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# Category Specific Guidance for Temporary Marketing Authorization: Supplemented Food

February 2016

Food Directorate  
Health Products and Food Branch



Canada 

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## Executive summary

A food that is supplemented by addition of non-permitted uses of vitamins, minerals, amino acids, or novel herbal or bioactive ingredients cannot be sold legally without prior authorization by Health Canada. Health Canada recognizes that there is a need to update the *Food and Drug Regulations* (FDR) to encompass this new category of pre-packaged, supplemented foods. The use of Temporary Marketing Authorization Letters (TMALs) has been determined to be an appropriate tool to allow the sale of these foods and to inform needed regulatory amendments.

In recent years, a number of products in food formats supplemented with these ingredients, which were not compliant with the FDR, were introduced into the marketplace as natural health products (NHPs) in accordance with the *Natural Health Products Regulations* (NHPR). Health Canada announced the intent to regulate as foods those products that had been marketed as NHPs but fit the definition of a food with regard to their product format, history of use, representation to consumers and public perception.

These products have been transitioned from the NHP framework to the food regulatory framework through the use of TMALs issued for individual products that fit within defined subsets of foods that are safe to consume but are currently non-compliant with specific sections of the FDR. The TMAL allows the product to be sold temporarily in accordance with the FDR Sections B.01.054 – B.01.055 while information is gathered during the TMA period to address gaps in the knowledge needed to develop amendments to modernize the food regulatory framework. The long-term plan is to facilitate market access for supplemented foods under the same regulatory system that applies to most other categories of food.

The present document provides guidance to stakeholders on obtaining TMALs for supplemented foods. Guidance on caffeinated energy drinks is provided in the updated [Category Specific Guidance for Temporary Marketing Authorization: Caffeinated Energy Drinks](#), published in December 2013.

This guidance sets out the definition of a supplemented food, the objectives of the TMA process, the scope of the types of foods for which a TMAL may or may not be issued, the regulatory requirements for food additives, flavours and novel food ingredients in the context of supplemented foods, eligibility criteria for TMAL submissions, including maximum levels of vitamins and minerals, and guidance on labelling, advertising and health claims associated with supplemented foods.

The requirements outlined in this guidance document are for supplemented food TMALs only and do not represent final regulatory requirements for these products.

## 1.0 Introduction

The purpose of this document is to set out Health Canada's definition of a supplemented food, as well as the scope, eligibility criteria and conditions for authorization of supplemented foods under Temporary Marketing Authorization Letters (TMALs).

Health Canada's Food Directorate will issue TMALs for pre-packaged supplemented foods that are safe to consume during the TMAL period, but are currently non-compliant with respect to the addition of some vitamins, minerals, and amino acids (see Section 8), provided those foods meet all conditions of use that are set out in this guidance. The Food Directorate will also consider, but only after more detailed safety assessments are completed and conditions for use are set, issuing TMALs for pre-packaged foods that contain the unapproved novel foods listed in Appendix 2.

Supplemented foods may be sold temporarily in accordance with FDR Sections B.01.054 – B.01.055 while generating information to address gaps in the knowledge needed to develop amendments that will modernize the food regulatory framework. The long-term plan is to facilitate market access for supplemented foods under the same regulatory system that applies to most other categories of food.

This guidance document applies to a sub-set of supplemented foods that were already issued TMALs as part of the transition to the food regulatory framework, and similar new products, until the objective of this TMA process has been achieved. Extensions of TMALs are anticipated to allow sufficient time for the gathering of in-market data and completion of policy and regulatory development.

TMALs issued to supplemented foods prior to the publication of this guidance document are set to expire on August 31, 2016. However, in order to give TMAL holders sufficient time to label and formulate their products in accordance with the information provided below these TMALs will be extended until February 22, 2017. At that time, supplemented foods must comply with the requirements outlined in this document to receive a further extension.

This guidance does not apply to caffeinated energy drinks, which are the subject of the [\*Category Specific Guidance for Temporary Marketing Authorization: Caffeinated Energy Drinks\*](#), published in December 2013.

A draft of this guidance document for supplemented foods was sent to industry, professional associations, consumer groups, academia and other government agencies, and was made available to other interested parties upon request, for a 60 day consultation period from June 2 to August 1, 2014. Fifteen groups provided comments, all of which were taken into consideration in the preparation of the present guidance.

This Supplemented Food guidance document should be read together with the [\*General Guidance Document for Temporary Marketing Authorization for Foods\*](#) and other applicable provisions of the *Food and Drugs Act* (FDA) and its Regulations, along with other legislation and regulations

applicable to food. Appendix 3 provides internet links for other guidance documents relevant for supplemented foods. It is important to note that the requirements for supplemented foods outlined in this document, which were developed based on information from a preliminary risk-based assessment of these foods conducted by Health Canada, are subject to change as relevant new information becomes available.

Health Canada will continue to review all relevant data to address the information gaps, conduct further assessments of these products and evaluate the effectiveness of risk management tools. Information received through the TMA process will facilitate this analysis. As such, the requirements set out in this guidance document should not be construed as final regulatory requirements for these products. Likewise, a TMAL should not be construed as a final approval for a product. Eventually, all products will be required to comply with the regulatory requirements set out in the FDR for these types of foods.

As described in [\*Eating Well with Canada's Food Guide\*](#), Health Canada recommends a balanced diet of vegetables and fruit, grain products, milk and alternatives, and meat and alternatives. Canadians are encouraged to choose foods from each of these four categories that are lower in fat, sugar or salt or prepared with little or no added fat, sugar or salt. This same advice applies when consumers choose to include a supplemented food as part of their diet. Stakeholders wishing to market supplemented foods are encouraged to keep this position of Health Canada in mind.

## 2.0 Background

In recent years, a number of products in food formats containing added vitamins, minerals, amino acids, herbal ingredients and bioactives, which were not in compliance with the FDR, were introduced into the marketplace as NHPs through the NHPR. These were mainly beverages and a small number of other food formats. Under the NHPR they were subject to individual pre-market assessment and licensing.

Health Canada determined, based on public perception, history of use, product representation to consumers and product format, that many of those products fit the definition of a food, as per the guidance document, [\*Classification of Products at the Food-Natural Health Product Interface: Products in Food Formats\*](#). In October 2011, the Minister of Health announced the intent to regulate caffeinated energy drinks (CEDs), which were formerly NHPs, as foods. In April 2012, it was announced to stakeholders that other NHPs that fit the definition of a food would also be regulated as foods.

As of December 2012, all TMA-eligible food products formerly regulated as NHPs had successfully transitioned to the food regulatory framework. Five-year TMALs were issued for CEDs and 2-year TMALs for other product categories. However, there remain a number of outstanding information gaps to address in order to determine the appropriate long-term risk management approach for these products. Examples of data gaps include, but are not limited to,

consumption patterns in the dietary context as food and the effectiveness of labelling as a risk mitigation tool for foods.

Transition supplemented food products that were deemed not to pose any immediate safety concerns following a preliminary risk-based assessment were issued a 2-year TMAL. In some instances, cautionary statements were applied to address potential risks, for example, for products that are not intended for children. Cautionary labelling requirements for those supplemented food products transitioned from the NHPR framework were based originally on their labels as NHPs. However, part of the TMA-generated research moving forward will be to determine the extent of cautionary labelling that is suitable for consumers to make informed choices and use supplemented foods safely and appropriately.

In other cases, petitioners whose transition products were identified as unsuitable to be sold as foods were given the option to reformulate. Additionally, some products that were part of the transition and were issued TMALs were advised by Health Canada's Food Directorate that the presence of certain ingredient(s) in their products may require a more detailed food safety assessment, which could result in additional changes to compositional or labelling requirements.

The nature of these pre-packaged food products challenges the traditional premise of food regulations, which generally assumes that foods can be consumed without conditions by the general population (i.e., consumed *ad libitum*). Health Canada has concluded that a number of data and information gaps must be addressed to support its efforts to regulate these types of food and to appropriately manage any potential health risks that may be associated with consumption of these products as foods rather than as NHPs. As a result, TMALs have been used to allow temporary market access to safe products for the purposes of gathering in-market data to inform regulatory amendments.

### 3.0 Supplemented food definition

#### 3.1 Context

The definition of a food in Section 2 of the FDA includes “any article manufactured, sold or represented for use as a food or drink for human beings, chewing gum, and any ingredient that may be mixed with food for any purpose whatever.” This guidance will set out the broad definition of supplemented food as a subset of foods as defined in Section 2 of the FDA. The Scope section (Section 4) below describes in greater detail the subset of all those foods that meet this definition and are either being considered for a TMA or are excluded, and why. Supplemented foods that fall within the scope for which Health Canada is currently issuing TMALs must meet all of the eligibility criteria and conditions of use set out in Sections 8 and 9 of this guidance. Appendix 6, *Is My Product a TMA-Eligible Supplemented Food?*, provides a simplified diagrammatic approach to help stakeholders determine whether or not a food product would require a Supplemented Food TMAL.

### 3.2 Definition of a supplemented food

A supplemented food is broadly defined as a pre-packaged product that is manufactured, sold or represented as a food, which contains added vitamins, minerals, amino acids, herbal or bioactive ingredients. These ingredients may perform a physiological role beyond the provision of nutritive requirements.

Foods containing already permitted or approved uses of vitamins, minerals, amino acids, herbal or bioactive ingredients, in compliance with the FDR, do not require premarket authorization (i.e., to be in receipt of a TMAL) to be sold legally in Canada. As with all foods sold in Canada, it is the responsibility of the manufacturer or distributor not to sell an article of food that is unsafe, as set out in Section 4 of the FDA.

