Health Canada Santé Canada

Classification of Products at the Food – Natural Health Product Interface: Products in Food Formats

Natural Health Products Directorate
Food Directorate

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Canada

“Health Canada is the Federal department responsible for helping Canadians maintain and improve their health, while respecting individual choices and circumstances.”

Health Canada

“Our vision is to be the most trusted authority providing policies, standards, advice and information on the safety and nutritional value of food.”

Food Directorate

“Our role is to ensure that Canadians have ready access to natural health products that are safe, effective and of high quality while respecting freedom of choice and philosophical and cultural diversity.”

Natural Health Products Directorate

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1. Introduction

In Canada, natural health products and foods are regulated under the *Food and Drugs Act* (FDA) and its associated regulations. Products that meet the definition "natural health product" in the *Natural Health Products Regulations* (NHPR) are subject to the FDA as it applies to a drug and to the NHPR. Products that are foods as defined in the FDA are subject to the FDA as it applies to food and to Parts A, B and D of the *Food and Drug Regulations* (FDR). A product, that is both a natural health product and a food is subject to the NHPR but is exempted from the FDA and its regulations as they apply to a food[1].

Since the implementation of the *Natural Health Products Regulations* on January 1, 2004, Health Canada has received several hundred Product License Applications for products in food format. Examples include energy drinks, vitamin or mineral supplements in candy format, and some juices or waters with added vitamins and minerals. Health Canada is also aware of products in food format that meet the definition "natural health product" that are currently offered for sale without a product licence having been issued or applied for.

This guidance document outlines the principles and considerations to be applied in determining if a product in a food format is a natural health product[2]. It has been created and published with a view to achieving greater consistency, transparency and quality of classification decisions relating to products in food format. It is intended to be used in conjunction with other existing guidance documents and policies[3].

[1] Section 3 of the *Natural Health Products Regulations.*

[2] It should be noted that every product is assessed on a case-by-case basis taking account of the available facts relevant to whether a product meets the definition "natural health product" as set out in the *Natural Health Products Regulations*.

[3] The criteria described in this document do not enable a determination of whether a product meets all the requirements of the relevant legislation. It is the responsibility of the manufacturer of a product to ensure that it complies with all the relevant requirements, legislation and associated regulations.

2. Interpretation

The following definitions are provided to assist in the interpretation of this guidance document:

"food" (Section 2 of the *Food and Drugs Act*) means any article manufactured, sold or represented for use as a food or drink for human beings, including chewing gum, and any ingredients that may be mixed with food for any purpose whatever.

"natural health product" (Section 1 of the *NHPR)* means a substance set out in Schedule 1 of the *NHPR*[4] or a combination of substances in which all the medicinal ingredients are substances set out in Schedule 1, a homeopathic medicine or a traditional medicine, that is 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 humans;
(*b*) restoring or correcting organic functions in humans; or
(*c*) modifying organic functions in humans, such as modifying those functions in a manner that maintains or promotes health.

For the purposes of this guidance document, a product is **"in food format"** if it is sold in a format and serving size consistent with food use. Examples of products in a food format include chewing gums, hard candies, candy bars, tea, juices and beverages. Capsules, pills, and tablets are not considered to be food formats.

For the purposes of this guidance document, **"therapeutic use"** means a product that is used for the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state or its symptoms in humans, or restoring or correcting organic function in humans, or modifying organic functions in humans.

[4] Substances listed in Schedule 1 to the NHPR ("Schedule 1 Substances") include:

1. A plant or a plant material, an alga, a bacterium, a fungus or a non-human animal material
2. An extract or isolate of a substance described in item 1, the primary molecular structure of which is identical to that which it had prior to its extraction or isolation
3. Any of the following vitamins: biotin, folate, niacin, pantothenic acid, riboflavin, thiamine, vitamin A, vitamin B6, vitamin B12, vitamin C, vitamin D, vitamin E, vitamin K1, vitamin K2,
4. An amino acid
5. An essential fatty acid
6. A synthetic duplicate of a substance described in any of items 2 to 5
7. A mineral
8. A probiotic

For the purposes of this guidance document, **“food purpose”** means a purpose that has been established by history of use, or by being regulated, defined or implied by the FDR, or that has been accepted following a novel food notification.

