opportunity to provide comments on all aspects of the workshop. A summary of these comments will be included in the workshop report.

3.8 Workshop Results and Records

3.8.1 The coordinator will notify participants in writing of the results of the assessment workshop as soon as possible after completion of the workshop. The Regional Director of Inspection will be notified of the results of all participants from their respective Region.

3.8.2 Records for all assessments, including the participants' and expert panellists' worksheets, will be retained by the coordinator for future reference. Copies of the participants' worksheets will be provided to them on request.

3.8.3 The results of all assessments will be forwarded to NHQ.

CHAPTER 14

NET CONTENT DETERMINATION

1. SCOPE

This document outlines the regulations, policy and procedures governing the net content determination of domestic and imported fish and fish products.

2. AUTHORITIES

Fish Inspection Act. R.S.C., 1985, c.F-12; Sections 3(c).

Fish Inspection Regulations (FIR), C.R.C., 1978, c.802; Interpretation, Section 2.

Fish Inspection Regulations (FIR), C.R.C., 1978, c.802; Part II, Labelling

Section 25 (FIR):

(1) In the case of canned fish, every can of fish or the wrapper or label thereon shall be correctly and legibly marked in English or French, in addition to any other language, to indicate:

(b) in the case of fish other than shellfish and crustaceans, the net weight of the contents;

(c) in the case of shellfish and crustaceans, the drained weight of the contents;

Section 26 (FIR):

(1) In the case of fish, other than canned fish, every container or the label thereon shall be correctly and legibly marked in English or French, in addition to any other language, to indicate:

(b) the net weight of the fish unless,

(i) in the case of oyster and clam meats that are not frozen, the container or label is marked with a statement of net contents in terms of fluid measure or by count,

(ii) in the case of oysters that are marketed in the shell, the container or label is marked with a statement of the contents in terms of bushels or pecks or by count, or

(iii) in any case not referred to in subparagraph (i) or (ii), the container or label states that the contents are to be weighed at time of retail sale.

Section 27 (FIR):

No person shall package any fish or mark or label any container of fish in a manner that is false, misleading or deceptive.

Consumer Packaging and Labelling Act (CPLA)

Section 7 (CPLA):

(3) Where a declaration of net quantity shows the purported net quantity of the prepackaged product to which it is applied, that declaration shall be deemed not to be a false or misleading representation if the net quantity of the prepackaged product is, subject to the prescribed tolerance, not less than the declared net quantity of the prepackaged product and the declaration otherwise meets the requirements of this Act and regulations.

Consumer Packaging and Labelling Regulations (CPLR), chapter 417. These regulations apply only to prepackaged consumer products.

Section 3 (CPLR):

(1) Prepackaged products that are produced or manufactured for commercial or industrial enterprises or institutions for use by such enterprises or institutions without being sold by them as prepackaged products to other consumers are exempt from all the provisions of the Act.

(2) Prepackaged products that are produced or manufactured only for export or for sale to a duty-free store, are exempt from all the provisions of the Act.

Section 21 (CPLR):

Subject to sections 22, 23 and 36 the declaration of net quantity of a prepackaged product shall show the quantity

of the product

(a) by volume, when the product is a liquid or gas or is viscous, or

(b) by weight, when the product is solid

unless it is the established trade practice to show the net quantity of the product in some other manner, in which case the declaration shall be in accordance with the established trade practice.

Section 22 (CPLR):

(2) The declaration of net quantity of a prepackaged product listed in the table to this subsection shall show the net quantity of the product by weight of the edible contents in the container exclusive of the free liquid or glaze content.

Item	Product
1	Canned shellfish
2	Canned crustaceans
3	Meat* packaged in brine or vinegar solutions
4	Frozen glazed fish

* Includes fish and fish products.

Section 38 (CPLR):

(1) For the purposes of Schedule I, "catch-weight product" means a prepackaged product that because of its nature cannot normally be portioned to a predetermined quantity and is, as a result, usually sold in varying quantities.

(2) The prescribed tolerance for the purposes of subsection 7(3) of the Act is that set out in column II of an item of the appropriate Part of Schedule I for the declared net quantity set out in column I of that item.

Weights and Measures Act (WMA) and Weights and Measures Regulations (WMR)
Note: These Regulations apply to commodities that are packed for industrial, commercial and institutional markets.

Section 49 (WMR):

(1) Subject to subsection (2), the prescribed limits of error for the purposes of sections 9 and 33 of the Act are those set out in column II of an item of the appropriate Part of Schedule II for the stated quantity set out in column I of that item.

Section 52 (WMR):

(1) The inspection of any quantity of prepackaged commodities, hereinafter referred to as a lot, each unit of which purports to contain the same quantity of commodity, that an inspector undertakes to determine whether the lot meets the requirements of the Act and these Regulations respecting the statement of quantity, shall be made by selecting and inspecting a sample from the lot.