Since the definition of a supplemented food is broad, the sections that follow will clarify the terms used in the definition.

#### 3.2.1 Pre-packaged products

For the purposes of this guidance, the definition of a supplemented food is limited to pre-packaged products because there are specific requirements for labelling (see Section 9 for more information) that can only be applied to foods when they are pre-packaged.

#### 3.2.2 Vitamins, minerals, and amino acids

For the purpose of this guidance, a vitamin means any of the vitamins listed in Section D.01.002 of the FDR. A mineral nutrient is any of the chemical elements, whether alone or in a compound with one or more other chemical elements, listed in Section D.02.001 of the FDR. Division 3 of Part D of the FDR sets out the regulatory requirements for the addition of vitamins, minerals or amino acids to foods.

A food may be supplemented by the addition of one or more vitamins, minerals, or amino acids that are not currently permitted in the food at any level, or it may involve addition of one or more of these nutrients to a level that exceeds what is permitted. These are some of the criteria for eligibility for a TMAL.

As described in Section 4.1.1 below, there are separate regulatory requirements for mandatory and voluntary nutrient fortification of foods for population-based public health needs. When the content of any of these nutrients in a supplemented food renders it non-compliant with the FDR, then the food will require premarket authorization through the TMA process.

### 3.2.3 Herbal and bioactive ingredients

Herbal and bioactive ingredients can be interpreted broadly to include plant (e.g., green tea), fungal (e.g., yeast), algal (e.g., Chlorella) and non-human animal (e.g., fish oil) materials, fatty acids and non-nutrient ingredients (e.g., glucosamine) that may be inherent in or added to food. Some of these ingredients may be considered novel food ingredients.

Division 28 of the FDR requires that all novel food ingredients undergo a mandatory pre-market assessment prior to being authorized for sale in Canada.

However, Health Canada's Food Directorate will consider issuing TMALs for pre-packaged foods that contain one of the unapproved novel food ingredients (i.e., typically these are ingredients that are not used for a conventional food purpose such as some herbals or bioactives) listed in Appendix 2 of this document. However, no final decisions will be made until Food Directorate scientists complete more detailed safety assessments of these ingredients, which will inform any conditions that would need to be met (e.g. level of addition, ingredient specifications) before a TMAL could be issued (see Section 7.3 for more detailed information).

## 4.0 Scope

The FDR specify that the purpose of TMALs is to generate information in support of a possible amendment to the Regulations. The goal is to modernize the food regulatory framework to safely manage and facilitate long-term market access of supplemented foods. Health Canada has determined that a subset of supplemented foods will provide a sufficient pool of products from which to gather data to inform future regulatory amendments.

To be eligible for a TMAL all supplemented foods that fall within the scope as set out below must meet the following general criteria:

- Are safe for use under the conditions of the TMA;
- Are pre-packaged;
- Contain a non-compliant vitamin, mineral or amino acid as per Section 8; and/or
- Contain an unapproved novel food listed in Appendix 2 (see Section 7.3).

Notwithstanding the above, a supplemented food:

- Shall not contain non-compliant food additives (see Section 7.1);
- Shall not contain unapproved novel ingredients that are not set out in Appendix 2 (see Section 7.3);
- Shall not contain alcohol;
- Shall not be represented as water (see Section 9.2.3); and
- Shall not be targeted to children less than 4 years of age, or to pregnant or breastfeeding women (see Section 4.1.2).

#### **4.1 Products excluded for the purposes of this guidance document**

The following subsections describe in detail categories of foods which Health Canada's Food Directorate does not consider to be supplemented foods for the purposes of this guidance.

##### **4.1.1 Foods with nutrients added for broad population-based public health needs**

The addition of vitamins, minerals and amino acids to food in Canada is controlled by the FDR. The FDR specify which foods may contain added nutrients, which nutrients may be added, and the permitted levels in the food. Reasons for the currently permitted addition to foods of essential nutrients include:

- To restore the levels of vitamins or minerals to the levels that were present in the food before processing or, in the case of amino acids, to provide protein of a nutritional quality that is equivalent to that which was present in the food before processing,
- To make the food that is intended to be sold as a substitute for another food nutritionally equivalent to the food that it is intended to replace in the diet in respect of (a) the levels of added vitamins or minerals, or (b) the quality of protein provided through the addition of amino acids,
- To prevent or correct a deficiency of vitamins or minerals in the population or specific population groups or,
- To modify the levels of vitamins, minerals or amino acids in the food for special dietary use.

Examples include the mandatory fortification of milk with vitamin D (as per FDR Part B Division 8) and of flour with thiamin, riboflavin, niacin or niacinamide, folic acid and iron (Division 13), or the voluntary restoration of nutrients lost during processing, such as the restoration to precooked rice of thiamin, niacin, vitamin B<sub>6</sub>, folic acid, *d*-pantothenic acid, and iron (Division 13).

There is a separate regulatory process for the approval of the addition of vitamins and minerals to foods for one or more of the four purposes above.

##### **4.1.2 Foods targeted to children under four, breastfeeding or pregnant women**

Supplemented foods intended for children under four years of age are not eligible for a TMAL. The minimum age threshold of 4 years is based on Health Canada's work with its partners to establish the Dietary Reference Intakes (DRIs) published by the Institute of Medicine (IOM). Toddlers between 1 and 3 years of age experience more rapid growth than older children, making them more susceptible to nutrient imbalances. This distinction provides the biological basis for establishing separate recommended nutrient intakes for the toddler age group.

Supplemented foods intended for breastfeeding women and pregnant women are also not eligible for a TMAL. These subpopulations are particularly vulnerable to the adverse effects of excessive nutrient intake. While there are botanical ingredients, such as peppermint for flavouring purposes, which have a long history of safe use in foods, many herbal and bioactive ingredients have never been assessed for their safety as food ingredients in pregnant or breastfeeding women and thus remain unapproved for such use.

Supplemented foods intended for infants and toddlers below 4 years of age, and pregnant and breastfeeding women, are not eligible for TMALs because the more in-depth risk assessment needed for foods targeted to these sensitive sub-populations is outside the scope of the supplemented food TMA submission evaluation process.

### **4.1.3 Infant foods**

Division 25 of the FDR sets out requirements for infant (less than one year of age) foods, including junior foods (having particles of a size to encourage chewing by infants) and strained foods, and human milk substitutes, i.e., infant formulas. There are already specific regulatory requirements for their composition, e.g., with respect to vitamins, minerals, protein and its quality, fatty acids, etc., and there is a premarket authorization process for new infant foods and human milk substitutes. Therefore, these types of foods are outside the scope of this guidance.

### **4.1.4 Foods for special dietary use**

Division 24 of the FDR sets out requirements for *Foods for Special Dietary Use* that have been specially processed or formulated to meet the particular requirements of a person in whom a physical or physiological condition exists as a result of a disease, disorder or injury, or for whom a particular effect, including but not limited to weight loss, is to be obtained by a controlled intake of foods.

Foods for special dietary use that are excluded from the scope of this guidance are, for example, formulated liquid diets, meal replacements, nutritional supplements and foods represented for use in very low energy diets. While in many cases these foods will have added vitamins, minerals and amino acids, the purpose of addition is to meet nutrient requirements and there are already specific requirements for their composition and marketing set out in Division 24, and as such are outside the scope of this guidance. If in doubt as to whether or not the provisions of Division 24 apply to a particular product, stakeholders may submit a request to Health Canada's Food Directorate for advice on the regulatory requirements applicable to their product.

Division 24 also sets out regulatory requirements for “gluten-free” foods, which are not excluded from supplemented foods. See Section 9.3 for further information on the voluntary labelling of supplemented foods with a “gluten-free” statement.

### 4.1.5 Novel foods

Unapproved novel foods and novel food ingredients other than as described in Section 7.3 are outside the scope of this guidance document. They have an alternate route to market through the premarket process set out in Division 28 of the FDR. Once approved as novel foods, they may be used as ingredients in foods, including in supplemented foods.

### 4.1.6 Foods containing caffeine

Beverages, mixes and/or concentrates which, when consumed according to the directions for use on the label, and contain caffeine within the limits set out in the [Category Specific Guidance for Temporary Marketing Authorization - Caffeinated Energy Drinks](#), will be assessed for market authorization as Caffeinated Energy Drinks (CEDs) in accordance with that guidance document.

Conditions of use for caffeine as a food additive are set out in the [List of Permitted Food Additives with Other Generally Accepted Uses](#) available on Health Canada's website. As indicated in the *List*, caffeine is currently permitted in cola-type beverages and other carbonated soft drinks at a maximum level of use of 200 parts per million (ppm) and 150 ppm, respectively. Additional guidance is currently being developed for beverages, beverage mixes and/or beverage concentrates which, when consumed according to the directions for use on the label, contain no more than 200 ppm caffeine and where provisions for such use do not already exist in the *List*.

### 4.1.7 Foods containing NHP and other drug ingredients

Health Canada recognizes that many NHP ingredients also have a safe history of use in foods, although generally not at as high a quantity per serving or per day. In order to distinguish between foods and NHPs, and to aid in determining product classification, Health Canada has developed the guidance document, [Classification of Products at the Food-Natural Health Product Interface: Products in Food Formats](#).

A history of safe use of an herbal or bioactive ingredient as a traditional medicine or for use in other NHPs would not be sufficient evidence on its own to support safe use of a proposed ingredient in a supplemented food due to their different conditions of use. Some products may have a more appropriate route to market under the NHPR.

Products containing drug ingredients, such as throat lozenges containing local anaesthetics and antiseptics, continue to be regulated as health products and are not eligible for a TMAL.

