



**Facilities Inspection
Manual**

Status
New

Date
2003/10/31

**CHAPTER 2, SUBJECT 4
REGULATION OF CANADIAN ESTABLISHMENTS PROCESSING FISH BY-PRODUCTS**

1. SCOPE

This policy provides for the appropriate regulation of Canadian fish processing establishments registered under the Fish Inspection Regulations (FIR) (registered establishments) that process fish by-products for export. It addresses the regulation of fish by-products that are imported for further processing by registered establishments. This policy refers to the regulation of fish by-products that are prepared for human consumption either by themselves, or as a food ingredient, or as a Natural Health Product (see definition below). This policy does not apply to fish by-products that are prepared for use in drugs, cosmetics or in products not consumed by human beings.

2. DEFINITIONS

The following definitions are included to provide clarity on issues specifically related to this document.

"cosmetic" includes any substance or mixture of substances manufactured, sold or represented for use in cleansing, improving or altering the complexion, skin, hair or teeth, and includes deodorants and perfumes. (Food and Drugs Act)

"drug" includes any substance or mixture of substances manufactured, sold or represented for use in

- a) the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state, or its symptoms, in human beings or animals,
- b) restoring, correcting or modifying organic functions in human beings or animals, or
- c) disinfection in premises in which food is manufactured, prepared or kept. (Food and Drugs Act)

"export" means to ship from Canada to any other country, or from any province to any other province. (Fish Inspection Regulations)



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"fish" means any fish, including shellfish and crustaceans, and marine animals, and any parts, products or by-products thereof. (Fish Inspection Act)

"fish by-products" refers to commodities that are manufactured from fish, including shellfish, crustaceans, and marine animals in a form that is different than conventional foods and which are intended for human consumption (either directly or as a food ingredient). Fish by-products include, but are not limited to:

- a) by-products derived from marine mammals (e.g., seal oil);
- b) by-products derived from fish, including fish cartilage, fish oils, and fish proteins; and
- c) by-products derived from the carapaces of crustaceans; but

do not include marine plants or marine plant products.

"Natural Health Product" - see Natural Health Products Regulations, SOR/2003-196. (Health Canada)

"processing" includes cleaning, filleting, icing, packing, canning, freezing, smoking, salting, cooking, pickling, drying or preparing fish for market in any other manner.(Fish Inspection Act)

3. ESTABLISHMENT REGISTRATION

Establishments that process fish by-products for the production of drugs, cosmetics, or other substances that are not intended for human consumption, (e.g., fish meal used for the production of animal feeds) will not require a certificate of registration. Note that these activities may be subject to requirements administered by other CFIA programs (see note below).

Establishments that process for export fish by-products intended for human consumption (including fish by-products used as food ingredients) must be registered in accordance with the policies and procedures described in Chapter 2, Subject 1 of this Manual.

The CFIA will not require registration of an establishment when fish by-products are used to manufacture Natural



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Health Products and/or drugs that are subject to the controls specified by a licence issued to the establishment by Health Canada.

An establishment not regulated by Health Canada that processes fish by-products for export to an establishment that manufactures Natural Health Products and/or drugs, must be registered under the FIR.

Note: Fish by-product renderers producing fish meal or fish oil products from inedible offal, fish or fish by-products from fish processing plants, or other sources, are subject to the *Feeds Regulations* and the *Health of Animals Regulations*, and must meet the requirements identified in said regulations.

4. QUALITY MANAGEMENT PROGRAM

The registered establishment must develop a Quality Management Program (QMP) Plan that meets the requirements described by the QMP Reference Standard (Chapter 3, Subject 4 of this manual). The hazard analysis will be performed as described in the QMP Reference Standard based on known hazards.

In a situation where an inspector needs to determine if a hazard exists, the inspector will forward an inquiry through the Program Network to the National Manager, Quality Management Programs, Fish Seafood and Production Division. Once the hazard has been identified, and has been deemed significant, critical limits must be determined and mechanisms for control implemented at the processing level. In lieu of a standard, critical limits will be determined through a case-by-case risk assessment. The results of the risk assessment will establish the critical limits for the product being produced by that particular establishment. The results of the risk assessment **may not be used** to establish critical limits for other establishments processing similar products.

5. FISH EXPORT CERTIFICATES

A fish export certificate will be issued for fish by-products when the products are in compliance with the Fish Inspection Regulations and were processed at a registered establishment. Export certificates will be issued following the policies and procedures described in Chapter



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10 of the Fish Products Inspection Manual.

6. FISH BY-PRODUCTS IMPORTED FOR FURTHER PROCESSING

All importers of fish by-products destined for further processing at a registered establishment must hold a Fish Import Licence or a Quality Management Program Import Licence. Fish by-products that are imported for further processing as products destined for human consumption (including fish by-products used as ingredients) by a registered establishment, will be inspected in accordance with the policies and procedures described in Chapter 3 of the Fish Products Inspection Manual.

Product of Canada designation and the application of policy pertaining to "substantial transformation", shall be granted as described in the policies and procedures found in Chapters 3 and 10 of the Fish Products Inspection Manual.