Interim Policy on the Use of Expired Interim Marketing Authorizations Related to Food Fortification

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Bureau of Nutritional Sciences
Food Directorate
Health Products and Food Branch
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Purpose

The purpose of this document is to set out Health Canada’s interim policy position with respect to the sale of foods fortified with vitamins, minerals, and/or amino acids pursuant to expired interim marketing authorizations (IMAs). This interim policy will be reviewed on an annual basis.

Scope

The following policy applies to foods fortified in accordance with the ten expired IMAs provided in Appendix A.

Roles and responsibilities

- **Health Canada**: federal authority responsible for establishing standards and regulations regarding, among other things, the fortification of foods sold in Canada.

- **Canadian Food Inspection Agency**: federal authority responsible for the compliance and enforcement of the food fortification standards and regulations set out by Health Canada.

- **Regulated industry**: responsible for ensuring that their food products comply with applicable food policies, standards and regulations.
Background

Protecting the health of Canadians is Health Canada's first priority when making decisions about the addition of vitamins, mineral nutrients and amino acids to foods. The addition of vitamins, mineral nutrients and amino acids to foods is controlled through the Food and Drug Regulations (FDR) to help ensure that Canadians get sufficient but not excessive amounts of certain nutrients in their diet. The FDR prescribes the foods to which vitamins, mineral nutrients and amino acids may or must be added and associated levels.

Modifying food fortification provisions to, for example, permit a different level of vitamin, mineral nutrient or amino acid addition to a food, or to allow a new food category to be fortified, requires a regulatory amendment to the FDR. As the process for amending regulations can be lengthy, the Interim Marketing Authorization (IMA) process was enacted in 1997 to bridge the time between the completion of the scientific evaluation of a request to amend the FDR and the actual publication of the amendment. During this IMA period, products could be legally sold on the Canadian market. However, in October 2012, when the Food and Drugs Act (FDA) was amended to allow for the Minister to issue Marketing Authorization (MA) for foods, the ability to issue IMAs was removed. As of this date, Health Canada is no longer issuing IMAs for foods.

Between 1997 and 2011, ten IMAs were issued related to the addition of vitamins and mineral nutrients to various food categories (see Appendix A for the list of the IMAs).

The IMA period for all ten of these IMAs has expired. Each IMA was pre-published in the Canada Gazette, Part I, pursuant to a thorough scientific evaluation that concluded that the proposed fortification was safe and appropriate. While no stakeholder objections to any of the ten proposals were received, Health Canada was unfortunately unable to proceed with final publication in the Canada Gazette, Part II, before their expiration. As it stands, although these food fortification proposals were and remain scientifically valid, as they are not currently prescribed in the FDR, foods fortified in accordance with these expired IMAs are not in compliance with the FDR.

The Canadian Food Inspection Agency (CFIA) and Health Canada have received requests from various stakeholders to obtain clarification as to the regulatory status of products that are the subject of these expired IMAs. Both the CFIA and Health Canada are also aware that a number of companies currently market products that comply with these IMAs, and some of these products have been available on the Canadian market for many years such as fortified soy beverages which have been sold in Canada for over 10 years.

Ultimately, regulatory changes are required to continue to permit the legal sale of these products in Canada. The appropriate regulatory tool to accomplish this goal is currently being examined. Until these regulatory changes are implemented, Health Canada has developed the following interim policy position respecting the sale of foods fortified in accordance with the ten expired IMAs.
Interim policy

Based on Health Canada’s analysis, the fortification specifications prescribed in the ten expired IMAs continue to address important public health needs. For example, the IMA to permit the optional addition of vitamins and mineral nutrients to plant-based beverages allows these products to be used as nutritionally adequate alternatives to cow’s milk for individuals who do not drink milk, for instance, due to allergies to milk protein, or lactose intolerance. Fortified plant-based beverages are an excellent source of calcium and vitamin B12, a good source of vitamin D, and a source of other essential nutrients, such as vitamin A and zinc. On the other hand, the IMA exempting formulated liquid diets for patients with renal failure from minimum requirements for vitamins A and D, and phosphorous and magnesium aims at protecting this vulnerable subpopulation. The dietary management of vitamins A and D and the mineral nutrients phosphorus and magnesium must be individualized for patients with renal failure based on the specific condition of the patient. Optimal intake levels of these vitamins and mineral nutrients will vary depending on the age and body weight of the patient and the severity of the renal failure. Patients with renal failure are under strict medical supervision which would ensure the safe use of such products.

Health Canada has determined that removing from the market products that comply with the fortification specifications of the expired IMAs may negatively impact the health of Canadians, including certain vulnerable subpopulations. The Department is of the view that the potential negative impacts on health far outweigh the risk posed by continuing to allow market access to these products.