## 5.0 Administrative matters

Supplemented foods are subject to all of the requirements applicable to food products, including the provisions of the FDA and its Regulations and the *Consumer Packaging and Labelling Act* and its Regulations, except for those requirements of the FDR which have been exempted as set out in a TMAL. In this guidance document, Health Canada sets out additional requirements established for supplemented foods issued TMALs to help reduce the potential risks associated with inappropriate consumption of these products and to alert the consumer to their uniqueness. These include:

- Compositional requirements;
- Labelling, advertising and marketing requirements; and
- Consumption incident reporting, as appropriate.

Products that are captured within the scope of this document are not eligible to be marketed as NHPs. Petitioners are required either to bring their products into compliance with current food regulations or to apply for a TMAL, and they must meet all other requirements under the FDR and all other applicable regulations that are not the subject of the TMA, including compositional and labelling requirements, before they can be marketed in Canada.

A [\*list of authorized products\*](#) which have been issued a TMAL is available on Health Canada's website. This list is updated regularly. The information is posted in accordance with the *Privacy Act*.

Should a petitioner wish to make a change to the conditions laid out in their TMA after it has been issued, an amendment to the TMAL is required. Petitioners should submit requests for amendments using the TMA application process (see Section 5.1).

Health Canada's Food Directorate and the Canadian Food Inspection Agency (CFIA) will work collaboratively to identify potential compliance issues for food products that are the subject of a TMAL and determine the appropriate compliance and enforcement actions that may need to be taken. Health Canada may revoke a TMAL if it is determined that the conditions of the TMA have been violated.

Note that the CFIA may take enforcement action, which may include recall of the products that are the subject of a TMAL, should Health Canada identify any significant health risks or contraventions to Sections 4 or 5(1) of the FDA.

### 5.1 TMA application process

Health Canada will issue TMALs for supplemented foods that fall within the scope (see Section 4) and also meet all compositional (e.g., levels of added vitamins and minerals) and labelling requirements set out in this guidance. Specific conditions for each product, if required, will be set out in the TMA.

Manufacturers or distributors are advised to follow the application process outlined in the document [General Guidance Document for Temporary Marketing Authorization for Foods](#). Submissions for a TMAL amendment must provide an updated TMA Application form and label. Products must meet the requirements set out in this guidance document to be eligible for a TMAL.

All submissions, whether new or amendments, should be sent electronically as outlined in the document [General Guidance Document for Temporary Marketing Authorization for Foods](#) to the following address: [smiu-ugdi@hc-sc.gc.ca](mailto:smiu-ugdi@hc-sc.gc.ca).

Please use the words “TMA application” or “TMA application amendment” in the subject line.

Should there be any questions regarding TMAs, please contact Health Canada at the email address indicated above using “TMA” as the subject.

### **5.2 TMA process timelines**

Health Canada has developed a performance standard for the TMA process for supplemented foods. This document can be requested by sending an email to [smiu-ugdi@hc-sc.gc.ca](mailto:smiu-ugdi@hc-sc.gc.ca) using the words “TMA performance standard document request” in the subject line.

## **6.0 TMA and letter of agreement**

### **6.1 Letter of agreement**

Once Health Canada completes its assessment of a TMA submission and is satisfied that the application meets all the requirements of a TMAL, including that the food will not pose a risk to the health of consumers, a Letter of Agreement is drafted and sent to the petitioner for signature. Within this agreement, the petitioner agrees to the conditions found in paragraph B.01.054(1)(b) of the FDR, in other words:

- i. Describe the food on a label or in an advertisement in a manner that is not false, misleading or deceptive;
- ii. Use such marks or statements on the label or in any advertisement as Health Canada may require;
- iii. On request, submit to Health Canada, the results of the data gathering conducted during the temporary marketing; and
- iv. On request, withdraw the food from sale where Health Canada is of the opinion that it is in the public interest to do so.

Further details are available in the [General Guidance Document for Temporary Marketing Authorization for Foods](#). Section 6.2 below describes the “data gathering” research aspect as it relates to supplemented foods.

### **6.2 TMA research**

Health Canada has concluded that a number of information and data gaps need to be addressed to support the development of appropriate regulations for supplemented foods.

As a condition of the TMA, the manufacturer or distributor is required to gather such data, in a manner agreed upon with Health Canada in advance, and submit it to Health Canada within a specified time frame. The specific details of the research protocol required for the TMA may be finalized after the TMAL is issued and can be appended to the TMAL at a later date, once an agreement is reached between Health Canada and the petitioner. Health Canada may revoke a TMAL should a manufacturer or distributor fail to supply the required data that addresses the identified knowledge gaps associated with the research protocol.

Health Canada requires data on Canadians’ consumption patterns of these foods to gain a better understanding of their impact, for example, on exposure to vitamins, minerals, and amino acids. Data will also be required on consumers’ understanding and their use of label information as well as the effectiveness of product labels as a risk management tool. Data generated by this research must be submitted to Health Canada within a specified time frame.

As a condition of the TMA, details of the research to be conducted during the temporary marketing period must be submitted to Health Canada for review. Research and data collection should be targeted to address data gaps, so that information generated will be relevant and supportive of an amendment to the FDR. Agreement between Health Canada and the petitioner must be reached on the research protocol prior to the implementation of any studies.

Data gaps that need to be addressed for a particular food product with added nutrients and/or other types of ingredients may be common to other food products with similar formulations, target demographics and/or marketing. Therefore, some of the research for categories of foods may be conducted collectively, possibly via a trade organization on behalf of the companies issued TMALs. However, additional product specific information may be required in some cases, and would need to be provided by individual manufacturers or distributors.

### **6.3 Reporting consumption incidents**

A consumption incident is characterized by the fact that a causal relationship between the consumption of a food and an adverse event is suspected. Those manufacturers and distributors whose TMAs include a requirement for cautionary labelling are required to undertake consumption incident reporting as a condition of their TMAs. Consumption incident reports must

be submitted to Health Canada annually. If there are no incidents within the year, this also needs to be reported to Health Canada. Failure to provide this information may result in revocation of the TMAL. Any serious consumption incidents should be reported to the CFIA using their [online food safety reporting form](#). A food consumption incident is interpreted as having a serious adverse health consequence according to the same criteria as those set out in the FDR for a serious adverse reaction to a drug, e.g., one that requires in-patient hospitalization or prolongation of existing hospitalization, that results in persistent or significant disability or incapacity, that is life threatening or that results in death.

Health Canada has developed a guidance document and form to assist with reporting information on consumption incidents. Additional details on reporting consumption incidents are outlined in the *Guidance Document for Food Industry: Consumption Incident Reporting*. This document can be requested by sending an email to [smiu-ugdi@hc-sc.gc.ca](mailto:smiu-ugdi@hc-sc.gc.ca) using the words “Consumption Incident Reporting document request” in the subject line.

Completed annual consumption incident reporting forms are to be sent to:

Submission Management and Information Unit  
Food Directorate  
Health Products and Food Branch, Health Canada  
251 Sir Frederick Banting Driveway  
Postal Locator 2202E  
Ottawa, Ontario, Canada, K1A 0K9

Email: [smiu-ugdi@hc-sc.gc.ca](mailto:smiu-ugdi@hc-sc.gc.ca)

## 7.0 Food additives, flavours, and novel food ingredients

### 7.1 Food additives

The [Lists of Permitted Food Additives](#) are posted on Health Canada’s website. The Lists, which are generally organized according to the functional classes of food additives, specify the food or foods an additive can be used in, the maximum level of use in that food and any other specific conditions of use. Products must be fully compliant with the [Lists of Permitted Food Additives](#) before a TMAL is issued. If the Lists do not allow for a particular use of a food additive, the food containing that additive may not be sold. Manufacturers wishing to use an unapproved additive, or an approved additive that is not approved in their particular food or that is at a level not currently permitted, may file a [food additive submission](#) in accordance with Section B.16.002 of the FDR seeking such approval. Health Canada will then evaluate the submission to determine whether the requested food additive use should be added to the [Lists of Permitted Food Additives](#).

Food additives that are set out in the Lists may be used legally in food provided they meet the specifications set out in the FDR or, in the absence of a specification in the Regulations, meet the specifications set out in the most recent edition of the *Food Chemicals Codex*, and provided they meet their respective maximum levels of use and any other conditions set out for the specific food. For those additives where provisions for use are in accordance with Good Manufacturing Practices (GMP), they may be used in the minimum amount required to achieve the intended purpose as per Section B.01.044 of the FDR.

## 7.2 Food flavours

Flavouring ingredients used in foods should be of food-grade quality and should be used at flavour levels. Ingredients used at higher levels than would be consistent with use as a flavour may require further evaluation. Flavouring preparations that meet the standards of identity and composition in Division 10 of the FDR are acceptable for use in foods. Other flavour ingredients would be considered food-grade if they meet the specifications that are prescribed in the latest edition of the *Food Chemicals Codex* or if they meet the most recent flavouring specifications set by the Joint FAO/WHO Expert Committee on Food Additives (JECFA).

The FDR do not require pre-market evaluation of most food flavouring ingredients and there is no “positive” list of permitted flavours in the FDR. However, the FDA prohibits the sale of adulterated foods and Section B.01.046 of the FDR lists certain flavouring substances that would render a food adulterated. These substances are not permitted in any food (see Appendix 1).

Ultimately, the seller is responsible for ensuring that flavouring substances in their food products do not result in a violation of Section 4 of the FDA, which prohibits the sale of an unsafe food. Any food additives used in a flavouring ingredient must also be permitted for such use under the FDR (see Section 7.1 above).

