Agriculture and Agri-Food Canada
Agriculture et Agroalimentaire Canada

# Canada's Regulatory System for Foods with Health Benefits—An Overview for Industry

Agriculture and Agri-Food Canada is committed to helping industry bring innovative food products to market. Currently, to address consumers' growing interest in health, the sector is focused on developing foods with enhanced nutritional value and functional properties. This fact sheet is a starting point for companies wanting to promote the health benefits of their products. It will help you better understand and navigate Canada's food regulatory system and point you to important resources.

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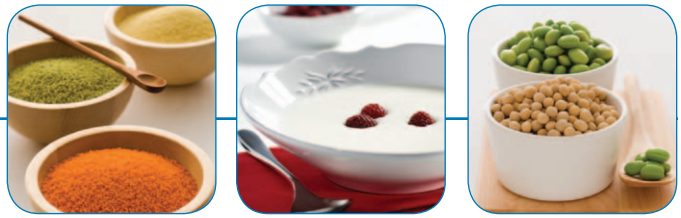
Canada

# The *Food and Drugs Act*



The *Food and Drugs Act* (FDA) is the primary legislation governing the safety and nutritional quality of food sold in Canada. Its scope includes food labelling, advertising and claims; food standards and compositional requirements; fortification; foods for special dietary uses; food additives; chemical and microbial hazards; veterinary drug residues; packaging material; and pesticides. The role of the FDA is to protect the public against health hazards and fraud from the sale of food (including beverages), drugs, medical devices and cosmetics.

Federal government departments have complementary roles in the development, enforcement and interpretation of policies and guidance based on the FDA and its regulations:

- **Health Canada** sets health and safety related requirements under the FDA and its accompanying regulations, policies and guidelines.
- **The Canadian Food Inspection Agency (CFIA)** is responsible for the enforcement of the health and safety requirements in the FDA and its associated regulations as well as establishing non-health and safety food labelling policies.
- **Agriculture and Agri-Food Canada (AAFC)** provides information and support to help industry understand regulatory requirements in order to get innovative foods into the marketplace.

## Core Principle of the FDA

A key underlying premise of the FDA is to enable consumers to make informed food choices based on information that is truthful and not misleading. All advertising and all statements on food packages are subject to subsection 5(1) of the FDA, which states:

> *"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."*

Food manufacturers and importers are responsible for ensuring that their products are accurately positioned in the marketplace and comply with Canadian legislation. Nutrition and health claims are voluntary; however, if they are made, they must comply with applicable regulations or guidelines including conditions for use. As more food products are being promoted for their health benefits, industry must continue to ensure that all advertising and label claims are scientifically validated and provide meaningful information to the consumer.

## Regulatory Modernization

The federal government is streamlining the way regulations are administered while continuing to protect the health and safety of Canadians. This includes recent amendments to the FDA to allow new tools called "Marketing Authorizations" and "Incorporation by Reference", which improve the efficiency of implementing science-based decisions. For example, these tools could be applied to approve a new or modified health claim or a new application for a food additive, allowing their use in the marketplace once the science has been substantiated. It will be important for industry to keep up-to-date on new procedures and tools. See the resources, including e-mail notification lists, provided on page 9.

## Food and Natural Health Product Classification

The FDA categorizes consumed products as either foods or drugs; drugs include the subcategory of natural health products (NHPs). The regulatory requirements are different depending on how the product is classified.

- **Foods** are items manufactured, sold or represented for use as a food or drink and any ingredients that may be mixed with food. Foods (and drugs that are not NHPs) are regulated under the Food and Drug Regulations (FDR).
- **NHPs** are over-the-counter substances taken in a specified dose for the prevention or treatment of an illness or condition, the reduction of health risks, or the maintenance of good health. They come in a wide variety of forms like tablets, capsules, tinctures, solutions, creams, ointments and drops. NHPs are regulated under the Natural Health Product Regulations (NHPR).

Some products, such as beverages with added vitamins, minerals or amino acids, as well as products making certain health claims, have previously been able to gain market access as NHPs under the NHPR. To resolve the confusion about which regulatory framework is appropriate, Health Canada outlined principles in a guidance document, *Classification of Products at the Food-Natural Health Product Interface: Products in Food Formats.* Products are classified as foods or as NHPs on a case-by-case basis and consideration is given to public health and safety. Four key criteria are used to make decisions: product composition, product representations, product format, and public perception and history of use.

