



**Fish Products
Inspection Manual**

Status
New

Date
22/07/08

CHAPTER 2, SUBJECT 9

NOVEL FOOD COMPLIANCE POLICY

1. SCOPE

This document outlines the approach governing Canadian Food Inspection Agency (CFIA) regulatory compliance activities applicable to persons that sell, or advertise for sale, novel fish products intended for human consumption in Canada.

This policy complements established policies applicable to fish.

2. AUTHORITIES

Fish Inspection Act, R.S., c. F-12
Fish Inspection Regulations, C.R.C., c. 802

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

3. DEFINITIONS

The following definitions are taken from the *Food and Drug Regulations*, Division 28 and apply to this document.

"*genetically modify*" means to change the heritable traits of a plant, animal or microorganism by means of intentional manipulation.

"*major change*" means, in respect of a food, a change in the food that, based on the manufacturer's experience or generally accepted nutritional or food science theory, places the modified food outside the accepted limits of natural variations for that food with regard to

- a) the composition, structure or nutritional quality of the food or its generally recognized physiological effects;
- b) the manner in which the food is metabolized in the body;
or
- c) the microbiological safety, the chemical safety or the safe use of the food

"*novel food*" means

- a) a substance, including a microorganism, that does not have a history of safe use as a food;



**Fish Products
Inspection Manual**

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22/07/08

- b) a food that has been manufactured, prepared, preserved or packaged by a process that
 - i) has not been previously applied to that food, and
 - ii) causes the food to undergo a major change;
- c) a food that is derived from a plant, animal or microorganism that has been genetically modified such that:
 - i) the plant, animal or microorganism exhibits characteristics that were not previously observed in that plant, animal or microorganism,
 - ii) the plant, animal or microorganism no longer exhibits characteristics that were previously observed in that plant, animal or microorganism, or
 - iii) one or more characteristics of the plant, animal or microorganism no longer fall within the anticipated range for that plant, animal or microorganism.

4. NOVEL FOOD COMPLIANCE POLICY

The CFIA will verify product compliance of novel fish and fish products through ongoing activities such as compliance verification, product inspection, surveys, etc.

5. RESPONSIBILITIES

5.1 Regulatory Responsibilities

The regulatory responsibility for novel fish product safety is shared between Health Canada and the Canadian Food Inspection Agency (CFIA).

Health Canada

Health Canada is responsible for:

- ▶ establishing novel food regulatory requirements,
- ▶ reviewing novel food pre-market notifications,
- ▶ notifying the manufacturer or importer in writing of the notification review,
- ▶ conducting novel food safety assessments, and
- ▶ issuing a letter of no objection to the sale of the novel food, as required.

**Fish Products
Inspection Manual**

Status
New Date
22/07/08

Canadian Food Inspection Agency

The CFIA is responsible for the monitoring of compliance with, and the enforcement of, legislative and regulatory requirements applicable to novel fish products at both the domestic and import levels.

5.2 Industry

Regulated parties are responsible for the safety of any product they manufacture, import or distribute.

6. NOVEL FOOD REGULATORY REQUIREMENT

Manufacturers and importers are responsible to seek regulatory approval from Health Canada prior to offering or advertising a novel fish product for domestic sale. A novel fish product has received regulatory approval for domestic sale when the manufacturer or importer has received a letter of no objection to the sale of the novel food from Health Canada, the product meets the requirements outlined in the letter of no objection, and the product meets the provisions of all other applicable regulation (i.e., *Fish Inspection Regulations*, etc.).

Novel fish products for which the importer or manufacturer has not received a letter of no objection or has not met the conditions identified in the letter of no objection set out by Health Canada will not be considered in compliance, and will not be permitted for sale in Canada.

Novel foods that are not approved for sale in Canada can be exported from Canada in accordance with paragraph 18(1)(j) of the *Fish Inspection Regulations* concerning exemption permits.

7. APPENDICES

Appendix A - Contact Information



**Fish Products
Inspection Manual**

**APPENDIX A
CONTACT INFORMATION - HEALTH CANADA**

Manufacturers or importers can contact or submit notifications to Health Canada at the following address:

Novel Food Notification
Food Program
Food Directorate
Health Canada
4th Floor West
Sir Frederick G. Banting Research Center
Tunney's Pasture, PL 2204A1
Ottawa, Ontario
K1A 0L2

Further information on safety assessment guidelines and novel food decisions is available on the Health Canada web site at www.hc-sc.gc.ca.