## 7.3 Novel foods

Health Canada’s Food Directorate has noted that some supplemented food products contain ingredients (e.g., herbal and/or bioactive ingredients) which are not typically associated with food. Many of these ingredients are considered novel based on the regulatory definition of a novel food and have not been approved for use in foods.

Division 28 of the FDR requires that all novel foods undergo a mandatory pre-market assessment prior to being authorized for sale in Canada. Novel foods are:

- Products and ingredients that do not have a history of safe use as a food,
- Foods resulting from a process not previously used for food, causing the food to undergo a major change, or
- Foods that have been modified by genetic manipulation, also known as genetically modified foods, genetically engineered foods or biotechnology-derived foods.

When products with certain novel ingredients transitioned from the NHP regulatory framework to the food regulatory framework, as part of its overall safety review, Health Canada's Food Directorate conducted hazard screens of those ingredients. TMALs were issued for 2 years when the hazard screen determined that there was no immediate risk or when the product label provided risk information that was required when the product was marketed as an NHP. For some transition products, this meant that additional labelling requirements beyond those that already exist for all pre-packaged foods were also required as a condition of the TMA because those products could not be consumed safely *ad libitum* by the general population. This was considered a temporary measure.

Recognizing that the approach taken during the transition (e.g., TMA conditions for use and product labelling) challenges the current food regulatory framework, which is based generally on an *ad libitum* pattern of consumption of a food category or product, Health Canada has developed an option to regulate a subset of ingredients on an interim basis. For the period of the TMA, a limited number of ingredients will be eligible for exemption from the Novel Food Regulations. The list of ingredients that are eligible for this exemption is shown in Appendix 2. This list was developed based on the following criteria:

- The ingredient is not included for a conventional food purpose, specifically: nutrition, hydration, flavour, or technical effect (i.e., a food additive) in the food, and
- The ingredient was contained in a product for which a TMAL was issued during the transition and up until December 31, 2014.

The date of December 31, 2014, was chosen to set a practical limit, based on operational concerns, on the number of novel ingredients in TMA submissions that can be screened for potential hazards that have to be assessed for safety prior to market authorization. As such, no additional ingredients will be added to this list. It is envisaged that under the future regulatory framework for supplemented foods, there would be a process to allow for consideration of additional novel ingredients as long as certain criteria are met.

It should be noted that the presence of an ingredient on this List (see Appendix 2) should not be construed as authorization for its use in supplemented foods. Rather, these ingredients will be assessed for safety in supplemented foods on a case-by-case basis. Given the nature of these assessments, the Food Directorate's review of TMAL requests for products containing ingredient(s) that appear on this List will not be subject to the regular performance targets discussed in Section 5.2. This being said, the Food Directorate will aim to complete these assessments and set any conditions of sale in as expeditious a manner as possible.

Products containing ingredients which meet the definition for novel foods and are included for a conventional food purpose will remain subject to the requirements of Division 28. Similarly, products containing unapproved novel foods not included for conventional food purposes, but not listed in Appendix 2, will remain subject to the requirements of Division 28. For these products, a TMAL will not be issued until the novel food/ingredients have been reviewed and authorized by Health Canada or the product is reformulated.

Petitioners unsure about the novelty status of particular ingredients are encouraged to get an opinion from the Novel Foods Section of Health Canada's Food Directorate before making a TMAL request. A Novelty Determination Information Form can be requested by sending an email to [smiu-ugdi@hc-sc.gc.ca](mailto:smiu-ugdi@hc-sc.gc.ca) with the subject "Novelty Determination Information Form".

More information about novelty determination and assessment can be found in the [\*Guidelines for the Safety Assessment of Novel Foods Derived from Plants and Microorganisms\*](#).

## 8.0 Guidance on eligibility for a TMA

### 8.1 Formulation benchmarks for vitamins, minerals, and amino acids

In order to be eligible for a TMAL, products must not exceed the maximum levels set out below for certain vitamins and minerals (see Table 2 and 3). Health Canada's Food Directorate used a risk-based approach to set the maximum levels of addition. The levels are not related to nutritional requirements and **they are not recommended levels for addition**.

The research conducted through the TMA period is expected to help with determining the usual and upper levels of intake of supplemented foods in order to understand their potential impact on intakes of vitamins, minerals and amino acids by Canadians. The research will also help to ascertain the effectiveness of label statements (e.g., cautionary or directions for use statements). Once the data are available, maximum levels of addition may be revised, or set if no previous benchmark was established. Note that the nutrients listed and their maximum levels are subject to change based on future review as new evidence becomes available.

If a petitioner wishes to pursue a TMAL for a supplemented food that contains added nutrients not identified in this guidance, a strong rationale for the product's composition must be provided as part of the TMA application. Furthermore, if a petitioner wishes to include a nutrient at a level that is higher than a maximum level stipulated below, a strong rationale must be provided. This information will be assessed on a case-by-case basis.

#### 8.1.1 Vitamins and minerals not acceptable for addition

Certain nutrients have the potential for considerable risk for the general population or for a specific vulnerable population for whom it is unlikely that cautionary labelling would be effective as a risk mitigation tool. Table 1 below includes nutrients not permitted to be added to supplemented food products at any level and the rationale for the decision.

**Table 1. Vitamins and minerals not acceptable for addition**

Nutrient	Rationale
Folic acid	53-73% of the Canadian population has blood values associated with intakes above the Tolerable Upper Intake Level (UL). The adverse effect associated with exceeding the UL is masking and potentially delaying diagnosis of vitamin B <sub>12</sub> deficiency.
Iodine	95 <sup>th</sup> percentile of estimated intake exceeds the UL for children 4 to 8 years of age and for adults. The adverse effect associated with exceeding the UL is thyroid dysfunction.
Iron	Hazard for those with undiagnosed hemochromatosis. Hereditary hemochromatosis is an inherited disorder of iron metabolism which affects 1 in every 200–300 individuals of Northern European descent.
Nicotinic acid	Has known side effects; niacinamide can be used more safely in foods. The adverse effect associated with exceeding the UL is flushing of the skin.
Vitamin K	Hazard for those on blood thinning medications.

### 8.1.2 Maximum levels

Maximum levels were established for the addition of vitamins and minerals to supplemented foods to help ensure that their addition does not contribute to excessive intakes. A two-path approach was developed: each path corresponds to a set of maxima and, in the case of Path 2, labelling requirements. The two-path approach was developed to help consumers to distinguish between supplemented foods that are safe for the general population to consume and those products that have recommended conditions of use such as “not intended for children.”

In order to be considered eligible for a TMAL, the food should provide no more than the maximum levels, including both naturally occurring and added sources, for the vitamins and minerals established for either Path 1 or Path 2 below.

Details on how the maximum levels were derived can be found in Appendix 4.

#### 8.1.2.1 Path 1 maxima

Path 1 is intended to capture products with a low potential for adverse health effects. These products are appropriate for use by the general population 4 years of age and older and are not required to carry additional labelling with regard to vitamin and mineral levels. Path 1 levels are set on a “per serving” basis (see Table 2 below).

**Table 2. Path 1 maximum levels of addition**

<b>Nutrient</b>	<b>Maximum level (per serving)</b>
<b>Vitamins</b>	
Beta-carotene (µg)	700
Choline (mg)	not permitted
Niacinamide (mg)	48
Vitamin A (µg retinol)	not permitted
Vitamin B <sub>6</sub> (mg)	7
Vitamin C (mg)	66
Vitamin D (µg)	5
Vitamin E (mg)	5
<b>Minerals</b>	
Calcium	not permitted
Chromium (III) (µg)	25
Copper (µg)	342
Magnesium (mg)	21
Manganese (mg)	not permitted
Molybdenum (µg)	72
Phosphorus (mg)	105
Potassium (mg)	150
Selenium (µg)	6
Zinc (mg)	not permitted

### 8.1.2.2 Path 2 maxima

Path 2 is intended to capture products containing nutrient levels with higher potential for adverse health effects. In order to mitigate potential risks to health, additional label statements are required. The type and number of statements is commensurate to the products’ potential for adverse health effects (see Section 9.2.1.1). Path 2 levels are set on a “per day” basis (see Table 3 below).

**Table 3. Path 2 maximum levels of addition**

<b>Nutrient</b>	<b>Maximum level (per day)</b>
<b>Vitamins</b>	
Beta-carotene (µg)	3500
Choline (mg)	980
Niacinamide (mg)	338
Vitamin A (µg retinol)	612
Vitamin B <sub>6</sub> (mg)	38
Vitamin C (mg)	735
Vitamin D (µg)	25
Vitamin E (mg)	30
<b>Minerals</b>	
Calcium (mg)	251
Chromium (III) (µg)	125
Copper (µg)	2840
Magnesium (mg)	175
Manganese (µg)	1840
Molybdenum (µg)	730
Phosphorus (mg)	524
Potassium (mg)	750
Selenium (µg)	85
Zinc (mg)	5

**8.1.3 Vitamins for which no maximum level has been established at this time**

No maximum levels have been established for the following nutrients:

- Biotin
- Pantothenic acid
- Riboflavin
- Thiamine
- Vitamin B<sub>12</sub>

Even though no maximum levels have been established for these nutrients, any levels above those found in currently marketed supplemented foods will be assessed by Health Canada during the TMA submission evaluation.

#### 8.1.4 Amino acids

Since the IOM was unable to establish ULs for specific amino acids due to insufficient information, the review of amino acid levels proposed in supplemented food TMA submissions will be assessed on a case-by-case basis taking into account the overall risk profile of the individual product.

