

FOOD BIOTECHNOLOGY - GENETICALLY MODIFIED FOODS

Biotechnology allows for the development of new food products through a variety of scientific tools and techniques. Genetically modified foods are part of what are commonly known as novel foods. They must comply with laws and regulations and federal guidelines.

Novel foods are defined as follows:

- ✚ Foods resulting from a process not previously used for food;
- ✚ Products that have never been used as a food; or
- ✚ Foods that have been modified by genetic manipulation, also known as genetically modified (GM) foods, genetically engineered foods or biotechnology-derived foods.

Health Canada and the Canadian Food Inspection Agency require product developers to follow regulatory directives and guidelines to get approval of federal authorities for the commercialization of genetically modified foods, novel feeds and for environmental release. The developers of genetically modified foods must supply evaluators with thorough and detailed information before they can receive approval to sell or advertise them in Canada.

The main regulations are :

Food and Drug Regulations – Division 28 Novel foods

http://laws-lois.justice.gc.ca/eng/regulations/C.R.C.%2C_c._870/FullText.html

Guidelines and Policies for the safety assessment of Novel Foods

<http://www.hc-sc.gc.ca/fn-an/gmf-agm/pol/index-eng.php>

Genetically Modified Foods Approval Process

<http://www.hc-sc.gc.ca/fn-an/gmf-agm/index-eng.php>

The novel foods guidelines and Food and Drug Regulations – Division 28 Novel foods outline requirements for data to support safety assessment. When a product developer believes he has enough information about the safety of a novel food to meet the guidelines, he/she makes a submission to Health Canada's Novel Foods Section. The office coordinates a full safety assessment of the product, which involves a rigorous scientific assessment.

Please note that the safety assessment of genetically modified foods includes:

- ✚ Molecular biological data describing the genetic change;

- ✦ Nutritional information about the novel food compared to a non-modified food of the same type;
- ✦ Potential for production of new toxins in the food;
- ✦ Potential for causing allergic reactions;
- ✦ Potential for any unintended or secondary effects;
- ✦ Key nutrients and toxicants;
- ✦ Major constituents, such as fats, proteins, carbohydrates, and minor constituents, such as minerals and vitamins; and
- ✦ Microbiological and chemical safety of the food.

For more information, please do not hesitate to contact Thomas Dastous, LL. B., D. D. N., N.C.A.; Paul-André Dastous Ph.D., LL. B., M. Env., eng.; or Louis-Philippe Préfontaine-Dastous, junior eng., at (613) 834-8054.

FOREST BIOTECHNOLOGY – DERIVED PRODUCTS

At the federal level, regulation of forest biotechnology-derived products is within the jurisdiction of the **Seeds Act** (plants with novel traits that are forest trees). The **Seeds Act** can be found at: <http://laws-lois.justice.gc.ca/PDF/S-8.pdf> .

Plants with novel traits are defined in Part V of the Seeds Regulations which can be found at: http://laws-lois.justice.gc.ca/eng/regulations/C.R.C.%2C_c._1400/FullText.html .

Genetically modified plants that are being imported are covered by the **Plant Protection Act** found at: <http://laws-lois.justice.gc.ca/eng/acts/P-14.8/> .

Biofertilizers and mycorrhizae are within the jurisdiction of the **Fertilizers Act** which can be found at: <http://laws-lois.justice.gc.ca/eng/acts/F-10/index.html> while the use of pesticides is the subject of the **Pest Control Products Act** which can be found at: <http://laws-lois.justice.gc.ca/eng/acts/P-9.01/> .

In accordance with the Canadian Government Toxic substances management policy (<http://www.ec.gc.ca/toxiques-toxics/default.asp?lang=En&n=2A55771E-1>), the developer of such products should consider the potential for toxicity, bioaccumulation and persistence of a pesticide when conducting environmental risk assessments. The brand is part of the evaluation for marketing or during the approval of such pesticide. Such risk assessment must be conducted before a product is tested or marketed.

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HEALTH BIOTECHNOLOGY - EVALUATING NEW SUBSTANCES

New substances are regulated under the **Canadian Environmental Protection Act** (<http://laws-lois.justice.gc.ca/eng/acts/C-15.31/>), and under the **New Substances Notification Regulations** (Chemicals and Polymers - <http://laws-lois.justice.gc.ca/eng/regulations/SOR-2005-247/index.html>), and under the (Organisms - <http://laws-lois.justice.gc.ca/eng/regulations/SOR-2005-248/index.html>) The Regulations were created to ensure that no new substances (chemicals, polymers or animate products of biotechnology) are introduced into the Canadian marketplace before an assessment of whether they are potentially toxic has been completed, and any appropriate or required control measures have been taken.

Any company or individual who plans to import or manufacture a substance subject to notification under the Regulations must provide Environment Canada with a New Substances Notification (NSN) package containing all information prescribed in the Regulations prior to import or manufacture.

The **New Substances Fees Regulations** (<http://laws-lois.justice.gc.ca/eng/regulations/SOR-2002-374/index.html>), the Guidelines for the Notification and Testing of New Substances (Chemicals and Polymers - <http://www.ec.gc.ca/subsnouvelles-newsups/default.asp?lang=En&n=5981665E-1>) and the Guidelines for the Notification and Testing of New Substances (Organisms - <http://www.ec.gc.ca/subsnouvelles-newsups/default.asp?lang=En&n=66C60DFB-1>) may also apply.

