Health Canada Santé Canada

GUIDANCE DOCUMENT

Classification of products at the food-natural health product interface: products in food formats

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Health Products and Food Branch

Our mission is to help the people of Canada maintain and improve their health. *Health Canada*	HPFB's Mandate is to take an integrated approach to managing the health-related risks and benefits of health related to health products and food by: • minimizing health risk factors to Canadians while maximizing the safety provided by the regulatory system for health products and food; and, • promoting conditions that enable Canadians to make healthy choices and providing information so that they can make informed decisions about their health. *Health Products and Food Branch*

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FOREWORD

Guidance documents are intended to provide assistance to industry and health care professionals on how to comply with governing statutes and regulations. Guidance documents also provide assistance to Health Canada employees on how Health Canada's mandates and objectives should be implemented in a manner that is fair, consistent and effective.

Guidance documents are administrative instruments not having force of law and, as such, allow for flexibility in approach. Alternate approaches to the principles and practices described in this document may be acceptable provided they are supported by adequate justification. Alternate approaches should be discussed in advance with the relevant program area to avoid the possible finding that applicable statutory or regulatory requirements have not been met.

As a corollary to the above, it is equally important to note that Health Canada reserves the right to request additional information or material, or define conditions not specifically described in this document, in order to allow the Department to adequately assess the safety, efficacy or quality of a product if required. Health Canada is committed to ensuring that such requests are justifiable and that decisions are clearly documented.

This document should be read in conjunction with the relevant sections of other applicable guidance documents.

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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 of a "natural health product" (NHP) as set out in the *Natural Health Products Regulations* (NHPR) are subject to the FDA as it applies to drugs and to the NHPR. Products that are foods as defined in the FDA are subject to the FDA as it applies to foods and to Parts A, B and D of the *Food and Drug Regulations* (FDR). It is important to note that the provisions of the FDR do not apply to products classified as NHPs except where such provisions are incorporated by reference into the NHPR, as per section 3 of the NHPR.

Since the implementation of the NHPR on January 1, 2004, Health Canada has received several hundred Product Licence Applications for products in food formats. Some products with added vitamins, minerals or amino acids that appear to be foods, as well as foods making certain health claims, previously gained market access as NHPs under the NHPR. Examples of food products that were marketed as NHPs include energy drinks, waters and juices with added vitamins and minerals, and bars with specific health claims. Given that these products share characteristics of both foods and NHPs, they caused confusion among consumers. Health Canada indicated its intent to resolve this confusion around foods that are marketed as NHPs and began working with manufacturers in May 2010 to safely transition food products marketed as NHPs to the food regulatory framework. As a first step, Health Canada announced in October 2011 its intent to transition caffeinated energy drinks to the food regulatory framework. Additional categories of foods that were marketed as NHPs began transitioning in April 2012 and the transition was completed in December 2012. The goal of the transition process was to ensure that products that look like foods and are consumed as foods are regulated as foods. In doing so, Canadians are able to make more informed choices due to consistent nutrition information and labelling requirements.

This guidance document outlines the principles and considerations to be applied in determining whether a product in a food format is an NHP or a food[1]. It is intended to help users (for example, industry, health care professionals, Health Canada and Canadian Food Inspection Agency (CFIA) staff) determine whether a product is subject to the regulatory requirements of the FDR or the NHPR, and to facilitate consistent and predictable decision-making when determining the regulatory pathway for products falling at the food-NHP interface. This guidance document is aimed at 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[2].

[1] It should be noted that classification is completed on a category basis (See APPENDIX 1 CLASSIFICATION CRITERIA) and/or a case-by-case basis taking account of the available facts relevant to whether a product meets the definition of a "natural health product" as set out in the NHPR or the definition of a "food" as set out in the FDR.

[2] 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 FDA) 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.

"food-NHP interface product" means any product that is in a food format and meets the scope of this document as outlined in Section 3 below.

"natural health product" (excerpt from Section 1 of the NHPR[3]) means a substance set out in Schedule 1[4] of the NHPR 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 consistent with food use. Examples of products in a food format include chewing gums, hard candies, candy bars and beverages. Capsules are not considered to be food formats. Capsules are defined as "a solid preparation with hard or soft shell, of variable shape and capacity, usually containing a single dose of active ingredient(s) for oral administration"[5]

For the purposes of this guidance document, **"health claim"** means a claim regarding 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.