### 9.0 Labelling, advertising and claims

All requirements pertaining to labelling and advertising in the FDA, the FDR and the *Consumer Packaging and Labelling Act and Regulations* will generally apply to supplemented foods. Refer to Section 3.0 of the [General Guidance Document for Temporary Marketing Authorizations for Foods](#) and CFIA's website regarding [Food Labelling and Advertising](#) for further information. For specific information on claims for foods, see Section 9.3.

It is important to note that the label review conducted by Health Canada during the TMA review is only related to the ingredients (and their levels) and restrictions specified in the TMA.

Certain relevant regulations and guidance applicable to foods in general are reiterated to assist applicants in avoiding some of the common issues identified by Health Canada's Food Directorate in reviewing label claims in TMA submissions.

Unless specified, the labelling requirements outlined below will apply to all product categories covered by this guidance document.

#### 9.1 Reference amount and serving of stated size

The reference amount and serving size refer to quantities of a type of food usually consumed by an individual at a single eating occasion, as determined from consumption data. Reference amounts are set out in Schedule M of the FDR for over 150 categories of food. Proposed [nutrition information labelling guidance](#) has been published on how serving sizes should more closely align with reference amounts. These two parameters provide the basis of compositional criteria for certain nutrition and health claims for foods. They are not meant to indicate a recommended or desirable intake. Reference amounts and serving sizes are subject to change as new consumption data become available, including from the TMA research.

Included in Table 4 below are the reference amounts for some of the product categories that fall within the scope of supplemented foods as set out in this guidance document. Reference amounts for many other common foods can be found in Schedule M to the FDR. For products that require preparation, such as powders or mixes that are to be reconstituted, the reference amount for the unprepared form is the amount required to prepare the reference amount of the prepared form.

For example, if 15 mL of a beverage powder is required to make 250 mL, which is the reference amount of the prepared beverage, then 15 mL is the reference amount for the beverage powder.

**Table 4. Reference amounts for selected food categories**

<b>Product category</b>	<b>Reference amount</b>
Carbonated and non-carbonated beverages	375 mL
Fruit drinks represented for use as substitutes for fruit juices	250 mL
Water-based beverages with added vitamins and minerals	500 mL

The serving size of a product stated on the label should be as close to the reference amount as possible. In the case of products sold in single-serving containers, the serving size will be determined by the net quantity in concert with the principle that a container size within 200% of the reference amount that can reasonably be consumed at a single eating occasion will be the serving of stated size.

Where a manufacturer or distributor is unsure of the reference amount for their product, they should contact the [Food Directorate’s Bureau of Nutritional Sciences](#) for guidance.

All declarations of content made on the product label must be based on the same size of serving that appears in the Nutrition Facts table.

## 9.2 Required label statements

### 9.2.1 Cautionary statements

Cautionary statements, as set out in this guidance, are distinct from and should not be confused with the Food Directorate’s policy on the use of food allergen precautionary labelling on prepackaged foods (see Section 9.2.2). Please see [The Use of Food Allergen Precautionary Statements on Prepackaged Foods](#) for more information.

The Food Directorate’s general position has been that extensive cautionary labelling of foods is not an acceptable method to mitigate potential risks to health. However, supplemented foods represent a unique category of food products. Supplemented foods transitioned from the NHP regulatory framework generally retained the same cautionary labelling that they had as NHPs. Cautionary labelling for “Path 2” vitamin- and mineral-containing supplemented foods is set out in Section 9.2.1.1. Path 1 products are not required to carry cautionary statements with regard to vitamin and mineral levels.

Cautionary labelling for other supplemented foods will depend on the identity and level of specific ingredients so the requirements are being assessed on a case-by-case basis, taking into consideration the overall risk profile of the individual product. The research conducted through

the TMA period is expected to help ascertain the effectiveness of cautionary label statements on supplemented foods.

Cautionary statements such as “Not intended for children” and “Do not consume this product with other supplemented foods” should be grouped together, without any intervening or preceding material, under a standardized bolded heading “Caution / Mise en garde” or “Caution / Attention”. A distinct and consistent heading that stands out from other information on a label makes the information more noticeable to consumers.

### 9.2.1.1 Cautionary statements for path 2 products

Supplemented foods containing vitamins or minerals at levels exceeding those set out in Path 1 are required to carry cautionary statements on their labels. The labelling statements required are dependent on the nutrient level. See Table 5 for a list of labelling statements and corresponding nutrient threshold levels. Details on how the nutrient threshold levels for each cautionary statement were derived can be found in Appendix 5.

In most cases, the cautionary statement “Not intended for children” or “For adults only” is required when the level of vitamins and/or minerals exceed those set out in Path 1.

With Path 2 nutrient levels, consumers may be at increased risk of excess intake, especially those who consume other supplemented foods and/or supplements (e.g., multi-vitamin/mineral or single nutrient supplements such as calcium). To mitigate the risk of excess nutrient intakes, the following label statements, or statements to the effect of, may be required:

- If you take a daily supplement [that has the same vitamins or mineral], you may be getting too much vitamins or minerals by consuming this product.
- Do not consume this product with other supplemented foods [that has the same vitamins or minerals].
- Do not exceed X servings, per day.

Text in parentheses is additional optional information which can be included on product labels at the petitioner’s discretion. For greater specificity, the names of the added nutrients can also be included in the statement. For example, the following statement would be appropriate for a product containing calcium and vitamin D: “If you take a daily supplement containing calcium and vitamin D, you may be getting too much calcium and vitamin D by consuming this product”.

**Table 5. Threshold levels for cautionary statements for path 2 products**

<b>Nutrient</b>	<i>Not intended for children or For adults only</i>	<i>If you take a daily supplement, you may be getting too much vitamins or minerals by consuming this product</i>	<i>Do not exceed X servings, per day<sup>1</sup></i> <b>AND</b> <i>Do not consume this product with other supplemented foods</i>	<b>Path 2 max level</b>
<b>Vitamins</b>	<b>per serving</b>	<b>per serving</b>	<b>per serving</b>	<b>per day</b>
Beta-carotene (µg)	> 1400	not required	> 700	3500
Choline (mg)	all products	not required	> 196	980
Niacinamide (mg)	> 48	not required	> 67	338
Vitamin A (µg retinol)	all products	not required	> 122	612
Vitamin B <sub>6</sub> (mg)	> 7	not required	> 8	38
Vitamin C (mg)	> 66	not required	> 147	735
Vitamin D (µg)	>5	not required	> 5	25
Vitamin E (mg)	not required	>26	> 6	30
<b>Minerals</b>	<b>per serving</b>	<b>per serving</b>	<b>per serving</b>	<b>per day</b>
Calcium (mg)	> 163	all products	> 50	251
Chromium (III) (µg)	> 50	not required	> 25	125
Copper (µg)	> 342	not required	> 568	2840
Magnesium (mg)	> 21	not required	> 35	175
Manganese (µg)	all products	all products	> 368	1840
Molybdenum (µg)	> 72	not required	> 146	730
Phosphorus (mg)	> 229	not required	> 105	524
Potassium (mg)	>300	not required	> 150	750
Selenium (µg)	> 6	not required	> 17	85
Zinc (mg)	all products	all products	> 1	5

<sup>1</sup> An appropriate number of servings can be up to the highest number of servings that would not exceed the Path 2 maximum for any nutrient. For example, a product containing 300 µg vitamin A (retinol) is required to state: “Do not exceed 2 servings per day” (i.e., 612 µg ÷ 300 µg = 2 servings).

### 9.2.2 Priority allergens, gluten sources, and sulphites

As with all foods, supplemented food products must comply fully with all food labelling requirements to be eligible for a TMAL. This includes the enhanced labelling requirements for priority allergens, gluten sources and added sulphites as set out in Sections B.01.010.1 to B.01.010.3 of the FDR.

Food manufacturers are also urged to use food allergen precautionary statements on labels, when warranted by unavoidable cross contact during manufacturing, to alert the consumer to the potential inadvertent presence of priority allergens in food. Health Canada's allergen labelling guidance, [\*The Use of Food Allergen Precautionary Statements on Prepackaged Foods\*](#), provides guidance on the appropriate use of precautionary statements on pre-packaged foods.

### 9.2.3 Supplemented food versus standardized food names

When the common name of a supplemented food includes the prescribed common name of a standardized food (Sections B.02 to B.14 of the FDR) it should be made clear that the supplemented food does not meet the standard. The common name should describe how the food differs from the standard in a clear and prominent manner.

For example, the regulatory requirements for “water” are outlined in Division 12 of the FDR. Products represented as “water” must meet the standard of identity for water outlined in Section B.12.001 and the other requirements of the Division, as applicable.

To comply with regulatory requirements, the common name for all food products should meet the [\*common name policy\*](#) established by the CFIA. Products with multiple added ingredients that use the term water as part of their common name should abide by the [\*modified standardized common name\*](#) requirements. These requirements outline that the common name must:

- Make it clear to consumers that the food so described does not meet the standard; and
- Describe to the consumer how the food differs from the standard in a clear and prominent manner. It is important to note that a modified standardized common name may still be considered misleading if it is not clear how the product differs from the standard (e.g., if there are too many added terms).

The brand name and [\*trademarked\*](#) phrases (see also 9.3.7.2) used to market the product are subject to different requirements than the common name and can be used in addition to the common name. The brand name or other phrases must not be applied in a manner that is false, misleading, or likely to create an erroneous impression with consumers.

#### **9.2.4 Identifier and accompanying label specifications**

Health Canada is currently exploring the possibility of a front-of-pack identifier (e.g., visual and/or text) to be included on the Principal Display Panel (PDP) of the label for all supplemented foods to assist consumers in recognizing that these products are different from regular food products. In addition, accompanying label specifications such as standard formatting around caution statements and directions for use is also being investigated for these products. The effectiveness of supplemented food labelling is one element of the research requirements set out in TMALs. Health Canada will update stakeholders with regard to these labelling requirements as more information becomes available.