In accordance with the classification guidance document, Health Canada determined that most food-like NHP products fit the regulatory definition of a food and therefore is transitioning them to the food regulatory framework, mainly through the issuance of Temporary Marketing Authorization Letters (TMALs). The transition process was initiated in early 2012, starting with caffeinated energy drinks and moving to additional categories (e.g. beverages, conventional foods, powders). Health Canada's Natural Health Products Directorate no longer accepts NHP applications for products that are represented, packaged and sold as foods.

# Food Labelling in Canada

## Mandatory Nutrition Facts Table

Most pre-packaged food products sold in Canada require a Nutrition Facts table on their label.

- The Nutrition Facts table provides nutrient information in an easy-to-find, standardized format. It must include information, based on the stated serving size, for Calories (energy content) plus 13 core nutrients. There are different presentation styles based on the nature of the product and the package size.
- Additional nutrients may also be listed in the Nutrition Facts table, either voluntarily or when triggered by a claim. For example, it becomes mandatory to display information on omega-6, omega-3 and monounsaturated fatty acids when any one of these is mentioned on the label.
- Information on the amount of some nutrients or food constituents may appear outside of the Nutrition Facts table. See "Quantitative Declaration of Nutrients and Non-Nutrients" on page 6.
- Some products are exempt, such as fresh fruits and vegetables or individual servings sold for immediate consumption. However, under certain conditions, such as the presence of a claim or addition of vitamins or mineral nutrients, these foods lose their exempt status and must carry a Nutrition Facts table.

Other mandatory information is required on food labels. The CFIA's *Guide to Food Labelling and Advertising*, Chapters 5 and 6, provides details to assist manufacturers with nutrition labelling requirements. CFIA also offers other Food Labelling and Advertising information, including an interactive tool that depicts food labelling requirements.

## Dietary Fibre

The *Policy for Labelling and Advertising of Dietary Fibre-Containing Food Products*, released in February 2012, affects the declaration of both dietary fibre and energy in the Nutrition Facts table. This policy aligns Canada with international standards on the definition of dietary fibre.

- Both the amount of dietary fibre naturally occurring in foods and the amount of dietary fibre from accepted novel fibre sources are included as part of the total dietary fibre declaration.
- An energy value of 2 kcal/g (8 kJ/g) is used for calculating the dietary fibre portion of the caloric declaration, unless another value has been accepted by Health Canada.

## Food Allergen Labelling

New regulations on food allergen labelling came into force on August 4, 2012 for all pre-packaged foods sold in Canada. Specific priority food allergens, gluten sources and added sulphites must be declared on food labels, either in the list of ingredients or immediately following the list of ingredients using the format "Contains: [common name of allergen]." Mustard is a new priority allergen.

## Priority Food Allergens in Canada

The foods or protein derived from the foods listed below are priority food allergens:

- Peanuts
- Tree nuts (almonds, brazil nuts, cashews, hazelnuts, macadamia nuts, pecans, pine nuts, pistachios, walnuts)
- Sesame seeds
- Milk
- Eggs
- Seafood (fish, crustaceans and shellfish)
- Soybeans
- Wheat (including kamut, spelt and triticale)
- Mustard seeds

**Gluten sources** need to be declared when a food contains gluten protein or modified gluten protein from barley, oats, rye, triticale, or wheat (including kamut and spelt). Health Canada's position on gluten-free claims restricts label statements to products containing less than 20 ppm of any gluten protein, including protein fractions.

**Added sulphites** need to be declared when directly added to a food, or when the total amount of added sulphites in the food is 10 parts per million or more.

Additional guidance on allergen labelling is available from Health Canada's Food Allergen Labelling web page and CFIA's Enhanced Labelling Regulations for Food Allergens web page.

### Precautionary Statements

A precautionary statement should only be used when, despite all reasonable measures, the inadvertent presence of an allergen in food is unavoidable. Furthermore, it should not be used unless there is a real risk of the allergen being present in the food. The policy on *The Use of Food Allergen Precautionary Statements on Prepackaged Foods* recommends that industry use only one set of wording on food labels: "May contain [common name of allergen]".