(4) The lot from which a sample was taken and inspected by an inspector does not meet the requirements of the Act and these Regulations respecting the statement of quantity where the inspector determines that:

(a) the weighted average quantity of the units in the sample, as determined by the formula set out in Part II of Schedule III, is less than the stated quantity;

(b) the number of units in the sample that contain less than the stated quantity by more than the prescribed limit of error set out in Schedule II for that quantity is equal to or greater than the number set out in column II of part IV of Schedule III for the sample size set out in column I thereof; or

(c) two or more units in the sample contain less than the stated quantity by more than twice the prescribed limit of error set out in Schedule II for that quantity.

Food And Drugs Act. R.S.C., 1985, c.42 (FDA) Sections 5(1) and 30(b).

Section 5 (FDA):

(1) No person shall label, package, treat, process, sell or advertise any food in a manner that is false, misleading or deceptive or is likely to create an erroneous impression regarding its character, value, quantity, composition, merit or safety.

(2) An article of food that is not labeled or packaged as required by, or is labeled or packaged contrary to, the regulations shall be deemed to be labeled or packaged contrary to subsection (1).

3. DEFINITIONS

Bulk Pack: means a container consisting of non-prepackaged fish or fish product (i.e., individual whole fish, glazed fish fillets, glazed shrimp) or prepackaged catch-weight product which do not have a declared net content on the label and are to be weighed at the time of sale.

Catch-Weight Product: means a prepackaged product that, because of its nature, cannot normally be proportioned to a predetermined quantity and is, as a result, usually sold in varying quantities.

Container: means any type of receptacle, package, wrapper or confining band used in packing or marketing fish. (FIA)

Destructive Inspection: means an inspection in which the container or product is destroyed, modified or rendered unusable. An example of this would be products requiring a "Drained Weight" declaration.

Drained Weight: means the weight of the edible contents of the container exclusive of free water, brine, pickling solution or glaze.

Dry Pack: a term applied to lobster or crustacean meat that has been vacuum packed, with no water or brine added to the final product. For the purpose of satisfying the Fish Inspection Regulations, it is recognised that there is no added liquid to be drained from the meat when lobster or crustacean meat is vacuum packed in this manner.

Individually measured product: means a commodity that is measured by any method other than by a packing device. (WMR)

Limits of error: The maximum net content deficiency (tolerance) permitted for an individual package (unit). (WMR)

Net Weight: with respect to unfrozen or frozen lobster meat, means the weight of the edible contents of a container after the liquid has been drained from the

container by a method approved by the Minister and, with respect to any other fish, means the total weight of the edible contents of a container.

Non-destructive inspection: means an inspection in which the container is not destroyed. An example of this would be products requiring a "Net Weight" declaration with the exception of unfrozen or frozen lobster meat.

Packing Device: means a device that, as part of a mechanical packing system, measures a predetermined quantity of commodity without recording the measurement of each quantity of commodity measured by the device or without being operated by a person who observes or records the measurement of each quantity of commodity measured by the device.

Pre-packaged product: any product that is packaged in a container, in such a manner that it is ordinarily sold to, used or purchased by a consumer or commercial enterprise without being repackaged. (CPLA)

Screening inspection: means an inspection to screen lots of imported or domestically produced fish and fish products from importers and processors who have had a good record of compliance with regard to net content and to avoid the necessity for the destructive examination of a large number of sample units.

T_1: a calculation that is equal to the declared weight minus the tolerance, as determined from Appendix A or B.

T_2: a calculation that is equal to the declared weight minus two times the tolerance, as determined from Appendix A or B.

Weighted average: Corresponds to the sum of the average content of a sample and a statistical adjustment value. This adjustment takes into consideration the sample size and standard deviation in order to ensure a confidence level of 99.5% (WMR) (see Appendix C).

4. POLICY

4.1 All fish and fish products intended for export or import must meet the requirements of the Fish Inspection Act and Regulations.

The authority to inspect and sample a lot of product for net content determination is derived from the Fish Inspection Act (FIA) and Regulations (FIR). The FIA and FIR provide the authority to choose the sampling plan to be used when a product lot is inspected for net content determination, and to define the plan in a policy statement.

4.2 When sampling a lot of product for net content determination, the sampling plan found in Annex A of the Sampling Policy and Procedures Chapter, Fish Products Standards and Methods Manual is to be followed. This sampling plan is used to obtain a sample from a lot undergoing destructive or non-destructive analysis and the sample obtained when using this plan is the official sample.

4.3 The only time when it would be mandatory for Inspectors to use the sampling plans associated with the Consumer Packaging and Labelling Regulations and the Weights and Measures Regulations, is when the Inspector is, in fact, enforcing those Regulations and acting under their authority.

4.4 Designating the sampling plan to be used by Inspectors acting under the Fish Inspection Act and Fish Inspection Regulations does not preclude the adoption of policy or information, as found in the Weights and Measures Act and Regulations, or the Consumer Packaging and Labelling Acts and Regulations, as procedural guidelines.