#### **9.2.5 Declaration of levels of vitamins and minerals**

At present, the levels of certain “core” vitamins and minerals in prepackaged foods are required to be declared as % Daily Values (% DV) in the Nutrition Facts table. Sodium is required in both absolute amount and as % DV (see FDR Sections B.01.401 to 467 and Schedule L). To help consumers assess their total intakes of nutrients from supplemented foods, it is necessary for the levels of both the core vitamins and minerals, and any added vitamins and minerals, in supplemented foods to be expressed in both absolute amounts and as % DV whenever the nutrients are required to be declared in the Nutrition Facts table. This requirement applies to all supplemented foods. The levels declared should reflect the total content of the nutrients in the food, regardless of whether the vitamins and minerals are naturally occurring in or added to the products as nutrients, or as part of food additives.

Figure 19.1 (B) in Schedule L to the FDR sets out the order of nutrients to be listed in the Nutrition Facts table. For the units of expression of the absolute amount to be shown in the Nutrition Facts table, please refer to the Table of Reference Standards following FDR Section B.01.001.1 and Tables I of Recommended Daily Intakes following FDR Sections D.01.013 and D.02.006. The values in these Tables should also be used in calculating % DV.

#### **9.2.6 Contact information**

The company name and identity of the principal place of business must be provided on the product label. Companies are encouraged to provide a toll-free number on the label to facilitate the reporting of consumption incidents by the public. Where a contact form or other contact information is available on the company’s website, the provision of the web address on the product label is encouraged.

### 9.2.7 Legibility and prominence of required statements

Required statements specific to supplemented foods should meet the same requirements for legibility and prominence as the Nutrition Facts table. This means that the required statements specific to supplemented foods should be displayed in letters of the same size and using the same leading as the nutrients in the Nutrition Facts table, using upper and lower case letters, contrast (for example, black text on white background) and prominence (see FDR Section B.01.450).

### 9.3 Voluntary statements

As noted in Section 3.2 of the [General Guidance Document for Temporary Marketing Authorization for Foods](#), certain statements, such as nutrient content claims (also called “nutrition claims”) and health claims may be made on the label or in advertisements for 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.

In Canada, regulatory requirements for gluten-free foods are set out in Section B.24.018 of the FDR. For more information on Health Canada’s position on foods labelled as gluten-free, please see [Health Canada’s Position on Gluten-Free Claims](#).

Two types of nutrition and health claims require regulatory amendment and pre-market review before they can be made. They are nutrient content claims (see Section 9.3.3 below) and claims about diseases or health conditions set out in Schedule A to the FDA (see Section 9.3.6.1 below). Note that conditions of the TMA require that the food labels not be false, misleading or deceptive in compliance with Section 5 of the FDA. Included below is general guidance on several common nutrition-related claims and health claims to help TMA petitioners make claims that would be compliant with requirements.

#### 9.3.1 Claims promoting general consumption

Nutrient function claims and other nutrition or health-related claims, including those referring to the maintenance of good health or normal growth and development, create an impression that the product can be consumed *ad libitum* long-term as part of a daily eating pattern and may be interpreted as encouraging general consumption. In the case of a product that is not suitable for the general population (e.g., not intended for children), a claim about the maintenance of normal growth and development would not be acceptable. In addition, claims that promote general consumption would also be unacceptable on products required to carry cautionary statements that have directions for restricted use, such as “do not consume more than two servings per day” if the claim could lead to unintended or inappropriate use by certain subpopulations.

Further, where the addition to a product of vitamins, minerals or other nutrients at high levels is not supported by a nutritional rationale, a claim “for the maintenance of good health” is

misleading if consumers perceive that they need high levels of these nutrients to maintain health. Some of these products could also pose nutritional risks if their consumption displaces the consumption of other foods that are more consistent with healthy eating.

### 9.3.2 Dietary guidance claims

Dietary guidance claims are statements intended to promote good health through healthy eating or to provide dietary guidance. They do not refer to a specific health effect, disease, or health condition. Examples include claims about “healthy”, “balance” and terms with a similar meaning.

Claims including the term “healthy” on food are best explained by linking the food to one of the directional statements in [\*Eating Well with Canada’s Food Guide\*](#). A “healthy” claim would not be acceptable on beverages whose energy value comes primarily from sugars, as the consumption of sweet beverages, including fruit juices, is to be limited. The Food Guide recommends having vegetables and fruit more often than juice. Similarly, a daily balance of nutrients is met by eating a variety of foods. No single food product should be represented to be “balanced”. A claim suggesting that the consumption of a product can deliver a daily balance of nutrients is unacceptable.

### 9.3.3 Nutrient content claims

“**Source of**” claims refer to the product as being a “source of” energy (calories) or nutrients such as vitamins, minerals or protein. The conditions for these claims are specified in Sections B.01.305, D.01.004, D.02.002, and in the table following B.01.513 of the FDR. The content claim for protein requires the calculation of the protein rating based on a reasonable daily intake (RDI) of the food. If the RDI for the same food or a similar food is not available in Schedule K to the FDR, the reference amount of the food should be used for this purpose. Unless permitted by regulation, no other nutrient content claims can be made that characterize the energy value of the food or the amount of a nutrient contained in the food (see FDR Section B.01.502(1)).

### 9.3.4 Health claims general guidance

Developing proper claim wording and conditions of use that are consistent with the supporting evidence is an important part of making a health claim that is truthful and not misleading or deceptive.

To enable consumers to understand the claimed benefit, products with substantiated claims should display on the food label, statements that:

- Link each claimed effect to specific substance(s) in the product;

- Indicate the amount of the substance or product required to achieve the effect along with the level of the substance contained in a serving of the food. Where there is a daily amount or recommended daily intake for the substance associated with the claimed effect, these amounts can be expressed as a percentage or fraction; and
- Express claimed effects in specific terms rather than general terms such that the claimed effects are both measurable and quantifiable reflecting their scientific validation. Claims that state a specific effect provide more useful information for the consumer and are less likely to be misleading or misunderstood than a claim about a general or broad effect.

General claims referring to the maintenance of good health and normal growth and development are acceptable for well-established functions of known nutrients (see Sections B.01.311, D.01.006, and D.02.004 of the FDR), with the exceptions noted in Section 9.3.1 when cautionary statements are required.

Where a product has unique properties or formulation and its claimed effect is supported by product-specific evidence using scientifically valid methodology, a link between the product and the claimed effect may be made, provided that the above guidance is also followed.

### 9.3.5 Substantiation of claims

Certain food health claims that are related to serious diseases and conditions listed on Schedule A to the FDA require pre-market authorization and regulatory amendments before they can be used. This involves an obligation to prepare and submit an application to Health Canada. Pre-market review of other types of food health claims is not required at present. However, manufacturers must be able to disclose the evidence in support of the claim upon request. Detailed information on the substantiation of new health claims (except for nutrient function claims and dietary guidance claims) can be found in the [Guidance Documents for Preparing Health Claim Submissions](#). The guidance in these documents also applies to the substantiation of claims that are not subject to pre-market review. For new nutrient function claims, an abbreviated process exists for documenting the supporting evidence for those that meet specified criteria (see [Acceptability of New Nutrient Function Claims](#)).

Consultation with Health Canada's Food Directorate is encouraged to ensure that applicable legislation, regulations and guidelines are followed or to assist when manufacturers are uncertain about the status of the claim they are planning to use. Questions or requests for consultation or pre-submission meetings may be directed to: [healthclaims-allegationsante@hc-sc.gc.ca](mailto:healthclaims-allegationsante@hc-sc.gc.ca).

### 9.3.6 Regulatory requirements for claims

Certain health claims or product representations may be subject to regulatory requirements, as detailed in the subsections that follow.

### 9.3.6.1 Schedule A and other claims regarding serious diseases

In accordance with Section 3 to the FDA, claims, explicit or implied, related to the diseases and health conditions listed in Schedule A to the FDA are prohibited on any foods unless already permitted in the FDR (Sections B.01.600 – B.01.603). Schedule A claims include those that refer to a sign, symptom, risk factor or biomarker that is closely associated with a Schedule A disease or condition. Examples such as “lowers/ reduces/ controls/ manages blood sugar”, “helps manage pre-diabetes”, and “improves insulin sensitivity” are claims related to diabetes, a Schedule A disease. For additional information on Schedule A claims, see the [Guidance Document – Schedule A and Section 3 to the Food and Drugs Act](#).

Schedule A does not contain a comprehensive list of all serious diseases. Serious diseases can be defined as those diseases, disorders or abnormal physical states, or their symptoms, for which supervision by a health care practitioner is necessary for the diagnosis, treatment, mitigation or prevention. Health claims related to any serious disease are not appropriate for supplemented foods unless already permitted in the FDR (Sections B.01.600 – B.01.603) or have been accepted by Health Canada (see [Acceptable Disease Risk Reduction or Therapeutic Claims](#)). To make one of these accepted claims, the product must meet the required conditions of use without the need for cautionary statements.

### 9.3.6.2 Weight reduction and related claims

Under Section B.24.003(3) of the FDR, the label, packaging or advertisement of a food must not give the impression that the food is for use in a weight reduction diet, unless the food is one of the foods listed in that subsection and meets the requirements set out in Division 24 for those foods, including the requirement for a statement “Useful in weight reduction only as part of an energy-reduced diet”. Manufacturers planning to use these claims should consult with Health Canada’s Food Directorate ([healthclaims-allegationssante@hc-sc.gc.ca](mailto:healthclaims-allegationssante@hc-sc.gc.ca)). However, no objection will be taken when the claim is limited to weight maintenance in the context of eating well and being active and when the claim is supported by a nutritional rationale (for example, the food is “lower in energy than ...”, “portion controlled”, etc.).