[3] Note that there are some substances excluded from the definition of a natural health product that are not listed here. See remainder of definition of an NHP in Section 1, as well as Schedule 2 and Section 2.2 to the NHPR for more details.

[4] Substances listed in Schedule 1 to the NHPR ("Included Natural Health Product Substances") are:

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 B_6, vitamin B_{12}, vitamin C, vitamin D, vitamin E, vitamin K_1, vitamin K_2
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

[5] As defined in the Natural Health Products Ingredient Database.

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 AND APPLICATION

This guidance document applies to products falling at the food-NHP interface whose classification with respect to the appropriate regulatory framework is not immediately apparent. It is intended to help users determine whether a product is subject to the regulatory requirements of the FDR or the NHPR.

4. GUIDING PRINCIPLES AND RELEVANT CONSIDERATIONS

The following principles guide classification decisions to determine whether a product in food format is an NHP or a food:

1. The definition "food" in the FDA and "natural health product" in the NHPR 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.[6]

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. Additional steps may be required to mitigate potential health risks following a classification decision. For example, if a liquid product is classified as an NHP, the product would need to be packaged appropriately and potentially include a measuring device to ensure that it is not perceived as a beverage or food as it would be unsafe to be consumed ad libitum.

In deciding whether a product in food format is an NHP or a food, the following criteria will be taken into account:

- Product composition;
- Product representation;
- Product format; and
- Public perception and history of use.

The above criteria are considered in combination, when determining the classification of products at the interface. Depending on the nature of the product, however, some criteria may be more influential in the classification decision than others. For example, product format is considered to be a primary factor in the classification of ready-to-drink beverages and conventional foods, as discussed further in section 4.3. Product representation is generally considered a very important factor in classification for all types of products at the interface.

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

Conversely, product composition, and public perception and history of use are always considered; however, they are typically not determining factors in classification (see sections 4.1 and 4.2).

The criteria outlined in this guidance document are used by Health Canada to determine whether a product in food format is an NHP or a food. Other information that may be useful in arriving at the appropriate classification will also be considered; for example, classification decisions of other regulatory bodies.[7]

4.1 Product Composition

All ingredients contained in a product at the food-NHP interface are considered when making a product classification decision.

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, energy (for example by providing a source of Calories) 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 of a "natural health product".

Conversely, if a product is or contains an added ingredient that has no known food purpose but does have a purpose as an NHP, that may support classification as an NHP[8]. The presence of "medicinal" ingredients, as defined in the NHPR, however, is generally not sufficient on its own to result in the classification of a product as an NHP; it could for example, be a non-compliant food with an unauthorized ingredient. If other characteristics of the product support its classification as a food, Health Canada may interpret it as a novel food[9].

The NHP Ingredients Database (NHPID) lists acceptable medicinal and non-medicinal ingredients that can be used in NHPs. The inclusion of ingredients in this database, however, does not preclude them from also being used in foods. Vitamins, for example, are found in the NHPID but are also commonly added to foods. Conversely, the absence of an ingredient in the NHPID does not automatically make it a food.

4.2 Product Representation

"Representation" includes indications of use, claims presented as a word, a sentence, a picture, a symbol, a paragraph or an implication on product labels, package inserts or advertisement (for example, on a manufacturer's website), and placement and location of sale.

[7] Health Canada recognizes the global nature of trade in these products. Decisions of other regulatory bodies will be interpreted in the context of the differences in legal systems, legislation and policies.
[8] Examples include cascara sagrada, senna and horsetail.
[9] As defined in Division 28, section B.28.001 of the FDR.

A product's label or associated advertising material may provide an indication that it is a food. For example, the use of terms consistent with a food, featuring flavour prominently on the label, the sale of a product in retail establishments among conventional foods, or the inclusion of claims or pictures that suggest an intent to provide nourishment, nutrition, hydration, satisfaction of hunger/thirst, or desire for taste, texture or flavour, supports classification of the product as a food. For further details, see APPENDIX 1 CLASSIFICATION CRITERIA.

A product that might, for composition or other reasons, be potentially classifiable as a food may nonetheless be classified as an NHP if the product is represented accordingly. Certain aspects of a product's label or associated advertising material may provide an indication that it is an NHP. For example, the use of terms such as, but not limited to, "lozenge", "cough/throat drop" or "cough tablets" supports classification as an NHP. In addition, health claims outside the context of a diet and/or traditional use claims[10], directions of use and risk information on the labelling, the inclusion of a measuring device or placement of sale among other NHPs suggest that a product is being manufactured, sold or represented for use as an NHP. However, the presence of a health claim is not necessarily sufficient on its own to result in the classification of a product as an NHP – based on the other characteristics of the product, Health Canada may interpret it as either an acceptable or unacceptable health claim for a food[11]. For further details, see APPENDIX 1 CLASSIFICATION CRITERIA.