As previously discussed, Health Canada intends to amend the regulatory framework to allow for the legal sale of these foods. While the necessary regulatory amendments are underway, Health Canada is of the view that the relative risks to vulnerable populations ought to be taken into consideration when establishing compliance and enforcement priorities respecting currently marketed and new products that fully comply with the conditions prescribed in any of the ten expired IMAs.
Appendix A: List of expired IMAs

1. Interim Marketing Authorization to permit the optional addition of vitamins and mineral nutrients to plant-based beverages


There is no provision in the Food and Drug Regulations to permit the addition of vitamins or mineral nutrients to beverages made from plant bases such as soy, rice, almond, etc. Health Canada has received a request to permit the optional addition of vitamins and mineral nutrients to plant-based beverages to enable them to be used as nutritionally adequate alternatives to milk for those individuals who are allergic to milk protein or are lactose intolerant.

Health Canada has completed a safety assessment of the proposal to fortify plant-based beverages as an alternative to milk and considers this request to be in the public interest. This fortification is consistent with the General Principles for the Addition of Essential Nutrients to Food published in the Codex Alimentarius, under the Joint Food and Agriculture Organization of the United Nations/World Health Organization Food Standards Programme. The General Principles state:

"Where a substitute food is intended to replace a food which has been identified as a significant source of energy and/or essential nutrients in the food supply, and particularly where there is demonstrated evidence of public health need, nutritional equivalence in terms of the essential nutrients of concern should be strongly recommended."

This rationale was used as a basis for the development of the current Regulations under the Food and Drugs Act governing the nutritional quality of simulated meat and poultry products, simulated whole egg products and substitutes for fruit juices.

Consultation with Canadian soy and dairy product producers, manufacturers and importers, industry associations, health professional associations, provincial governments and members of the public was conducted in 1996. There was general support for the fortification of plant-based beverages with vitamins and mineral nutrients. In order to inform consumers that not all of these products contain the levels of protein found in milk, the statement "Not a source of protein" would be required on the labels of products which do not have a minimum level and quality of protein.

Some respondents had concerns regarding the labelling and representation of these products. The Canadian Food Inspection Agency has determined that advertising and labelling should be covered by the general labelling provisions of the Food and Drugs Act and Food and Drug Regulations and the Guide to Food Labelling and Advertising.

Health Canada intends to recommend that the Regulations be amended to provided that:
(1) Notwithstanding sections D.01.009, D.01.011 and D.02.009 and subject to subsection (5), no person shall sell a beverage derived from legumes, nuts, cereal grains, or potatoes to which a vitamin or a mineral nutrient has been added unless the food, when ready-to-serve,
   (a) contains not less than 2.5 g of protein of a nutritional quality equivalent to not less than 75% of casein per 100 mL;
   (b) contains not more than 3.3 g of fat per 100 ml of which not more than 65% shall be saturated fatty acids, not more than 5% trans fatty acids and not less than 2.5% linoleic acid;
   (c) subject to subsection (3) and (4), contains the vitamins and mineral nutrients listed in column I of Table I to this Section in the amounts listed in column II.

(2) Subject to subsections (3) and (4), one or more of the vitamins and mineral nutrients listed in column I of Table II to this section may be added to a beverage meeting the requirements of subsection (1) provided that the beverage contains the added vitamin or mineral nutrient in the amount set out in column II of Table II.

(3) The amount of a vitamin or mineral nutrient that is not an added ingredient in the food may exceed the amount listed in column II of Table I and Table II to this Section.

(4) The amount of a vitamin or mineral nutrient listed in column II of Table I and Table II to this Section does not include overages.

(5) The label of a beverage that does not meet the requirements of paragraph (1)(a), but meets all other requirements of subsection (1) shall carry the expression "Not a source of protein" in close proximity to and in the same size type used for the common name.

(6) The common name of a beverage meeting the requirements of subsection (1) shall be "fortified (naming the plant) beverage".

(7) Ingredients or components derived from milk, goat's milk or milk products may not be used in the manufacture of a fortified (naming the plant) beverage.

(8) The label shall carry the following information per serving of stated quantity:
   (i) the energy value of the food, expressed in Calories (Calories or Cal) and kilojoules (kilojoules or kJ),
   (ii) the protein, fat, linoleic acid and carbohydrate contents expressed in grams,
   (iii) the contents of the vitamin and mineral nutrients listed in Table I to this section and any of those vitamin and mineral nutrients, except potassium, listed in Table II to this section that have been added to the food, expressed as a percentage of the recommended daily intake specified in column II of the tables to Divisions 1 and 2 of Part D for those vitamin and mineral nutrients,
   (iv) the content of sodium and potassium expressed in milligrams
Interim Policy on the Use of Expired Interim Marketing Authorizations Related to Food Fortification