3. Scope

This guidance document pertains to a product that is in a food format and that:

- contains a substance listed in Schedule 1 to the *Natural Health Products Regulations* at a level that is not permitted for use in a food under the food provisions of the *Food and Drug Regulations*; or
- makes a claim for a therapeutic use that is not permitted to be made for a food under the food provisions of the *Food and Drug Regulations*.

4. Guiding Principles and Relevant Considerations

The following principles guide classification decisions to determine if a product in food format is a natural health product:

1- The definition “food” in the *Food and Drugs Act* and “natural health product” in the *Natural Health Products Regulations* must be interpreted in a manner that respects the primary objectives of the *Act* and its associated regulations: the protection of public health and safety.[5]

2- While potential health risks alone do not classify a product as either a food or an NHP, risk can be taken into account in interpreting definitions and applying appropriate regulatory frameworks that best achieve objectives relating to health protection. For example, a product’s use as a food implies that the product can be consumed freely and without regard to quantity.

In deciding whether a product in food format is a natural health product, the regulator will take account the following criteria:

- Product Composition;
- Product Representations;
- Product Format; and
- Public Perception and History of use.

4.1 Product Composition

Many foods and ingredients in food have health effects. When a food or ingredient is present in a product solely to provide nourishment, nutrition or hydration, or to satisfy hunger, thirst or a desire for taste, texture or flavour this is an indication that the product is a food and not an NHP – even if the product or ingredient falls within a class of substances included in the definition “natural health product”.

Conversely, a product that is or that contains an added ingredient that has no known food purpose but that has only a therapeutic use is likely to be classified as a natural health product[6]. Similarly, a product that is or that contains a substance that has a known food purpose – but is present at a level incompatible with its use as a food and that is consistent only with a therapeutic use – is likely to be classified as a natural health product. The nature of and risks associated

[5] Consistent with the objectives of Health Canada and the applicable regulatory frameworks.

[6] Examples include glucosamine sulfate, chondroitin sulfate, methylsulfonylmethane, Valerian, 5-HTP, St. John's Wort, and Ginkgo Biloba.

with the health effects related to such an ingredient are also relevant to how the product is to be classified.

4.2 Product Representations

"Representation" includes indications of use, claims presented as a word, sentence, a picture, a symbol, a paragraph or an implication on product labels, package inserts or advertisement, placement and location of sale. A product that might for composition or other reasons be classified as a food may nonetheless be a natural health product if it is represented or sold as a product having therapeutic uses. The nature of, and risks associated with a product's representation of its therapeutic uses are also relevant to how the product is to be classified.

Some representations on a product's label or in advertising associated with it will provide an indication that it is an NHP. Claims that speak to a product having therapeutic uses that are not based on the use of the product as a food suggest the product is an NHP.

4.3 Product Format

NHPs are typically sold in a format that allows them to be consumed in measured or controlled amounts (doses). If a product is sold in a *particular* food format (for example, a beverage) that lends itself to dosing **(for example if it is sold in single dosage units or it is sold with a measure that indicates it to be consumed in controlled amounts)** this is one indication that the product is an NHP as defined in the *Natural Health Products Regulations*.

4.4 Public Perception and History of Use

If a product has a historical pattern of use as a food or if the public perception associated with the use of a product in the marketplace is that it is a food, these are indications that the product is a food rather than an NHP.

Conversely, if the public perception associated with a product and its history and pattern of use indicate it is sold for a therapeutic purpose this supports the conclusion that the product is a natural health product.

5. The Classification Decision-Making Process

Classification decisions are used to administer, monitor compliance with, and enforce the *Food and Drugs Act* and its regulations; and in particular the *Natural Health Products Regulations* and Parts A, B and D of the *Food and Drug Regulations*.

The criteria outlined in this guidance document are used by Health Canada to determine if a product in food format is a natural health product. These classification decisions will be made by the Food-NHP Classification Committee (F-NCC). The F-NCC will be made up of representatives from both the *Food Directorate* and *Natural Health Products Directorate* with expertise in the science underlying their respective product lines.

The F-NCC will apply this guidance document in making classification decisions. The Committee will also consider other information that may be useful in arriving at classification decisions. For example, the Committee may consider the classification decisions of other regulatory bodies.[7]

[7] Health Canada recognizes the global nature of trade in these products. Decisions of other regulatory bodies would be interpreted to take account of the difference in legal systems, legislation and policies.