4.3 Product Format

Products in conventional food formats, as well as prepackaged, ready-to-consume drink products (see APPENDIX 1 CLASSIFICATION CRITERIA for examples), are commonly consumed *ad libitum*, which is consistent with most foods. Products in these formats are generally regarded as foods, as part of the regular diet, with the intent to provide nourishment, nutrition, hydration, satisfaction of hunger/thirst or desire for taste, texture or flavour. Therefore, product format is a primary factor in determining classification for these particular product categories.

Products that are available in other formats may also be classified as foods if the product representation and final product format is consistent with foods. For example, products that are

[10] Traditional health claims are based on the belief systems, theories, and/or experiences specific to the relevant traditional healing paradigm, and not on modern evidence. Traditional use claims should reflect the sum total of knowledge, skills, and practices based on theories, beliefs, and experiences indigenous to a specific culture, used in the maintenance of health, as well as prevention, diagnosis, improvement, or treatment of physical and mental illness.

[11] Health claims may be made in the labelling or advertising of food products on a voluntary basis. However, when they are made, they must comply with the FDA and the food provisions of the FDR and applicable guidance. All foods must comply with section 5 of the FDA by using only health claims that are truthful and not misleading. This means that manufacturers must have scientific evidence to substantiate the claim prior to its use. In addition, a claim referring to a disease or condition stated in Schedule A of the FDA is subject to pre-market authorization. Detailed information on the substantiation of health claims can be found in the Guidance Documents for Preparing a Submission for Food Health Claims. Note that where health claims made for food products have not been reviewed and accepted by Health Canada, they may be subject to post-market compliance and enforcement actions by the CFIA. For guidance on health claims for NHPs see: Pathway for Licensing Natural Health Products Making Modern Health Claims or Pathway for Licensing Natural Health Products used as Traditional Medicines.

represented as beverages but are in powder format (to be reconstituted into drinks) or even tablets for effervescing drinks, may be considered as foods.

Format is not always a sufficient criterion on its own to classify a product as food or as an NHP. For example, many confections, which are considered to be foods, have shapes identical to a tablet, pill or caplet, which are common dosage forms for NHPs; and some NHPs with a long history of use are in tea bag (tisane), liquid or powder formats, which are also common formats for food products.

NHPs are typically sold in a format that allows them to be consumed in measured or controlled amounts (doses). Liquid products packaged in a way that lends itself to dosing, such as in a single dosage unit of less than 90 mL or packaged with a measuring tool such as a dropper or a cap of a specified volume, help the consumer to know that the product is intended to be taken in controlled amounts, may support the product being classified as an NHP (for example, tinctures). The presence of child-resistant packaging (see NHPR section 97 and the incorporated subsections of the FDR: C.01.001(2) to (4)) may also support classification as an NHP.

4.4 Public Perception and History of Use

If a product has a historical pattern of use as a food or if the public perceives the use of a product in the marketplace as a food, these are indications that a product would be classified as 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 health purpose outside the context of a diet, this is one indication that the product would be classified as an NHP.

5. THE CLASSIFICATION DECISION-MAKING PROCESS

It is important to note that product classification is only the first step in the regulatory process. Product classifications are used to determine the applicable sections of the FDA and its regulations such as the NHPR or Parts A, B and D of the FDR, with which a product must be in compliance. A classification, however, is not a determination of whether or not 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.

Representatives from Health Canada's Food Directorate and the Natural and Non-Prescription Health Products Directorate are involved in the classification decision-making process.

For products falling at the food-NHP interface, any modifications to the product representation, including changes to the label and claims can change the classification of the product.

For further information regarding the classification of products at the food-NHP interface, please contact the Food Directorate at smiu-ugdi@hc-sc.gc.ca or the Natural and Non-Prescription Health Products Directorate at ingredient_support@hc-sc.gc.ca.

APPENDIX 1 CLASSIFICATION CRITERIA

1.0 Prepackaged, ready-to-consume drink products:

Health Canada has determined that products which embody the following criteria fit the definition of a food and will therefore be classified as foods:

Product format[12,13]**:** The product is a drink product that is packaged in a container typical of beverages including, but not limited to: cups, aseptic packaging, drink boxes, bottles, canettes or cans such as those in which soda, bottled water or fruit juices are sold. Such formats are consistent with the *ad libitum* consumption of beverages. Format is a primary factor in determining classification for this product category.