## Foods with Added Vitamins and Minerals

The FDR (Part D) controls the addition of vitamins and mineral nutrients by prescribing which foods may contain added nutrients, and the nutrients and levels allowed; additions not listed in the regulations are prohibited.

However, manufacturers may request that Health Canada allow for the addition of vitamins and mineral nutrients to foods where not currently permitted.

- To permit the addition, Health Canada may either pursue a regulatory amendment to Part D of the FDR or create a ministerial regulation (a "Marketing Authorization" [MA]).
- In some instances, a Temporary Marketing Authorization (TMA) may be used if the manufacturer needs to generate additional marketplace and consumer information to support the amendment or the creation of the MA. Consult the *General Guidance Document for Temporary Marketing Authorization for Foods*.

# Novel Foods, Novel Fibres and Food Additives



Novel foods, novel fibres and food additives require a pre-market safety assessment by Health Canada before they can be sold in Canada. Prior to making a submission, industry is encouraged to contact Health Canada's Submission Management and Information Unit (SMIU) to clarify the regulatory requirements.

**Novel foods** are products that do not have a history of safe use as a food, foods resulting from a process not previously used for food, or foods that have been modified by genetic manipulation (also known as genetically modified foods, GM foods, genetically engineered foods or biotechnology-derived foods).

- Health Canada maintains a list of accepted novel foods.
- Consult *Guidelines for the Safety Assessment of Novel Foods Derived from Plants and Microorganisms* for information on the notification process and data requirements for a safety assessment.

**Novel fibres** are ingredients manufactured to be sources of dietary fibre. They are synthetically produced or obtained from natural sources that have no history of safe use as dietary fibre or have been processed so as to modify the properties of the fibre. Fine grinding is no longer a factor in determining whether a product is a novel fibre source. Accepted novel fibres have at least one physiological effect demonstrated by generally accepted scientific evidence. Once a novel fibre source has been accepted by Health Canada, it is considered to be a dietary fibre and should be declared on food package labels as dietary fibre.

- Consult *Policy for Labelling and Advertising of Dietary Fibre-Containing Food Products*.
- Consult *Guideline Concerning the Safety and Physiological Effects of Novel Fibre Sources and Food Products Containing Them*.

**Food additives** are any substances added to a food for a specific function during manufacturing or processing that become a part of the food or affect the food's characteristics (specific exclusions are outlined in the FDR). Pre-market approval is required for new food additives that are not already regulated in the FDR, and for proposed new uses of an existing food additive.

- Consult *A Guide for the Preparation of Submissions on Food Additives*.
- A *Food Additive Submission Checklist* is also available.

Submissions for novel foods, novel food processes, food additives and food processing aids that have a demonstrated capacity to enhance microbiological food safety may be given priority.

- Consult *Priority Scheduling and Expedited Handling of Submissions that Have the Capacity to Enhance Food Safety* for the information required in the submission.

# Nutrition Claims Permitted in Canada

Several types of nutrition-related claims and declarations can be made in Canada. Many of these relate to the nutrients or nutrient content. For the purposes of food labelling and advertising, Health Canada considers a substance to be a nutrient if it is recognized as such by the U.S. Institute of Medicine (IOM) of the National Academies. Canada is a participant on IOM committees.

## Nutrient Content Claims

Nutrient content claims describe the quantity of energy or of a nutrient in a food. Only those claims listed in the FDR are permitted. For each claim, the regulations prescribe the compositional criteria, the wording, the reference amount, and any additional labelling requirements.

- The vitamin or mineral nutrient must have an established Recommended Daily Intake, and the food must contain a minimum 5% of the Daily Value.
- Specific guidelines govern statements that identify the amount of a nutrient in a food (e.g. "source", "good source", "excellent source") and compare nutrient content (e.g. "reduced", "less", "light"), based on a regulated standardized reference amount for foods and the serving size for the particular food.
- When a nutrient content claim is made, a Nutrition Facts table must be provided.
- Details are outlined in Chapter 7 of the *Guide to Food Labelling and Advertising*.

## Quantitative Declaration of Nutrients and Non-Nutrients

Simple label declarations of the amount of a food ingredient, component, or food constituent present in a food may be made on a voluntary basis provided the information is truthful and not misleading.

