Agriculture and Agri-Food Canada | Agriculture et Agroalimentaire Canada

Canada

REGULATORY READINESS: A DECISION MODEL FOR CANADIAN FOOD PRODUCTS

The Regulatory Readiness decision model leads food product developers, researchers and marketers through a logical step-by-step approach to promote compliance with food regulatory requirements.

This tool provides general guidance to help get started; it does not necessarily cover all situations.

Food manufacturers and importers are legally responsible for ensuring that their products are accurately positioned in the marketplace and comply with Canadian legislation. Regulations are focused on protecting consumer health and safety as well as preventing fraud.

OVERVIEW OF THE DECISION MODEL

- The Regulatory Readiness decision model is designed to help the agri-food industry navigate Canada's food regulatory environment and take advantage of market opportunities.
- The decision model helps industry identify food regulatory requirements and information gaps to consider in advance of product development or marketing, and directs them to the right resources.
- The model is based on six key questions to consider prior to launching a new food product:

1. **Which regulatory framework is relevant?**
   This step focuses on determining whether the product would be best classified as a food or as a natural health product according to the regulations.

2. **Does the food need to meet specific standards?**
   The purpose of this step is to establish whether the product is intended to meet specific nutritional or medical needs or is a standardized food subject to compositional or other conditions.

3. **Are the foods or ingredients approved for use in Canada?**
   The focus of this step is to determine whether the food or any of its ingredients would be considered novel foods, novel fibres or food additives, which require a pre-market safety assessment before they can be sold in Canada.

4. **What must go on the product label – mandatory information?**
   This step addresses the mandatory label components, such as the Nutrition Facts table and list of ingredients. It also includes allergen-related topics: both mandatory labelling of priority food allergens and voluntary allergen statements and claims.

5. **What claims could go on the product label – voluntary information?**
   The focus of this step is to assess options for voluntary claims and the conditions for their use. It explores claims that have already been accepted by Health Canada and the requirements for making new claims, including scientific substantiation.

6. **Are your research, business and marketing plans aligned?**
   The purpose of this step is to consider the time and costs for complying with regulatory requirements for ingredients and claims for the food product from the perspective of research, business and marketing plans, to guide decisions on product positioning.

- At each step, the model considers whether a pre-market submission is required.
- The flow chart provides a visual overview of the steps to follow when pursuing new food products. Industry should also review the information and decisions required at each step, including key resources such as regulations, policies and guidance.

© Her Majesty the Queen in Right of Canada, represented by the Minister of Agriculture and Agri-Food, (2015) AAFC No. 12453E

REGULATORY READINESS: A DECISION MODEL FOR CANADIAN FOOD PRODUCTS

STEP 1 — Which regulatory framework is relevant?

Foods
Items manufactured, sold or represented for use as a food or drink, and any ingredients that may be mixed with food. This includes herbs, spices, chewing gum, candy, energy drinks, vitamin waters, energy bars and most powdered drinks.

Natural Health Products (NHPs)
Over-the-counter substances taken in a specified dose for the prevention or treatment of an illness or condition, or maintenance of good health. They have their own regulatory requirements, such as site and product licenses. Skip to Step 6.

STEP 2 — Does the food need to meet specific standards?

Foods for Special Dietary Use
Foods specially processed or formulated for specific nutritional or medical purposes in targeted populations.

Standardized Foods
Specific foods with standards of identity that define the name, composition and processes allowed for the foods.

STEP 3 — Are the foods or ingredients approved for use in Canada?

Novel Foods
Foods with no history of safe use as a food in Canada, from a process not previously used for food, or modified by genetic manipulation.
! Pre-market approval (for safety) is required.

Novel Fibres
Ingredients manufactured to be a source of dietary fibre, with no history of safe use in Canada or with modified properties.
! Pre-market approval is voluntary. Review by Health Canada is required for it to be included in the list of accepted dietary fibres.

Food Additives
Substances added to food for a specific function which become part of the final product or affect its characteristics.
! Pre-market approval (for safety) is required for new food additives, new uses of existing food additives or new sources of enzymes.

Foods with Added Vitamins, Minerals and/or Bioactives

- **Fortified Foods**
  Foods to which prescribed levels of vitamins and mineral nutrients have been added to address a public health need.
- **Supplemented Foods**
  Foods to which substances, such as vitamins, minerals, amino acids, herbals or bioactives, have been added with the intent of providing a health benefit.
  ! Pre-market approval (Temporary Marketing Authorization) is often required to support a regulatory amendment or ministerial regulation (Marketing Authorization).

STEP 4 — What must go on the product label? — Mandatory information

Core Labelling Requirements
Mandatory basic product information including common name, net quantity, durable life date and name and address of manufacturer.

Nutrition Facts Table
Mandatory standard information on most prepackaged food and triggered by the use of a claim or quantitative declaration.

Ingredient List
Mandatory list of ingredients, generally presented in descending order of predominance by weight.

Priority Allergen Labelling
Mandatory declaration of specific priority allergens, gluten sources and added sulphites.

- **Precautionary Statements**
  Voluntary declarations to be used only when inadvertent presence of an allergen cannot be avoided.
- **Allergen-Free Claims**
  Voluntary claims for foods specially formulated or processed to ensure the absence of an allergen that may be present in a similar food.

STEP 5 — What claims could go on the product label? — Voluntary information

Accepted Claims

Nutrient Content Claims
Claims that describe the quantity of energy or a known nutrient in a food.

Quantitative Declarations of Nutrients and Non-Nutrients
Label declarations made outside the Nutrition Facts table about the amount of energy, nutrients, or non-nutrient food constituents.

Dietary Guidance Claims
Broad claims that promote health through recognized healthy eating patterns or dietary guidance.

Nutrient Function Claims
Claims about established roles for energy or nutrients essential for maintenance of good health or for normal growth and development.

Function Claims
Claims that describe specific beneficial effects of a food or food constituent on the normal functions or biological activities of the body for health or performance.

Disease Risk Reduction and Therapeutic Claims
Claims that link a food or food constituent to reducing the risk of a diet-related disease or condition, or to the treatment or mitigation of a disease or health-related condition, including restoring or correcting a body function.

New Health Claims

New Nutrient Function Claims, Function Claims, Disease Risk Reduction Claims and Therapeutic Claims
! Pre-market approval is generally voluntary for new claims. Review by Health Canada is required for the claim to appear in a list of accepted claims.
! Pre-market approval is required if the claim associates food as a treatment, preventative or cure for any of the diseases referred to in Schedule A of the *Food and Drugs Act*.

Product Attribute Claims

Composition, Quality, Origin and Method of Production Claims
Claims that describe specific characteristics of a product, such as “organic”, “natural”, “halal”, “local”, “Product of Canada”, or “GMO free”. They may be regulated or require third party certification.

STEP 6 — Are your research, business and marketing plans aligned?

Research Plan
Scientific evidence is needed to substantiate the health benefits and safety of the product.

Business Plan
Resources, including costs and time, will be required to support the regulatory approval process.

Marketing Plan
Product launch timelines will be affected by regulatory requirements. Information on the label or in advertising must comply with regulations and be truthful and not misleading.