4.5 CFIA will not inspect the following fish or fish products for net content verification;

a) products from an importer or processor servicing a subsidiary or affiliated buyer in Canada, provided the subsidiary or affiliate is the end user;

b) products which are intended for further processing in an establishment registered with the CFIA.

4.6 An Inspector may, at the request of the purchaser, owner or agent, sample and inspect lots of imported or domestically produced fish and fish products as described in a) and b) above to ensure products comply with regard to net content. In such cases, an appropriate fee will be charged to the person requesting the inspection in accordance with the cost recovery sections of the Fish Inspection Regulations.

4.7 Catch-weight products may be prepackaged product packaged in a master carton and therefore the net content of the master carton will be verified (e.g., sides of smoked salmon prepackaged in a master carton, where the weight for the individual prepackaged side of smoked salmon is determined at retail point of sale).

4.8 Screening Inspection

4.8.1 For the purpose of interpreting "false, misleading or deceptive" with respect to the net content of fish and containers subject to the Fish Inspection Regulations, a screening inspection may be conducted for bulk-packed products provided the following criterion has been satisfied:

a) in the case of domestic product, no lot from the same processor has been rejected for net content during the previous four inspections carried out by the processor according to their QMP; or

b) in the case of imported product, the processor is not recorded for the product type in question on the Import Alert List because of net content.

4.8.2 A screening inspection is permitted for bulk packed product only. The number of samples will consist of three units.

4.8.3 A screening inspection will not be permitted when:

a) the product has been rejected as a result of net content determination;

b) the product is listed on the Import Alert List (IAL) as a result of net content determination;

c) the inspector, based on record checks, plant practise, confidence in the operation and compliance history, has reason to believe that a screening inspection should not be permitted.

5. LOT COMPLIANCE

5.1 Screening Inspection

If a lot fails a screening inspection, the owner or agent will be advised and the lot will be subject to an initial inspection using the sample size, tolerances and acceptance

criteria as specified in this Chapter.

If the lot fails an initial inspection, the owner or agent may be offered a suspended inspection or reinspection in which case they must follow the policy and procedures for these inspections set out in this Manual.

All lots for which a suspended inspection or a reinspection has been approved will be sampled and inspected in accordance with the sample sizes, tolerances and acceptance criteria as specified in this Chapter.

5.1.1 The tolerances and acceptance criteria for a screening inspection are the same as for the initial inspection with the exception that if the average net content of all the sample units examined fails to meet the declared net content, then the weighted lot average will not be calculated for evaluation of compliance.

5.2 Initial Inspection

5.2.1 Prepackaged Products

a) A lot of other than catch-weight products examined for net content will fail the inspection when:

i) the number of units in a sample that have a net content less than the declared net content by more than the tolerance set out in Appendix A, Schedule I, Part III or IV, Column II, is greater than the acceptance number in brackets (c) found in the attribute sampling plan in the Fish Products Standards and Methods Sampling chapter; or

ii) two or more units in the sample contain less than the declared net content by more than twice the tolerance set out in Appendix A, Schedule I, Part III or IV, Column II; or

iii) the weighted average quantity of all sample units examined, as determined by the formula set out in Appendix C, Schedule II and III, Part II, is less than the declared net content.

b) A lot of catch-weight products examined for net content will fail the inspection when:

i) the number of units in a sample, that have a net content less than the declared net content by more

than the tolerance in Appendix A, Schedule I, Parts I and II, Column II, is greater than the acceptance number in brackets (c) found in the attribute sampling plan in the Fish Products Standards and Methods Sampling chapter; or

ii) two or more units in the sample contain less than the declared net content by more than twice the tolerance set out in Appendix A, Schedule I, Parts I or II, Column II.

iii) the weighted average quantity of all sample units examined, as determined by the formula set out in Appendix C, Schedule II and III, Part II, is less than the declared net content.

5.2.2 Products for Industrial, Commercial and Institutional Markets.

a) A lot of other than individually measured products will fail the inspection when:

i) the number of units in a sample, that have a net content less than the declared net content by more than the tolerance set out in Appendix B, Schedule II, Parts V or VI, Column II, is greater than the acceptance number in brackets (c) found in the attribute sampling plan in the Fish Products Standards and Methods Sampling chapter; or

ii) two or more units in the sample contain less than the declared net content by more than twice the tolerance set out in Appendix B, Schedule II, Parts V or VI, Column II; or

iii) the weighted average quantity of all sample units examined, as determined by the formula set out in Appendix C, Schedule II and III, Part II, is less than the declared net content.

b) A lot of individually measured products will fail the inspection when:

i) the number of units in a sample, that have a net content less than the declared net content by more than the tolerance set out in Appendix B, Schedule II, Parts V or VI, Column II, is greater than the acceptance number in brackets (c) found in the attribute sampling plan in the Fish Products

Standards and Methods Sampling chapter; or

ii) two or more units in the sample contain less than the declared net content by more than twice the tolerance set out in Appendix B, Schedule II, Parts V or VI, Column II; or

iii) the weighted average quantity of all sample units examined, as determined by the formula set out in Appendix C, Schedule II and III, Part II, is less than the declared net content.