- These declarations must be made outside of the Nutrition Facts table in grams or milligrams per serving of the food.
- Quantitative statements can be made for energy and nutrients, as well as for food constituents that are not nutrients, such as lutein, lycopene, and epicatechin (a polyphenol).
- The declarations should preferably be grouped together immediately below the Nutrition Facts table or adjacent to the ingredient listing. Word sets such as "only", "contains", or "more than" may not be used.

## Composition and Quality Claims

Claims can be made about the composition, quality, or origin of products—such as "organic" or "natural"—as long as they are truthful, not misleading, and in compliance with other regulatory requirements.

- Details are outlined in Chapter 4 of the *Guide to Food Labelling and Advertising* and additional information from CFIA on Method of Production.
- Consult *Guidelines on Natural, Naturally Raised, Feed, Antibiotic and Hormone Claims*.

## Nutrient Function Claims

Nutrient function claims describe the well-established roles of energy or known nutrients in a food that are essential for the maintenance of good health or for normal growth and development.

- The following two **general** nutrient function claims are acceptable for all nutrients when conditions for their use are followed:
  - "Energy (or Name of the nutrient) is a factor in the maintenance of good health."
  - "Energy (or Name of the nutrient) is a factor in normal growth and development."
- Other examples of nutrient function claims include:
  - "Vitamin A supports night vision."
  - "Calcium aids in the formation and maintenance of bones and teeth."
  - "DHA, an omega-3 fatty acid, supports the normal physical development of the brain, eyes and nerves primarily in children under two years of age."
- A list of acceptable nutrient function claims and conditions for their use is found in Chapter 8 of the *Guide to Food Labelling and Advertising* (section 8.6).

# Health Claims Permitted in Canada

A health claim is any representation in labelling or in advertising that states, suggests, or implies that a relationship exists between consumption of a food or food constituent (including an ingredient in the food), and health. Health claims may be stated explicitly with words, or implied through symbols, graphics, logos or other means such as a name, trademark or seal of approval.

Health claims are grouped into several categories based on how they are regulated and evaluated: **general health claims, function claims, disease risk reduction claims** and **therapeutic claims.**

All health claims must be truthful and not misleading, and substantiated with scientific evidence before they appear on food product labels or in advertising. For a summary of the types of health claims permitted in Canada, along with requirements for pre-market approval and scientific substantiation, see the table on page 8.

## General Health Claims

General health claims promote health through healthy eating or provide dietary guidance. These claims do not refer to a specific product or to a health effect, disease, or health condition.

An example of acceptable general health claims is:

- "Canada's Food Guide recommends eating at least one dark green and one orange vegetable each day."

## Function Claims

Function claims are health claims that describe the specific beneficial effects that the consumption of foods or food constituents has on the normal functions or biological activities of the body associated with health or performance.

A function claim must not refer directly or indirectly to the treatment, mitigation or prevention of any disease, disorder or abnormal physical state, or of their symptoms. It also may not refer directly or indirectly to correcting or restoring abnormal functions or to modifying organic functions beyond the normal physiological effects of food.

Examples of acceptable function claims include:

- "Consumption of 1 cup of green tea helps to protect blood lipids from oxidation."
- "1/4 cup of [naming the food] contains 7 grams of fibre from coarse wheat bran, which promotes regularity."

## Disease Risk Reduction Claims and Therapeutic Claims

**Disease risk reduction claims** highlight a specific relationship between a food, a food constituent, or the characteristics of a diet and a reduced risk of developing a diet-related disease or condition. For example, "[naming the food or food constituent] may reduce the risk of cardiovascular disease". Any food that meets the criteria may carry the claim using the prescribed wording for the claim.

Since 2003, Health Canada has allowed disease risk reduction claims that reflect five substantiated relationships:

- low sodium, high potassium and reduced risk of high blood pressure;
- calcium, vitamin D and reduced risk of osteoporosis;
- low saturated and trans fat and reduced risk of heart disease;
- vegetables and fruit and reduced risk of some types of cancers; and
- non-fermentable carbohydrates in gums and hard candies and the non-promotion of dental caries (cavities).

**Therapeutic claims** highlight the therapeutic effect of a food, food constituent or diet, including restoring, correcting, or modifying body functions. For example, "[naming the food or food constituent] lowers blood cholesterol". The composition of a food that carries the claim must contribute to a healthy dietary pattern as outlined in the conditions for use.