### 9.3.6.3 Nutrient function claims

“Nutrient” is not defined in the FDR. For the purposes of food labelling and advertising, a substance is considered a nutrient if it is recognized as such by the Institute of Medicine of the National Academies, Washington, DC.

Nutrient function claims on food should be made in accordance with the scope and conditions of use provided for in the FDR (Sections B.01.311, B.01.312, D.01.004, D.01.006, D.02.002, and D.02.004):

- Nutrient function claims may only be made about the energy value or nutrients in a food, they are not made for a food per se. Therefore, the nutrient must be declared as part of the claim.
- The function must describe the generally recognized role of the energy value or the nutrient in maintaining the functions of the body that are necessary to the maintenance of good health and normal growth and development.
- The energy value or nutrient that is the subject of the claim must be at or above a “source” level. For a vitamin or mineral nutrient, this means that the food must contain a minimum of 5% of the Recommended Daily Intake for that vitamin or mineral nutrient.

### **9.3.7 Other health-related claims**

#### **9.3.7.1 Amino acid claims**

TMA petitioners are reminded that any statements or claims about amino acids in food (outside the ingredient list) are subject to Section B.01.305(2) of the FDR, unless the product meets specified exemptions described in B.01.305(3). According to B.01.305(2) of the FDR, the label or advertisement must include a declaration of the amount of histidine, isoleucine, leucine, lysine, methionine, phenylalanine, threonine, tryptophan and valine contained in the food, expressed in grams per serving of stated size when a statement or claim about amino acids in food is made.

Where a product does not meet the requirement as a “source of protein”, an exemption from B.01.305(2)(a) will be required in the TMAL when the product contains one or more added amino acids for which a claim is made. An exemption will be considered case-by-case on the scientific basis of the amino acid claim being made.

#### **9.3.7.2 Claims implied by trademarks, graphics and other representations**

Trademarks, brand names, logos and slogans are subject to Subsection 5(1) of the FDA and Subsection 7(1) of the *Consumer Packaging and Labelling Act*. All information appearing on labels or in advertising, including the use of graphics, brand names, text or other forms of representations that suggest or imply a health benefit by any means, are considered claims. The CFIA provides food labelling guidance for [\*Pictures, Vignettes, Logos and Trade-marks\*](#).

#### **9.3.7.3 Highlighted ingredients**

A voluntary statement about an ingredient made or highlighted on the label, other than as part of the ingredient listing, would be considered an implied claim (see CFIA [\*Highlighted Ingredients Claims\*](#) labelling guidance). In principle, any emphasis on the presence of an ingredient or component should be accompanied by a statement regarding the amount of that substance

present in the food. Where the intent of the statement is to highlight the presence of a substance for a health benefit, the level of that substance in the product should be consistent with the amount needed to achieve that benefit in a specified number of servings. This means that the required amount of the substance should be able to be consumed by the general population as part of a balanced diet.

### **9.3.8 Legibility and prominence of voluntary statements**

To ensure that voluntary claims do not detract from the cautionary statements, it is recommended that voluntary claims not be more prominent than the required cautionary statements.

## **9.4 Advertising**

Under the FDA, “advertisement” includes any representation by any means whatever for the purpose of promoting directly or indirectly the sale or disposal of a product. Therefore, all statements, messages and representations, communicated in any medium that are designed to promote the consumption or sale of a food are considered to be advertising.

In order to make informed decisions about their health, consumers should always be provided with fair and balanced information about the benefits and the risks associated with the products being advertised. In accordance with Subsection 5(1) of the FDA, a food must be advertised in a manner that does not create an erroneous impression regarding the product’s character, value, quantity, composition, merit or safety.

When cautionary statements are required on the label of a supplemented food (see Section 9.2.1), Health Canada recommends that all forms of advertising of these products also contain the following information (or similar wording):

- “This product may not be suitable for everyone.”
- “Read the label and follow the directions for use.”

For broadcast advertising, the use of visual disclosures (supers) would be acceptable provided that they are of a size, shade and duration sufficient for an average person to read and comprehend. In print advertisements, disclosures should be in a location, type size and contrast sufficiently noticeable for an average person to read and comprehend.

Information that is unacceptable on the label is also unacceptable in advertising. Products not suitable for certain subpopulations due to the presence or levels of certain ingredients which are therefore required to have cautionary statements, also must not be advertised to these same subpopulations. For example, products labelled as “Not intended for children” or “For adults only” must not be advertised to children. Please refer to Sections 9.3.1 (cautionary statements) and 9.3 (voluntary statements) for further information.

## 9.5 Resources

The following resources administered by the CFIA provide additional information that will assist TMA petitioners in meeting food labelling requirements:

- [Compendium of Templates for Nutrition Facts tables](#) is available upon request from your [local CFIA office](#)
- [Food Labelling and Advertising](#)
- [Nutrition Labelling Toolkit](#)

## Appendix 1: Ingredients not permitted in foods

The ingredients found on this list are divided into two categories: flavouring ingredients that are not permitted in any foods (including supplemented foods) and other ingredients that are not permitted in foods. These lists of ingredients are not exhaustive and may be revised as new information becomes available.

### Prohibited flavouring substances (FDR Section B.01.046):

- Coumarin, an extract of tonka beans, the seed of *Dipteryx odorata* Willd. or *Dipteryx oppositifolia* Willd.
- Dihydrosafrole
- Isosafrole
- Oil of American sassafras from *Sassafras albidum* (Nutt.) Nees
- Oil of Brazilian sassafras from *Ocotea cymbarum* H.B.K.
- Oil of camphor sassafrassy from *Cinnamomum camphorum* Sieb.
- Oil of micranthum from *Cinnamomum micranthum* Hayata
- Safrole
- Oil, extract or root of calamus from *Acorus calamus* L.
- Cinnamyl anthranilate

### Other ingredients inappropriate for consumption as foods<sup>1</sup>:

- Cascara sagrada (*Frangula purshiana* Cooper)
- Chaparral (*Larrea tridentata* (Sessé & Moc. ex DC.) Coville, *L. divaricata* Cav.)
- Ephedra (*Ephedra* spp.)
- Germander (*Teucrium chamaedrys* L.)
- Horsetail (*Equisetum* spp.)
- Kava-kava (*Piper methysticum* G.Forst.)
- Khat (*Catha edulis* (Vahl) Endl.)
- Senna (*Senna alexandrina* Mill.)
- Arnica (*Arnica montana* L., wolf's bane, leopard's bane)
- Comfrey (*Symphytum* spp.)
- Magnolia (*Magnolia officinalis* Rehder & E.H.Wilson)
- Pleurisy root (*Asclepias tuberosa* L.)
- Stephania (*Stephania tetrandra* S.Moore)
- Yellow jessamine (*Gelsemium sempervirens* (L.) J.St.-Hil.)

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<sup>1</sup> Gotu kola has been removed from the List of “Ingredients Inappropriate for Consumption as Foods”. The removal of gotu kola from this list does not mean gotu kola ingredients are automatically approved for food use. Please contact Health Canada’s Food Directorate for further information.

## Appendix 2: List of novel food ingredients eligible for consideration for TMALs

Health Canada's Food Directorate is considering using the TMAL tool to exempt supplemented foods from the Novel Food Regulations (FDR, Division 28) for those products containing a limited number of novel food ingredients. In these cases, petitioners would not need to file a novel food notification with the Food Directorate. The following is a list of those novel food ingredients being considered. It should be noted that the presence of an ingredient on this list should not be construed as authorization for use in supplemented foods. Rather, these ingredients are being considered on a case-by-case basis for use subject to further safety assessment to determine whether they are appropriate for use in supplemented foods and what requirements (e.g., use levels, specifications, and/or labelling statements) would be a condition of that product's sale.

- Acetyl-L-carnitine
- Alpha GPC, Choline alfoscerate
- Alpha-lipoic acid
- Ashwagandha root extract, Winter cherry
- Astragalus root extract
- Calcium fructoborate
- Cha de Bugre leaf powder
- Damiana leaves
- Glucosamine hydrochloride
- Glucosamine sulfate
- Grape seed extract
- Green tea extract
- Horny goat weed extract
- 5-HTP (5-Hydroxytryptophan)
- L-Carnitine
- Maca root extract
- Mangosteen rind extract
- Milk thistle extract
- Panax ginseng
- Passionflower extract
- Phosphatidylserine
- Pomegranate rind extract
- Quercetin
- Raspberry seed extract
- Resveratrol
- Rhodiola extract
- Schisandra chinensis extract
- Siberian ginseng root extract
- Theobromine
- Valerian root extract
- White willow bark extract

### **Appendix 3: List of documents relevant to this guidance**

[Eating Well with Canada's Food Guide](#)

[General Guidance Document for Temporary Marketing Authorization for Foods](#)

[Category Specific Guidance for Temporary Marketing Authorization - Caffeinated Energy Drinks](#)

[TMA Web listing](#)

[Classification of Products at the Food-Natural Health Product Interface: Products in Food Formats](#)

[Food Labelling for Industry](#)

[Guidance Document – Schedule A and Section 3 to the Food and Drugs Act](#)

[Guidance Documents for Preparing Health Claim Submissions](#)

## Appendix 4: Derivation of vitamin and mineral maximum levels

Definitions and rationales for terms used in this Appendix are provided on the following page.