5.2.3 If the lot fails an official inspection, the owner or agent may be offered a suspended inspection or reinspection in which case they must follow the policy and procedures for these inspections set out in this Manual. All lots for which a suspended inspection or a reinspection has been approved will be sampled and inspected in accordance with the sampling plan specified in Annex A of the Sampling chapter of the Fish Products Standards and Methods Manual, and the tolerance and acceptance criteria as specified in the attribute sampling plan in the Fish Products Standards and Methods Sampling chapter.

5.3 Initial Inspections, Suspended Inspections and Reinspection

If the average net content of all sample units examined fails to meet the declared net content then the weighted lot average must be calculated and this value is used for evaluation of compliance.

5.4 A lot of product that has been rejected for net content may be re-labeled by the processor or importer. The determination of the new net content for the label will be the responsibility of the processor or importer.

The CFIA will verify the net content as re-labeled by performing a net content determination calculation.

- The new net content becomes the declared net weight for the product.
- Based on this declared net weight, a tolerance is obtained from Appendix A or B.
- The T_1 and T_2 values are calculated for the declared weight.
- These calculations and the original sample unit weights are used to determine compliance according to the policy.

6. PROCEDURE: TOTAL CONTENTS

6.1 Application

This procedure is applicable to products where the entire package contents are considered to be edible.

Note: See Section 9 for the evaluation of products which specifically require a "washed drained weight" analysis for export certification purposes.

6.2 Sample Preparation

No preliminary product preparation is necessary.

6.3 Weight Determination

6.3.1 Non-Destructive Inspection

a) Determine and record actual individual tare weights, average tare weight and tare range in accordance with the following:

i) collect a minimum of ten containers;

ii) clean and dry the containers;

iii) determine the weight of each of the containers;

iv) calculate the average tare ($\bar{t}$):

$$\bar{t} = \frac{\Sigma t}{n}$$

where Σt= total weight of containers
n= number of containers

v) determine the tare range (R), i.e., the difference between the heaviest and the lightest container.

$R = t_H - t_L$ where R = tare range
t_H = weight of heaviest container
t_L = weight of lightest container

b) Determine and record the T1 ± ½R and the T2 ± ½R values.

c) Determine the gross weight of each unopened sample unit.

d) Determine and record the net content of each sample unit using the following calculation:

net content = gross weight of unopened sample unit - average tare

e) Identify any container that may be within the areas of the T1 ± ½R value and the T2 ± ½R value. Any container which lies within these areas is to be reweighed using the actual tare (destructive inspection) of the container unit.

6.3.2 Destructive Inspection

a) Determine and record the gross weight of each unopened sample unit.

b) Determine and record the individual tare weight of each sample unit.

c) Determine and record the net content of each sample unit using the following calculation:

net content = gross weight of sample unit - tare weight of the sample unit

d) Determine and record the number of defective containers both with greater than one tolerance or limit of error (>T1) and greater than two tolerances or limits of error (>T2). Note: Every unit found to be greater than T2 is automatically beyond T1.

7. PROCEDURE: DRAINED CONTENTS

7.1 Products Packed in Water, Brine or Vinegar (many canned and semi-preserved products fall into this category)

7.1.1 Sample Preparation

Allow the sample units to come to a temperature of 20-25 °C. No additional preliminary product preparation is necessary.

7.1.2 Weight Determination

a) After opening the container, transfer product to a sieve*, distributing evenly over the surface of the mesh. Incline the sieve* at an angle of 20 to 30 degrees from horizontal; or for canned product, incline the can at an angle of 20 to 30 degrees from

horizontal.

b) Without shifting the product, drain for a period of 2 minutes.

c) Transfer the drained product to a tare pan and weigh, or weigh can and contents and tare the weight of the can. The resultant figure is the net content for that sample unit.

7.2 Glazed Frozen Products (including glazed shellfish and crustacean products)

This is a drained weight because the glaze is being removed from the product. The product remains frozen.

7.2.1 Sample Preparation

a) Remove package from storage, open and place product under gentle spray of cold water.

b) Agitate carefully, spraying the product until all glaze which can be seen or felt is removed.

7.2.2 Weight Determination

a) After deglazing, transfer product to a sieve*.
b) Incline the sieve* at an angle of 20 to 30 degrees from horizontal and drain for a period of 2 minutes. This will remove the spray water from the product. The product remains frozen during this step.

c) Transfer the drained product to a tare pan and weigh. The resultant figure is the net content for that sample unit.