Health Canada has authorized the use of therapeutic claims on the following food–health relationships:

- replacement of saturated fats with unsaturated fats and blood cholesterol lowering;
- psyllium fibre and blood cholesterol lowering;
- plant sterols (phytosterols) and blood cholesterol lowering;
- oat fibre and blood cholesterol lowering; and
- barley fibre and blood cholesterol lowering.

If a disease risk reduction or a therapeutic claim associates a food as a treatment, preventative or cure for any of the diseases referred to in Schedule A of the *Food and Drugs Act,* then a regulatory amendment is needed. Otherwise a regulatory amendment may not be required before the claim can be used.

**Probiotic claims** are claims about live microorganisms in foods which, when administered in adequate amounts, may confer a health benefit (e.g. "promotes regularity" and "improves nutrient absorption and aids in digestion"). Pre-market consultation is recommended for new probiotic claims as there are specific requirements for the safety, quality (stability) and labelling of such food products. The type of claim available will be determined by the scientific evidence.

- Consult *Guidance Document – The Use of Probiotic Microorganisms in Food*.
- Details are outlined in Chapter 8 of the *Guide to Food Labelling and Advertising* (section 8.7).

## A Summary of Health Claim Requirements in Canada

| Type of Claim | Pre-Market Approval | Scientific Substantiation |
|---|---|---|
| **All Health Claims**<br>• Any representation in labelling or in advertising that states, suggests, or implies that a relationship exists between consumption of a food, or an ingredient in the food, and health<br>• Applies to symbols, graphics, logos, trademarks or seals of approval as well as words | • Follow the *Canadian Food Health Claim Roadmap* for a logical approach to regulatory considerations en route to using claims | • All claims must be supported by scientific evidence in a systematic, comprehensive and transparent manner |
| **Nutrient Function Claims**<br>• Describe well-established roles of energy or nutrients that are essential for maintenance of good health or for normal growth and development | • Pre-market notification is not required for accepted nutrient function claims listed in GFLA* Chapter 8 (section 8.6) | • New nutrient function claims will be considered only for nutrients with established recommended intakes and if the function reflects consensus among authoritative scientific bodies |
| **General Health Claims**<br>• Broad statements on healthy eating patterns or dietary guidance<br>• Do not refer to a health effect, disease, or health condition | • Pre-market notification is not normally required<br>• Statements that imply "healthy choice" or the use of a logo or symbol are subject to review and must not be false, misleading or deceptive | • Consult GFLA* Chapter 8 (sections 8.8–8.15) |
| **Function Claims**<br>• Link the consumption of a food or a food constituent with normal body functions or biological activities<br>• Based on the role that the food or food constituent plays when consumed at levels consistent with normal dietary patterns | • A list of acceptable function claims and conditions for use is maintained in GFLA* Chapter 8 (section 8.5)<br>• Pre-market notification is recommended for new function claims<br>• Evidence should be available upon request | • Claims must be supported by acceptable standards of evidence<br>• Claims should clearly state a specific and scientifically supported physiological effect associated with good health or performance<br>• Consult Guidance Documents for Preparing Health Claim Submissions |
| **Disease Risk Reduction and Therapeutic Claims**<br>• Link a food, food constituent, or dietary characteristic to a reduced risk of developing a diet-related disease or condition (e.g. heart disease) or highlight a therapeutic effect, including restoring, correcting, or modifying body functions (e.g. lowering cholesterol)<br>• Food must contribute to a healthy dietary pattern<br>• The health effect is based on food's normal use as part of the diet | • A list of claims reviewed by Health Canada for scientific validity is published on Health Canada's Health Claim Assessments web page<br>• Conditions of use and prescribed wording apply<br>• If a claim associates a food as a treatment, preventative or cure for any of the diseases referred to in Schedule A of the FDA, then a regulatory amendment is needed prior to use<br>• If the claim is not subject to Schedule A, then a regulatory amendment may not be required before the claim can be used | • Consult Guidance Documents for Preparing Health Claim Submissions<br>• Submissions for new claims must characterize the food and the health effect, substantiate claim validity, demonstrate feasibility of consumption of effective dose, and propose claim wording |