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HEALTH BIOTECHNOLOGY - IMPORT AND EXPORT OF MEDICAL DEVICES

The import and export of health products are regulated under the **Food and Drugs Act** (<http://laws-lois.justice.gc.ca/eng/acts/F-27/>) and its **associated Regulations** which include Human Drugs; Natural Health Products; Medical Devices; Veterinary Drugs; Blood and Blood Components for Transfusion; Human Cells, Tissues and Organs for Transplantation; and Semen for Assisted Conception.

Moreover, some health products may also have additional restrictions placed on them by other Acts and Legislation, such as the **Controlled Drugs and Substances Act** (<http://laws-lois.justice.gc.ca/eng/acts/C-38.8/>)and its associated Regulations. Please note that where two different restrictions/requirements exist, such as the quantity allowed for importation, the most restrictive or prescriptive will take precedence.

Further, several policies may also apply such as:

- # Definitions for Genomic Biomarkers, Pharmacogenomics, Pharmacogenetics, Genomic Data and Sample Coding Categories - **ICH** Topic E15 (<http://www.hc-sc.gc.ca/dhp-mps/prodpharma/applic-demande/guide-ld/ich/efficac/e15-eng.php>)
- # Submission of Pharmacogenomic Information (http://www.hc-sc.gc.ca/dhp-mps/brgtherap/applic-demande/guides/pharmaco/pharmaco_guid_ld-eng.php)
- # Guidance Document on the Regulation of Medical Devices Manufactured from or Incorporating Viable or Non-Viable Animal Tissue or their Derivative(s) (http://www.hc-sc.gc.ca/dhp-mps/md-im/applic-demande/guide-ld/anim_tiss-eng.php)
- # Pre-Market Guidance on Bare Cardiovascular Stents (http://www.hc-sc.gc.ca/dhp-mps/md-im/applic-demande/guide-ld/stents_nues-eng.php)
- # Premarket Review Document for Breast Implant and Tissue Expander Device Licence Applications (http://www.hc-sc.gc.ca/dhp-mps/md-im/applic-demande/guide-ld/breast_impl_mammaires-eng.php)
- # *In Vitro* Diagnostics Devices (http://www.hc-sc.gc.ca/dhp-mps/md-im/applic-demande/guide-ld/test_iv3-eng.php)
- # Conditions for Provisions of Packaging/Labelling Services for Drugs under Foreign ownership (http://www.hc-sc.gc.ca/dhp-mps/compli-conform/gmp-bpf/docs/gui_67_tc-tm-eng.php)
- # What you Need to Know About Medicine for Human Use and International Borders (<http://www.hc-sc.gc.ca/dhp-mps/compli-conform/import-export/medicinebord-medicamentsext-eng.php>)
- # Policy for Importation or Sale of Active Pharmaceutical Ingredients for Veterinary Use (http://www.hc-sc.gc.ca/dhp-mps/compli-conform/import-export/pol_0018_tc-tm-eng.php)
- # Guidance on Evidence to Demonstrate Drug Good Manufacturing Practices Compliance on Foreign Sites (<http://www.hc-sc.gc.ca/dhp-mps/compli-conform/gmp-bpf/docs/gui-0080-eng.php>)
- # Explanatory Notes for Industry on the Preparation of a Site Master File (http://www.hc-sc.gc.ca/dhp-mps/compli-conform/licences/directives/gui_0005_tc-tm-eng.php)
- # Import Requirements for Health Products under the Food and Drugs Act and its Regulations (http://www.hc-sc.gc.ca/dhp-mps/compli-conform/import-export/gui-0084_biu-uif-eng.php)
- # Import and Export Policy for Health Products under the Food and Drugs Act and its Regulations (http://www.hc-sc.gc.ca/dhp-mps/compli-conform/import-export/pol-0060_biu-uif-eng.php)
- # Border Integrity Approach (http://www.hc-sc.gc.ca/dhp-mps/compli-conform/import-export/pol-0059_biu-uif-eng.php)

- ✦ Guidance Document on the Application for Certificate of a Pharmaceutical Product (http://www.hc-sc.gc.ca/dhp-mps/compli-conform/licences/directives/gui-0024_doc-eng.php)

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HEALTH BIOTECHNOLOGY - COSMETICS

Cosmetic products are subject to the provisions of the **Food and Drugs Act** (<http://laws-lois.justice.gc.ca/eng/acts/F-27/>) and its **Cosmetic Regulations** (http://laws-lois.justice.gc.ca/eng/regulations/C.R.C.,_c._869/index.html). The Act and Regulations govern the composition, safety, labeling and advertising.

Moreover, cosmetics are also subject to the provisions of the **Consumer Packaging and Labelling Act** (<http://laws-lois.justice.gc.ca/eng/acts/C-38/>) and to the **Consumer Packaging and Labelling Regulations** (http://laws-lois.justice.gc.ca/eng/regulations/C.R.C.,_c._417/index.html). The three most significant features of the Canadian cosmetic regulatory system are mandatory notification of all cosmetic products, safety of ingredients and products, and product labelling.

Health Canada has also established **Guidelines for cosmetics Manufacturers, Importers and Distributors** (http://www.hc-sc.gc.ca/cps-spc/pubs/indust/cosmet_guide/index-eng.php) to be followed by the industry. Manufacturers, importers and distributors of cosmetics will pay particular attention to the **List of Prohibited and Restricted Cosmetic ingredients** (<http://www.hc-sc.gc.ca/cps-spc/cosmet-person/indust/hot-list-critique/index-eng.php>).

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