### Path 1 nutrient levels

$$\text{Path 1 formula: } (\text{Safe Daily Maximum} - \text{Dietary Intake} - \text{Estimated Supplement Intake}) \div 5$$

For most vitamins and nutrients, the Path 1 maxima were determined by subtracting the 95<sup>th</sup> percentile of daily dietary intake and an estimated daily supplement intake from the Safe Daily Maximum. The resulting value was divided by five to allow for the possibility that consumers might have up to five servings of supplemented foods in a day. Path 1 maxima correspond to an amount per serving rather than an amount per day.

The Safe Daily Maximum and corresponding 95<sup>th</sup> percentile of dietary intake selected for the calculation were based on the most vulnerable age-gender group, 4 years of age and older (most commonly children, 4-8 years). See Table 6 for details.

### Path 2 nutrient levels

$$\text{Path 2 formula: } (\text{Safe Daily Maximum} - \text{Dietary Intake}) \div 2$$

For most vitamins and minerals, Path 2 maxima were determined by subtracting the 95<sup>th</sup> percentile of daily dietary intake from the Safe Daily Maximum. The resulting value was divided by an uncertainty factor of two in order to mitigate the potential risk of exceeding the Safe Daily Maximum due to slight variation from label directions. Path 2 maxima correspond to an amount per day rather than an amount per serving.

The specific Safe Daily Maximum and corresponding 95<sup>th</sup> percentile of dietary intake were based on the most vulnerable age-gender group, 14 years of age and older. See Table 6 for details.

## **Definitions and rationales**

### **Safe daily maximum:**

For most nutrients, the Tolerable Upper Intake Level (UL), established by the Institute of Medicine (IOM) was used. The UL is the highest level of continuing nutrient intake that is likely to pose no risk of adverse health effects in almost all individuals in the life-stage group for which it has been designed. As intake increases above the UL, the potential risk of adverse effects may increase (IOM 2006). In cases where there was no UL established, or other information was determined more appropriate, a Safe Daily Maximum was determined from other authoritative scientific references (See Table 6).

### **Most vulnerable age-gender group:**

The most vulnerable age-gender group was the one with the smallest difference between the Safe Daily Maximum and the 95<sup>th</sup> percentile dietary intake.

### **Dietary Intake:**

The 95<sup>th</sup> percentile of dietary intake was selected as a reference value in order to address potential health risks from overconsumption in agreement with the approach for the safe addition of vitamins and minerals to foods recommended by Flynn et al. (2003) and Rasmussen et al. (2006). To ensure safe intakes from added nutrients, it is necessary to take into account individuals who already consume high levels of nutrients from foods. Thus, the 95<sup>th</sup> percentile represents individuals who have intakes considerably above the population mean, i.e., those in the top 5% of consumption for each nutrient (Flynn et al., 2003). Unless otherwise specified in Table 6, dietary intake data was sourced from the Canadian Community Health Survey 2.2 (Health Canada and Statistics Canada, 2009).

### **Estimated supplement intake:**

Supplement use in Canada is as high as 60% in certain age-gender groups of the population (Statistics Canada, 2014). However, limited information is available on Canadians' supplement intake from the Canadian Community Health Survey. Therefore, the value used in the Path 1 calculation was estimated by determining, for each nutrient, the highest level found in the top five selling multi-vitamin/mineral supplements for children and adults currently marketed in Canada, based on an AC Nielsen market survey (Nielsen Market Track, 2012). There is uncertainty in the assumed supplement intake value applied as it may underestimate supplement intake for individuals using single vitamin/mineral supplements at higher levels and overestimate supplement intake for individuals who do not consume supplements.

**Table 6. References for derivation of maximum levels**

Nutrient	Safe daily maximum	Dietary Intake	Supplement intake	Notes
<b>Vitamins</b>				
Beta-carotene (µg)	United Kingdom Expert Group on Vitamins and Minerals, 2003	Not considered. Safe Daily Maximum based on supplements only	Included in calculation	
Choline (mg)	IOM, 1998	Included in calculation	Not applicable, see notes	Dietary intake data (source): Estimated average intake (Life Sciences Research Office/Federation of American Societies for Experimental Biology, 1981 and Zeisel, 1981 as cited in IOM, 1998)  Not permitted in Path 1 since the estimated average intake exceeds the Safe Daily Maximum (UL) for one or more age-gender groups
Niacinamide (mg)	European Scientific Committee on Food, 2002	Not considered. Safe Daily Maximum based on supplements only	Included in calculation	
Vitamin A (µg retinol)	IOM, 2001	Included in calculation	Not applicable, see notes	Not permitted in Path 1 since the 95 <sup>th</sup> percentile dietary intake exceeds the Safe Daily Maximum (UL) for one or more age-gender groups
Vitamin B <sub>6</sub> (mg)	IOM, 1998	Included in calculation	Included in calculation	
Vitamin C (mg)	IOM, 2000	Included in calculation	Included in calculation	
Vitamin D (µg)	Prescription Drug List (PDL), Health Canada, 2015	Not considered. There is a large margin of safety between the IOM UL and the PDL	Not considered. There is a large margin of safety between the IOM UL and the PDL	An UF of two was not applied to Path 2 products due to the large margin of safety between the IOM UL and the PDL
Vitamin E (mg)	Lowest-Observed-Adverse-Effect-Level (LOAEL) (Klein et al., 2011; Bairati et al., 2005). Uncertainty factor of 3 applied for extrapolation of a LOAEL to a No-Observed-Adverse-Effect-Level (Food Standards Agency, 2003)	Not considered. Safe Daily Maximum based on supplements only	Included in calculation	

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Nutrient	Safe daily maximum	Dietary Intake	Supplement intake	Notes
<b>Minerals</b>				
Calcium (mg)	IOM, 2011	Included in calculation	Included in calculation	Not permitted in Path 1 since the 95 <sup>th</sup> percentile of intake (dietary and supplement combined) exceeds the Safe Daily Maximum (UL) for one or more age-gender groups
Chromium (III) (µg)	European Food Safety Authority, 2010 and World Health Organization, 1996	Not considered. UL based on supplement sources only.	Included in calculation	Application of the Path 1 formula resulted in a “per serving” maximum disproportionate to the Path 2 maximum. Therefore, the Path 1 level was derived by dividing the Path 2 maximum by five
Copper (µg)	IOM, 2001	Included in calculation	Included in calculation	Dietary intake data (source): 95 <sup>th</sup> percentile intake (National Health and Nutrition Examination Survey III, 1988–1994 (IOM, 2001))
Magnesium (mg)	IOM, 1997	Not considered. UL based on supplement sources only.	Included in calculation	Application of the Path 1 formula resulted in a maximum less than 5% Daily Value (DV). Therefore, maximum permitted at 5% DV
Manganese (mg)	IOM, 2001	Included in calculation	Not applicable, see notes	Dietary intake data (source): 95 <sup>th</sup> percentile intake (United States Total Diet Study, 1991–1997 (IOM, 2001)). Not permitted in Path 1 since 95 <sup>th</sup> percentile dietary intake exceeds Safe Daily Maximum (UL) for one or more age-gender groups
Molybdenum (µg)	IOM, 2001	Included in calculation	Included in calculation	Dietary intake data (source): Upper range of intake (Tsongas et al. 1980 as cited in IOM, 2001)
Phosphorus (mg)	IOM, 1997	Included in calculation	Included in calculation	Application of the Path 1 formula resulted in a “per serving” maximum disproportionate to the Path 2 maximum. Therefore, the Path 1 level was derived by dividing the Path 2 maximum by five
Potassium (mg)	Bakris and Olendzki, 2015	Safe Daily Maximum based on intake from supplemented foods only	Safe Daily Maximum based on intake from supplemented foods only	Application of the Path 1 formula resulted in a “per serving” maximum disproportionate to the Path 2 maximum. Therefore, the Path 1 level was derived by dividing the Path 2 maximum by five.
Selenium (µg)	IOM, 2000	Included in calculation	Included in calculation	Dietary intake data (source): 95 <sup>th</sup> percentile intake (National Health and Nutrition Examination Survey III, 1988–1994 (IOM, 2000))
Zinc (mg)	IOM, 2001	Included in calculation	Not applicable, see notes	Not permitted in Path 1 since 95 <sup>th</sup> percentile dietary intake exceeds Safe Daily Maximum (UL) for one or more age-gender groups

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## **Appendix 5: Determination of threshold levels for cautionary statements on path 2 products**

### **Not intended for children or For adults only**

This statement is required on products containing nutrients at levels exceeding that which was determined to be safe for children, 4 years of age and older, if they were to consume no more than 5 servings daily.

For vitamin A, zinc, manganese and choline, there was no level of nutrient addition that could be safely permitted in children. Therefore, products supplemented with these nutrients, at any levels, are required to carry this statement.

### **Do not exceed X servings, per day AND Do not consume this product with other supplemented foods [that have the same vitamins or minerals]**

These statements are required if consuming five servings per day would result in total daily intakes exceeding Path 2 maxima, for any nutrient.

For the first labelling statement, petitioners are required to calculate the appropriate number of servings to be cited in the statement based on the nutrient quantity in their product. An appropriate number of servings can be up to the highest number of servings that would not exceed the Path 2 maximum for any nutrient. See footnote of Table 5 for an example. Health Canada advises that labelling statements regarding number of servings be included only on products where it is required (See Table 5).

### **If you take a daily supplement [that has the same vitamins or minerals], you may be getting too much vitamins or minerals by consuming this product**

This statement is required on products which contain nutrients at levels which could result in intakes exceeding the Path 2 maximum when combined with a supplement.

**Appendix 6: Is my product a TMA-eligible supplemented food (SF)?**