Public perception and history of use: It is Health Canada's position that Canadians tend to perceive drink products as beverages rather than as NHPs because they are expected to provide nourishment, nutrition, hydration, satisfaction of hunger/thirst, or desire for taste, texture or flavour irrespective of any associated health claim. Drink products, such as sodas, juices, waters, milks and fruit drinks have a long history of being consumed as foods. This history of consumption, regardless of any specific directions of use, promotes consumer perception that they can be consumed *ad libitum*.

Product representation to consumers: "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. Drink products that use terms including but not limited to "drink", "beverage", "water", "juice", "punch", "cocktail", "milk" or similar descriptors in the product name, trade name or elsewhere on the product label, and are found in retail food establishments (for example, grocery, convenience stores, etc.), among soft drinks, juices and other beverages are typically represented to consumers as foods. Regardless of any specific health claims, they are normally regarded as foods, as part of the regular diet, with the intent to provide nourishment, nutrition, hydration, satisfaction of hunger/thirst, or desire for taste, texture or flavour.

Product composition: In general, products containing ingredients which are expected to provide nourishment, nutrition, hydration, satisfaction of hunger/thirst, or desire for taste, texture or flavour support classification as a food. The presence of medicinal ingredients, as defined in the NHPR, in the prepackaged, ready-to-consume drink products is not a primary factor in determining classification.

[12] Products classified as NHPs include those packaged in formats 90 mL or less, and to be consumed in a single dose (not to be reconstituted as a beverage), or those packaged in formats greater than 90 mL and less than 125 mL represented as shots and that do not meet the above Prepackaged, ready-to-consume drink products classification criteria. Products classified as foods include those packaged in formats greater than 90 mL and less than 125 mL that meet our Prepackaged, ready-to-consume drink products classification criteria or products packaged in a format 125 mL or greater that are represented as foods.

[13] For information regarding prepackaged, ready-to-consume energy drink products, please consult the Category Specific Guidance for Temporary Marketing Authorization – Caffeinated Energy Drinks.

2.0 Products with Conventional Food Formats:

Health Canada has determined that products which embody the following criteria fit the definition of a food and will therefore be classified as foods:

Product format: Products in conventional food formats including, but not limited to prepackaged or sold-in-bulk products such as whole foods (for example, nuts, seeds, fruits or vegetables), edible oils, spreads, bars, cereals (for example, bran, oat), dairy products (for example, yogurts, cheese), condiments and seasonings (for example, ketchup, salts, syrups, sweeteners), soups, purees, confections (see Section 2.1 of the appendix for additional guidance) and bakery products (for example, breads, crackers). Such formats, and any others that are consistent with *ad libitum* consumption, are considered conventional food formats. Format is a primary factor in determining classification for this product category.

Public perception and history of use: It is Health Canada's position that Canadians tend to perceive and consume prepackaged or sold-in-bulk, conventional food in the formats summarized above as foods rather than as NHPs because they are expected to provide nourishment, nutrition, hydration, satisfaction of hunger/thirst, or desire for taste, texture or flavour irrespective of any associated health claim. Pre-packaged or sold-in-bulk products such as whole foods, edible oils, spreads, cereals, dairy products, condiments and seasonings, soups, purees, confections and bakery products have a long history of being consumed as foods. This history of consumption, regardless of any specific directions of use, promotes consumer perception that they can be consumed *ad libitum*.

Product representation to consumers: "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, and placement and location of sale. Prepackaged or sold-in-bulk products that use terms including but not limited to "meal replacement", "yogurt", "bar", "cereal" or "candy" in the product name, trade name or elsewhere on the product label, and are found in retail food establishments (for example, grocery, convenience stores, etc.) amongst other conventional foods are typically represented to consumers as foods. Regardless of any specific health claims, they are normally regarded as foods, as part of the regular diet, with the intent to provide nourishment, nutrition, hydration, satisfaction of hunger/thirst, or desire for taste, texture or flavour. The presence of a health claim is not always a distinguishing factor for classification but the product's specific or implied representation for a health benefit within the context of the diet supports the classification of the product as a food.