7.3 Frozen Crustacean Products Immersed in Water or Brine (e.g., popsicle pack lobster)

7.3.1 Sample Preparation

Thaw the sample unit by submerging in cool running or circulating water until a core meat temperature of between 10 °C - 15 °C (50 °F - 59 °F) is reached. This may be accomplished by using a sink with running tap water or a circulating water bath. Under some thawing conditions it may be necessary to allow the product to sit at room temperature until a minimum core temperature of 10 °C (50 °F) is reached.

7.3.2 Weight Determination

a) After the product has thawed, as determined by a loss of rigidity, transfer the product to a sieve*, distributing it evenly over the surface of the mesh, or for canned product invert over a beaker.

b) Without shifting the product, incline the sieve* or can at an angle of 20 to 30 degrees from horizontal and drain for a period of 2 minutes.

c) Transfer the drained product to a tare pan and weigh; or weigh the package (can) and the contents and then tare the weight of the packaging (can). The resultant figure is the net content for that sample unit.

7.4 Frozen Crustacean Products or Molluscan Shellfish Meats to which Water or Brine has been Added to the Final Product (e.g., frozen canned lobster meat)

7.4.1 Sample Preparation

a) Open container of frozen product.

b) Place contents of individual package in a wire mesh basket and immerse in a container of fresh water at 26 ± 3 °C (80 ± 5 °F) such that the top of the basket extends above the water level. The wire-mesh basket must be large enough to hold the contents of one package and with openings small enough to retain all pieces of the product.

c) Introduce water of the same temperature, 26 ± 3 °C (80 ± 5 °F), at the bottom of the container at a flow rate of 4-11 litres per minute.

7.4.2 Weight Determination

a) As soon as the product thaws, as determined by loss of rigidity, transfer all material to a sieve*, distributing evenly.

b) Without shifting the material, incline the sieve* to 30 degrees from horizontal in order to facilitate drainage.

c) After two minutes, transfer product to a tare pan and weigh. The resultant figure is the net content for that sample unit.

*** See Appendix E: Sieve Size Designations**

8. PROCEDURE: FLUID MEASURE

8.1 Application

Applicable to all products where the contents are expressed as volume.

8.2 Sample Preparation

Allow the sample unit to come to a temperature of between 20 and 25 °C.

Prepare clean and dry wide-neck cylinders equal to the number of containers to be examined. The cylinders must be accurate to 1 mL.

8.3 Fluid Measure Determination

8.3.1 Open the container and allow to drain into a separate cylinder for 2 minutes. For viscous products which do not drain completely, use an appropriately sized plastic spatula to thoroughly transfer the contents of each container to the appropriate cylinder.

8.3.2 Determine and record the volume of the product in each cylinder. The resultant figure shall be considered the net content for that sample unit.

8.4 Fluid Measure Determination - Thick Soup and Chowder

8.4.1 Sample Preparation

Allow the sample unit to come to a temperature of 20 °C.

Ensure that the pycnometer used during this procedure is properly calibrated and certified.

8.4.2 Fluid Measure Determination

a) Open container and empty contents into a clean and dry container. Using a blender, blend the product contents until homogenized into a smooth and uniform mixture.

Remove the air bubbles which may have formed during this process by slowly mixing the contents with a spatula.

b) Tare the weight of the pycnometer on a balance, and then fill it to capacity with the product, put the lid in place and wipe off the excess product. The pycnometer (tare) with its contents is then weighed (M).

c) Calculate the density of the product by using the formula D=M/V where V is the calibrated capacity of the pycnometer, and M is the weight of the contents in the pycnometer.

d) Repeat the entire procedure two more times and calculate the mean density.

e) Determine the volume (V) of the remaining samples by weighing each sample and using the formula V=M/D where M is the weight of each sample and D is the calculated mean density.

9. PROCEDURE: WASHED DRAINED WEIGHT

9.1 Application

Applicable only to products which are presented for certification for export to countries that specifically require the net content determination to be conducted as a "washed drained weight".

9.2 Sample Preparation

a) Allow the sample unit to come to a temperature of 20 - 25 °C.

b) Open the container, tilt, and using hot tap water (approx. 40 °C), wash the sauce from the product. Transfer the contents to a sieve*, distributing the product evenly over the surface of the mesh.

9.3 Weight Determination

a) Wash the contents of the sieve* with hot water until the product is free of adhering sauce. Where necessary remove optional ingredients (spices, vegetables, fruits) with pincers.

b) Without shifting the product, incline the sieve* at an angle of 20 to 30 degrees from horizontal and drain for a period of 2 minutes.

c) Transfer the drained product to a tare pan and weigh. The resultant figure is the net content for the sample unit.

*** See Appendix E: Sieve Size Designations**

10. FORMS/DOCUMENTS

Appendix A - Tolerances under the Consumer Packaging and Labelling Regulations

Schedule I

Part I: Tolerances of Net Quantities Declared in Metric Units of Mass for Catch-Weight Products.