*GFLA = CFIA's *Guide to Food Labelling and Advertising*

# Resources

## AAFC Food Regulatory Issues Division

- Food Policy and Regulatory Issues
  *www.agr.gc.ca/food-regulatory-issues*
- Canadian Food Health Claim Roadmap
  *www4.agr.gc.ca/AAFC-AAC/display-afficher.do?id=1311966040606&lang=eng*

## Health Claims, Food Labelling and Advertising

- Health Canada Guidance Documents
  *www.hc-sc.gc.ca/fn-an/legislation/guide-ld/index-eng.php*
- Health Claim Assessments
  *www.hc-sc.gc.ca/fn-an/label-etiquet/claims-reclam/assess-evalu/index-eng.php*
- Canadian Food Health Claim Roadmap
  *www4.agr.gc.ca/AAFC-AAC/display-afficher.do?id=1311966040606&lang=eng*
- Guide to Food Labelling and Advertising
  *www.inspection.gc.ca/english/fssa/labeti/guide/toce.shtml*
- Food Labelling and Advertising Resources
  *www.inspection.gc.ca/food/labelling/eng/1299879892810/1299879939872*
- Updates to Food Labelling and Advertising Information
  *www.inspection.gc.ca/english/fssa/labeti/amende.shtml*

## Food Additives and Novel Foods

- Genetically Modified (GM) Foods and Other Novel Foods (pre-submission consultation procedures, list of accepted novel foods, guidelines for safety assessment)
  *www.hc-sc.gc.ca/fn-an/gmf-agm/index-eng.php*
- Priority Scheduling and Expedited Handling of Submissions that have the Capacity to Enhance Food Safety
  *www.hc-sc.gc.ca/fn-an/securit/addit/priority-priorite/index-eng.php*

## Food and Natural Health Product Classification

- Foods Marketed as Natural Health Products
  *www.hc-sc.gc.ca/fn-an/prodnatur/index-eng.php*
- Authorized Food Products (specific classification criteria for the categories being transitioned to the food regulations)
  *www.hc-sc.gc.ca/fn-an/prodnatur/auth-food-aliment-eng.php*
- Classification of Products at the Food–Natural Health Product Interface: Products in Food Formats
  *www.hc-sc.gc.ca/dhp-mps/prodnatur/legislation/docs/food-nhp-aliments-psn-guide-eng.php*

## Food Allergen Labelling and Gluten-Free Claims

- Food Allergen Labelling
  *www.hc-sc.gc.ca/fn-an/label-etiquet/allergen/index-eng.php*
- Enhanced Labelling Regulations for Food Allergens
  *www.inspection.gc.ca/food/consumer-centre/food-allergens/eng/1330450829791/1330450993196*
- Health Canada's Position on Gluten-Free Claims
  *www.hc-sc.gc.ca/fn-an/securit/allerg/cel-coe/gluten-position-eng.php*
- CFIA Compliance and Enforcement of Gluten-Free Claims
  *www.inspection.gc.ca/food/labelling/other-requirements/gluten-free-claims/eng/1340194596012/1340194681961*

## Health Canada Submission Management and Information Unit (SMIU)

*www.hc-sc.gc.ca/fn-an/legislation/guide-ld/smiu_qa-qr-eng.php*

## Email notification lists

- AAFC Food Regulatory Issues: *www.agr.gc.ca/FRID-bulletin*
- Food Additives: *www.hc-sc.gc.ca/fn-an/securit/addit/enot-add-avise-eng.php*
- Food Allergies: *www.hc-sc.gc.ca/fn-an/securit/allerg/fa-aa/allergen_e-notice_avis-eng.php*
- Labelling: *www.inspection.gc.ca/english/util/listserv/listcsube.shtml?LABETI-DEC*
- Nutrition Bulletin: *www.hc-sc.gc.ca/fn-an/nutrition/listserv-eng.php*
- Nutritional Sciences (NUTSCI): *www.hc-sc.gc.ca/fn-an/res-rech/res-prog/nutri/nustci_mailing_list-liste_correspondant_nutsci-eng.php*
- Food and Nutrition RSS feed: *www.hc-sc.gc.ca/rss/fn-an/fn-an-eng.xml*

To learn more about policy and regulatory issues facing Canada's food industry, visit *www.agr.gc.ca/food-regulatory-issues*.

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