Product composition: In general, products containing ingredients which are expected to provide nourishment, nutrition, hydration, satisfaction of hunger/thirst, or desire for taste, texture or flavour support classification as a food. The presence of medicinal ingredients, as defined in the NHPR, in the prepackaged or bulk sold product is not a primary factor in determining classification.

2.1 Products with Conventional Food Formats - Confectionery Products:

Health Canada has determined that confectionery products, which embody the following criteria and are represented as a conventional food, fit the definition of a food and will therefore be classified as foods:

Product format: Confectionery products are typically sold in bulk, tearable or resealable packages or are individually wrapped, and may be sold in single-serving or multi-serving packages. Products in confectionery food format include, but are not limited to: hard/soft/semi-soft candy (for example, sticks, lollipops), chocolates, chocolate bars, cookies, jellies, chews and gummies, gum, mints, fondants, glazes, syrups, wafers, fudges, toffee/taffy and caramels, frozen desserts, liquid or foam sprays, dissolvable strips and powders, and any other formats that may be consistent with *ad libitum* consumption as foods. Note that products sold in child-resistant packaging would generally not support classification as foods.

Public perception and history of use: It is Health Canada's position that Canadians perceive and consume confectionery products as foods. Confectionery products have a long history of being consumed as foods. This history of consumption, regardless of any specific directions of use, promotes the public perception that they can be consumed *ad libitum*.

Product representation to consumers: Product representation is considered an important factor for classification decisions for this category. "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, and placement and location of sale. Confectionery products that use terms such as, but not limited to, "candy", "snack", "sweets", "treat" and "refreshing"; feature flavour prominently on the label; are represented as part of the regular diet; or are marketed in retail establishments among conventional foods are typically represented to consumers as foods. These products are typically marketed to the general public and may be targeted specifically to children. These products are normally regarded as foods, with the intent to provide satisfaction of hunger/thirst, or desire for taste, texture or flavour. The product's specific or implied representation for a health benefit within the context of the diet supports classification of the product as a food. Products containing terms including, but not limited to: "lozenges", "cough/throat drops" or "cough tablets" would not support classification as foods.

Product composition: All ingredients contained in a confectionery product should be considered when making a product classification decision, but composition is not a primary factor for product classification decisions. Confectionery products may contain ingredients such as, but not limited to, sugar and/or other sweetening agents, flavouring and/or colouring agents, vitamins and minerals.

3.0 Granulated and Powdered Products:

Health Canada has determined that "granulated and powdered products" embodying the following criteria fit the definition of a food:

Product format: Since both granulated and powder formats are consistent with classification both as foods and as NHPs, format is not a primary factor for classification. Characteristics of format which are supportive of a classification as food include, but are not limited to: bulk powders, resealable packaging, sachets, or any other formats consistent with the *ad libitum* consumption as foods.

Public perception and history of use: It is Health Canada's position that Canadians perceive and consume granulated and powdered products as foods when they contain conventional food ingredients and are mixed with or added to food. Consumers perceive these products as foods rather than as NHPs because they are expected to provide nourishment, nutrition, hydration, satisfaction of hunger/thirst, or desire for taste, texture or flavour irrespective of any associated health claim. The majority of the ingredients contained in these products have a long history of being consumed as foods. This history of consumption, regardless of any specific directions of use, promotes the public perception that they can be consumed *ad libitum*.

Product representation to consumers: "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. Granulated and powdered products that use terms such as, "meal replacement", "food", "energy", "shake", "drink", "beverage", "juice", "cocktail"; feature flavour prominently on the label; are represented as part of a diet; or are marketed in retail food establishments among conventional foods are typically represented to consumers as foods. Regardless of any specific health claims, they are normally regarded as foods, as part of the regular diet, with the intent to provide nourishment, nutrition, hydration, satisfaction of hunger/thirst, or desire for taste, texture or flavour. The presence of a health claim is not always a distinguishing factor for classification but the product's specific or implied representation for a health benefit within the context of the diet supports the classification of the product as a food.

Product composition: All ingredients contained in a granulated or powdered product should be considered when making a product classification decision but composition is not a primary factor for product classification decisions. Products intended for classification as food are those in which the ingredients are expected to provide nourishment, nutrition, hydration, satisfaction of hunger/thirst, or desire for taste, texture or flavour regardless of any associated health claim.