Part II: Tolerances of Net Quantities Declared in Canadian Units of Mass or Weight for Catch-Weight Products.

Part III: Tolerances for Net Quantities Declared in Metric Units of Mass or Volume for Prepackaged Products other than Catch-Weight Products.

Part IV: Tolerances for Net Quantities Declared in Canadian Units of Mass or Weight for Prepackaged Products other than Catch-Weight Products.

Appendix B - Limits of Error under Weights and Measures Regulations

Schedule II

Part I: Limits of Error for Quantities Measured in Metric Units of Mass for Individually Measured Commodities.

Part II: Limits of Error for Quantities Measured in Canadian Units of Mass for Individually Measured Commodities.

Part V: Limits of Error for Quantities Measured in Metric Units of Mass or Volume for Commodities other than Individually Measured Commodities.

Part VI: Limits of Error for Quantities Measured in Canadian Units of Mass or Weight for Commodities other than Individually Measured Commodities.

Appendix C - Formula for Determining the Weighted Average Quantity of the Units in a Sample

Appendix D - Method of Rounding-Off Calculated Figures

Appendix E - Sieve Size Designations

Appendix F - Product Examination Worksheet - Net Content

Appendix G - Worksheets

1) Tolerance and T1/T2 Defective Determination; and

2) Calculation of Weighted Lot Average

(These are Excel 97 worksheets that are downloadable from the Internet at http://www.cfia-acia.agr.ca/english/animal/fish_and_seafood/product/index.html)

New 02/06/00

APPENDIX A

Tolerances for the declared net content under Consumer Packaging and Labelling Regulations - Section 38(2)

SCHEDULE I
PART I

Tolerances of Net Quantities Declared in Metric Units of Mass For Catch-Weight Products

Item	Column I Declared Net Quantity	Column II Tolerance %	grams
	grams		
1.	more than 0 to not more than 60	10	--
2.	more than 60 to not more than 600	--	6
3.	more than 600 to not more than 1 000	1	--
	kilograms		
4.	more than 1 to not more than 1.5	--	10
5.	more than 1.5 to not more than 3	0.66	--
6.	more than 3 to not more than 4	--	20
7.	more than 4 to not more than 10	0.5	--
8.	more than 10 to not more than 15	--	50
9.	more than 15 to not more than 250	0.33	--
10.	more than 250 to not more than 500	--	750
11.	more than 500	0.15	--

New 02/06/00

SCHEDULE I
PART II

Tolerances of Net Quantities Declared in Canadian Units of Mass or Weight for Catch-Weight Products

Item	Column I Declared Net Quantity	Column II Tolerance %	 ounces
	ounces		
1.	more than 0 to not more than 2	10	--
2.	more than 2 to not more than 20	--	0.2
	pounds		
3.	more than 1.25 to not more than 2.2	1	--
4.	more than 2.2 to not more than 3.3	--	0.35
5.	more than 3.3 to not more than 6.6	0.66	--
6.	more than 6.6 to not more than 8.8	--	0.71
7.	more than 8.8 to not more than 22	0.5	--
8.	more than 22 to not more than 33	--	1.76
9.	more than 33 to not more than 550	0.33	--
10.	more than 550 to not more than 1 100	--	26.4
11.	more than 1 100	0.15	--

SCHEDULE I
PART III

Tolerances for Net Quantities Declared in Metric Units of Mass or Volume for Prepackaged Products other than Catch-Weight Products

Item	Column I Declared Net Quantity	Column II Tolerance %	 grams or millilitres
	grams or millilitres		
1.	more than 0 to not more than 50	9	--
2.	more than 50 to not more than 100	--	4.5
3.	more than 100 to not more than 200	4.5	--
4.	more than 200 to not more than 300	--	9
5.	more than 300 to not more than 500	3	--
6.	more than 500 to not more than 1 kilogram or litre	--	15
	kilograms or litres		
7.	more than 1 to not more than 10	1.5	--
8.	more than 10 to not more than 15	--	150
9.	more than 15	1	--

New 02/06/00

SCHEDULE I
PART IV

Tolerances for Net Quantities Declared in Canadian Units of Mass or Weight for Prepackaged Products other than Catch-Weight Products

Item	Column I Declared Net Quantity	Column II Tolerance %	 ounces
	ounces		
1.	more than 0 to not more than 1.75	9	--
2.	more than 1.75 to not more than 3.5	--	0.16
3.	more than 3.5 to not more than 7	4.5	--
4.	more than 7 to not more than 10.6	--	0.32
5.	more than 10.6 to not more than 17.6	3	--
	pounds		
6.	more than 1.1 to not more than 2.2	--	0.53
7.	more than 2.2 to not more than 22	1.5	--
8.	more than 22 to not more than 33	--	5.28
9.	more than 33	1	--

New 02/06/00

APPENDIX B

Limits of error for the declared net content under Weights and Measures Regulations - Section 49(1)

SCHEDULE II
PART I

Limits of Error for Quantities Measured in Metric Units of Mass for Individually Measured Commodities

Item	Column I Stated Quantity	Column II Limits of error %	 grams
	grams		
1.	more than 0 to not more than 60	10	--
2.	more than 60 to not more than 600	--	6
3.	more than 600 to not more than 1 000	1	--
	kilograms		
4.	more than 1 to not more than 1.5	--	10
5.	more than 1.5 to not more than 3	0.66	--
6.	more than 3 to not more than 4	--	20
7.	more than 4 to not more than 10	0.5	--
8.	more than 10 to not more than 15	--	50
9.	more than 15 to not more than 250	0.33	--
10.	more than 250 to not more than 500	--	750
11.	more than 500	0.15	--

SCHEDULE II
PART II

Limits of Error for Quantities Measured in Canadian Units or Mass for Individually Measured Commodities

Item	Column I Stated Quantity	Column II Limits of error %	 ounces
	ounces		
1.	more than 0 to not more than 2	10	--
2.	more than 2 to not more than 20	--	0.2
	pounds		
3.	more than 1.25 to not more than 2.2	1	--
4.	more than 2.2 to not more than 3.3	--	0.35
5.	more than 3.3 to not more than 6.6	0.66	--
6.	more than 6.6 to not more than 8.8	--	0.71
7.	more than 8.8 to not more than 22	0.5	--
8.	more than 22 to not more than 33	--	1.76
9.	more than 33 to not more than 550	0.33	--
10.	more than 550 to not more than 1 000	--	26.4
11.	more than 1 000	0.15	--

New 02/06/00

SCHEDULE II
PART V

Limits of Error for Quantities Measured in Metric Units of Mass or Volume for Commodities other than Individually Measured Commodities

Item	Column I Stated Quantity	Column II Limits of error %	 grams or millilitres
	grams or millilitres		
1.	more than 0 to not more than 50	9	--
2.	more than 50 to not more than 100	--	4.5
3.	more than 100 to not more than 200	4.5	--
4.	more than 200 to not more than 300	--	9
5.	more than 300 to not more than 500	3	--
6.	more than 500 to not more than 1 000	--	15
7.	more than 1 000 to not more than 10 000	1.5	--
8.	more than 10 000 to not more than 15 000	--	150
9.	more than 15 000	1	--

New 02/06/00

SCHEDULE II
PART VI

Limits of Error for Quantities Measured in Canadian Units of Mass or Weight for Commodities other than Individually Measured Commodities

Item	Column I Stated Quantity	Column II Limits of Error %	 ounces
	ounces		
1.	more than 0 to not more than 1.75	9	--
2.	more than 1.75 to not more than 3.5	--	0.16
3.	more than 3.5 to not more than 7	4.5	--
4.	more than 7 to not more than 10.6	--	0.32
5.	more than 10.6 to not more than 17.6	3	--
	pounds		
6.	more than 1.1 to not more than 2.2	--	0.53
7.	more than 2.2 to not more than 22	1.5	--
8.	more than 22 to not more than 33	--	5.28
9.	more than 33	1	--

APPENDIX C

FORMULA FOR DETERMINING THE WEIGHTED AVERAGE QUANTITY OF THE UNITS IN A SAMPLE

SCHEDULE II & III
PART II

For the purpose of Section 38 (4) (a) under the Consumer Packaging and Labelling Regulations and Section 52(4)(a) under the Weights and Measures Regulations, the formula for adjusting the sample mean to determine the weighted average quantity of the units in the sample is as follows:

$$\overline{X}_a = \quad + s(t \div \sqrt{n})*$$

In the formula above:

$\overline{X}_a$ is the weighted average quantity of the units in the sample

is the sample mean calculated as follows:

$$= \Sigma x \div n$$

Σx is the sum of the net quantities of all units in the sample

t is the value determined in accordance with Part III for the selected sample size

n is the number of units in the sample

s is the standard deviation of the sample, calculated as follows:

$$s = \quad \sqrt{\Sigma \frac{(\quad - x)^2}{(n-1)}}$$

$\Sigma(\quad - x)^2$ is the sum of the squared differences between the sample mean and the net quantity of each unit in the sample

These formulas provide a statistical method that prevents any bias introduced by the selection of the sample from adversely affecting the inspection result. The mean (average) of the

sample is adjusted by a factor that is related to the demonstrated packaging accuracy (standard deviation). Relating the sample mean to the calculated lot average in this way provides a confidence level of 99.9% that good lots will not be failed in error.

* The value of $(t \div \sqrt{n})$ may, instead of being calculated in accordance with this Part, be determined using the applicable value set out in column III of the table to Part III.