3.1 Granulated and Powdered Products and Other Formats - Beverage Mix Food Products

Health Canada has determined that beverage mix products sold in formats including, but not limited to, granules, powder, syrup, tea or gels, and which are intended to be reconstituted for consumption as a beverage and which embody the following criteria, fit the definition of a food and will therefore be classified as foods:

Product format[14]: Since beverage products in granulated, powder, syrup, tea or gel formats are consistent with classification both as foods and as NHPs, format is not a primary factor for classification. Characteristics of format which are supportive of a classification as food include, but are not limited to: resealable packaging, sachets, pouches, sticks/tubes or any other formats that are consistent with the *ad libitum* consumption as foods.

Public perception and history of use: It is Health Canada's position that Canadians perceive and consume beverage mix products as foods. Consumers perceive these products as foods rather than as NHPs because they are expected to provide nourishment, nutrition, hydration, satisfaction of hunger/thirst, or desire for taste, texture or flavour regardless of any associated health claim. Beverage mixes have a long history of being consumed as foods. This history of consumption, regardless of any specific directions of use, promotes the public perception that these products can be consumed *ad libitum*.

Product representation to consumers: Representation is considered a primary factor for product classification decisions for this category. "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. Beverage mix products that use terms such as, but not limited to, "meal replacement", "food", "energy", "energy drink", "snack", "drink/drink mix", "beverage", "cocktail/cocktail mix", "juice/juice mix"; feature flavour prominently on the label; or are marketed in retail establishments among conventional foods are typically represented to consumers as foods. These products are normally regarded as foods, as part of the regular diet and/or as part of a specialized diet (for example, weight reduction diet by means of caloric reduction), with the intent to provide nourishment, nutrition, hydration, satisfaction of hunger/thirst, or desire for taste, texture or flavour. The presence of a health claim is not always a distinguishing factor for classification but the product's specific or implied representation for a health benefit within the context of the diet supports classification of the product as a food.

Product composition: All ingredients contained in a beverage mix product should be considered when making a product classification decision but composition is not a primary factor for product classification decisions. Beverage mixes may contain ingredients such as, but not limited to, caffeine, sweetening agents, fruit/vegetable concentrates, vitamins, minerals and amino acids.

[14] Products classified as foods include those packaged in formats of any size that are to be reconstituted for consumption as a beverage and meet the Beverage mix classification criteria.

4.0 Granulated and Powdered Products and Other Formats - Natural Health Products:

Health Canada has determined that products in powder, granulated, tea or gel formats which are not represented as a beverage as defined in the "3.1 Granulated and Powdered Products and Other Formats - Beverage Mix Food Products" classification criteria (Section 3.1) and are not conventional foods, and which embody the following criteria, fit the definition of an NHP and will therefore be classified as NHPs:

Product format: Since granulated, powder and gel formats are consistent with classification both as foods and as NHPs, format is not a primary factor for classification. Characteristics of format which are supportive of a classification as NHPs include, but are not limited to: security features and packaging that includes measuring devices.

Public perception and history of use: It is Health Canada's position that Canadians perceive and consume certain powdered, granulated or gel products as NHPs instead of foods because they have not been typically sold amongst conventional foods in retail establishments. These products are typically marketed under specific conditions of use, for example, to a specific sub-population, for a specific purpose and with specific directions of use. Although these products may be a source of macronutrients and may provide nourishment, nutrition, hydration, satisfaction of hunger, thirst, or desire for taste, texture or flavour, the history of consumption suggests that these products are used as supplements to the diet, and that consumers recognize that these products are not consumed in an *ad libitum* manner, but according to the recommended conditions of use.

Product representation to consumers: Representation is considered a primary factor for product classification decisions for this category. "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. Powdered, granulated, tea or gel products that use terms such as, but not limited to, "multi-vitamin", "multi-mineral", "detox", "resistance training", "muscle gains", "muscle building", "mass building" and "increased protein synthesis", that include pictures that depict the above terms, and are marketed in retail establishments among other supplements to specific sub-populations, are typically represented to consumers as NHPs. The presence of a health claim is not always a distinguishing factor for classification but the product's specific or implied representation for a health benefit outside the context of the diet (for example, supplemental to the diet) or the use of a traditional claim supports classification of the product as an NHP.

Product composition: All ingredients contained in a powdered, granulated, tea or gel product should be considered when making a product classification decision but composition is not a primary factor for product classification decisions. These types of products may contain ingredients such as, but not limited to, vitamins and minerals, protein or protein isolates (for example, whey, soy, rice proteins), amino acids, carbohydrates, fatty acids, herbs, fibre, caffeine and other stimulants, sweetening agents, fruit/vegetable concentrates or extracts.