PART III

TABLE FOR VALUES OF t AND (t ÷ √n)

Column I Sample size	Column II t*	Column III (t ÷ √n)*
2	63.657	45.01
3	9.925	5.73
4	5.841	2.92
5	4.604	2.06
6	4.032	1.65
7	3.707	1.40
8	3.499	1.24
9	3.355	1.12
10	3.250	1.03
11	3.169	0.955
12	3.106	0.897
13	3.055	0.847
14	3.012	0.805
15	2.977	0.769
16	2.947	0.737
17	2.921	0.708
18	2.898	0.683
19	2.878	0.660
20	2.861	0.640
21	2.845	0.621
22	2.831	0.604
23	2.819	0.588
24	2.807	0.573
25	2.797	0.559
26	2.787	0.547
27	2.779	0.535
28	2.771	0.524
29	2.763	0.513
30	2.756	0.503
31	2.750	0.494
32	2.746	0.485
64	2.657	0.332
96	2.643	0.269
125	2.615	0.234

Linear Interpolation of Values

Where a sample size is selected that is not listed in column I of this table and lies between 32 and 125, the value of t will be determined by linear interpolation as follows:

$$t = a - \frac{(c-e)}{(c-d)} (a-b)$$

where:

a is the value of t for closest sample size below the selected sample size

b is the value of t for the closest sample size above the selected sample size

c is the result of 120 divided by the closest sample size below the selected sample size

d is the result of 120 divided by the closest sample size above the selected sample size

e is the result of 120 divided by the selected sample size

* Where all units in a lot are selected to constitute a sample, zero shall be used as the value of t and (t ÷ √n).

Because the "t" values are used to calculate the weighted lot average from the sample mean, it is not required in those cases where every package in the lot is tested, and therefore, as the note above shows, it is equal to zero for those cases.

APPENDIX D

METHOD OF ROUNDING OFF CALCULATED FIGURES

Since calculations usually imply the rounding of results, it is important to know how and when figures can be rounded. The policy is always to round off in favor of the packer.

Average Tare:

Round-off to the next lower graduation of the scale.

Examples: Calculated average tare: 52.567 g
Scale graduations: 1 g
Average tare to be used: 52 g

Calculated average tare: 52.567 g
Scale graduations: 0.1 g
Average tare to be used: 52.5 g

Sample Mean:

If for practical reasons the sample mean has to be rounded, round-up the fourth or fifth significant digit as indicated below.

Examples:

Sample mean value not rounded off	Number of significant digits that must be kept
< 1 kg	4
1 kg and more	5

Calculated Sample Mean	Rounded-Off Sample Mean
498.4564 g	498.5 g
2363.3045 g	2363.4 g
9.67432 kg	9.6744 kg
29.86542 kg	29.866 kg
857.4256 mL	857.5 mL

APPENDIX E

SIEVE SIZE DESIGNATIONS

The sieve numbers associated with the sieves used to determine the drained weight of product have been designated by the American Society for Testing and Materials (ASTM). These numbers, No. 8, 10, 20, 50, etc., relate to the standardised nominal aperture size of the wire mesh used to make the sieve (size of openings in the mesh). The aperture size is a measure of the distance between parallel wires of the mesh.

The table below contains the sieve numbers and the corresponding aperture size for the mesh used to make the sieve.

Sieve No.	Aperture Opening (mm)
No. 4	4.75
No. 5	4
No. 6	3.35
No. 7	2.8
No. 8	2.36
No. 10	2
No. 12	1.7
No. 14	1.4
No. 16	1.18
No. 18	1
No. 20	0.85
No. 30	0.6
No. 50	0.3
No. 80	0.18
No. 200	0.075

In order to build flexibility into the policy document, the sieve number to be used when determining the drained weight is not designated; the intention is that the appropriately sized sieve

will be used as dictated by the particulate size of the product.

There is guidance in the Codex Alimentarius and in publications of the American Organization of Analytical Chemists (AOAC) regarding the sieve size that may be chosen for a particular product type.

References

Canadian General Standards Board (CGSB)

- CGSB 8.1.88: Sieves, Testing, Woven Wire, Inch Series
- CGSB 8.2 M88: Sieves, Testing, Woven Wire, Metric, Canadian Metric Sieve Series

American Society For Testing And Materials (ASTM)

- E11-95 Standards Specification For Wire Cloth And Sieves For Testing Purposes

International Organisation For Standardization (ISO)

- ISO 565:1990 Test sieves - Metal wire cloth, perforated metal plate and electroformed sheet - Nominal sizes of openings
- ISO 2395:1990 Test sieves and test sieving - Vocabulary

New 02/06/00

APPENDIX F

APPENDIX G

DETERMINING THE WEIGHTED AVERAGE QUANTITY OF THE UNITS IN A SAMPLE

TOLERANCE AND T1/T2 DEFECTIVE DETERMINATION

New 02/06/00

CALCULATION OF WEIGHTED LOT AVERAGE