<table>
<thead>
<tr>
<th>Table I</th>
<th></th>
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<tbody>
<tr>
<td><strong>Item</strong></td>
<td><strong>Vitamin or Mineral Nutrient</strong></td>
</tr>
<tr>
<td>1.</td>
<td>Vitamin A</td>
</tr>
<tr>
<td>2.</td>
<td>Vitamin D</td>
</tr>
<tr>
<td>3.</td>
<td>Vitamin B12</td>
</tr>
<tr>
<td>4.</td>
<td>Riboflavin</td>
</tr>
<tr>
<td>5.</td>
<td>Calcium</td>
</tr>
<tr>
<td>6.</td>
<td>Zinc</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Table II</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Item</strong></td>
<td><strong>Vitamin or Mineral Nutrient</strong></td>
</tr>
<tr>
<td>1.</td>
<td>Vitamin B6</td>
</tr>
<tr>
<td>2.</td>
<td>Vitamin C</td>
</tr>
<tr>
<td>3.</td>
<td>Thiamine</td>
</tr>
<tr>
<td>4.</td>
<td>Niacin</td>
</tr>
<tr>
<td>5.</td>
<td>Folacin</td>
</tr>
<tr>
<td>6.</td>
<td>Pantothenic acid</td>
</tr>
<tr>
<td>7.</td>
<td>Phosphorus</td>
</tr>
<tr>
<td>8.</td>
<td>Potassium</td>
</tr>
<tr>
<td>9.</td>
<td>Magnesium</td>
</tr>
</tbody>
</table>

This notice is, therefore, to advise the public of the intention to promulgate an amendment to the Food and Drug Regulations to permit the optional addition of vitamins and mineral nutrients to plant-based beverages at levels which are consistent with Codex Alimentarius General Principles for the Addition of Essential Nutrients to Foods as indicated in the table above.
As a means to improve the responsiveness of the regulatory system while enhancing the nutritional well-being of consumers, an Interim Marketing Authorization (IMA) is hereby being issued to permit the immediate sale of fortified plant-based beverages as nutritionally adequate alternatives for milk while the legal process to amend the Regulations formally is undertaken.
2. Interim Marketing Authorization to permit the addition of certain vitamins and mineral nutrients to corn meal


Provision currently exists in the Food and Drug Regulations for the restoration of certain vitamins and mineral nutrients to milled grain products such as flour, pasta and precooked rice; however, this provision does not extend to corn meal. Health Canada has received a request to permit the optional addition of vitamins and mineral nutrients to corn meal at levels which are the same as those of the United States.

An Interim Marketing Authorization (IMA) was published in the Canada Gazette, Part I, on November 29, 1997, to permit the immediate sale of enriched corn meal or foods containing enriched corn meal while the regulatory process to amend the Regulations formally was undertaken. At the time of the publication of the above IMA, the assessment of the safety of the maximum levels of calcium addition that were requested by the petitioner was not complete. Therefore, as an interim measure, the maximum level of calcium that could be added to cornmeal, and that was specified in the IMA published on November 29, 1997, in the Canada Gazette, Part I, was left at the same level as the minimum amount allowable.

Health Canada has now completed the safety assessment of the proposal concerning the maximum level of calcium allowable in cornmeal. Enrichment of corn meal remains in the public interest and is in accordance with Health Canada’s policy on restoration and fortification of nutrients in foods and is consistent with the General Principles for the Addition of Essential Nutrients to Food published in the Codex Alimentarius, under the Joint Food and Agriculture Organization of the United Nations / World Health Organization (FAO/WHO) Food Standards Programme.

This amendment will benefit industry by establishing a range for calcium to facilitate compliance with the requirements.

Therefore it is the intention of Health Canada to amend Division 13 of Part B of the Food and Drug Regulations to provide that:

(1) No person shall sell corn meal to which a vitamin or mineral nutrient set out in column I of any item of the table to this section has been added unless each 100 g of the corn meal contains the added vitamin or mineral nutrient in an amount not less than the minimum amount set out in column II of that item and not more than the maximum amount set out in column III of that item.

(2) No person shall represent corn meal as “enriched” unless the corn meal contains added thiamine, riboflavin, niacin, folic acid and iron, in accordance with the table to this section.
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<table>
<thead>
<tr>
<th>Item</th>
<th>Vitamin or Mineral Nutrient</th>
<th>Amount per 100 g of Corn Meal</th>
<th>Amount per 100 g of Corn Meal</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Thiamine</td>
<td>0.44 mg</td>
<td>0.66 mg</td>
</tr>
<tr>
<td>2.</td>
<td>Riboflavin</td>
<td>0.26 mg</td>
<td>0.40 mg</td>
</tr>
<tr>
<td>3.</td>
<td>Niacin</td>
<td>3.5 mg</td>
<td>5.3 mg</td>
</tr>
<tr>
<td>4.</td>
<td>Folic Acid</td>
<td>0.15 mg</td>
<td>0.22 mg</td>
</tr>
<tr>
<td>5.</td>
<td>Iron</td>
<td>2.9 mg</td>
<td>5.7 mg</td>
</tr>
<tr>
<td>6.</td>
<td>Calcium</td>
<td>110 mg</td>
<td>165 mg</td>
</tr>
</tbody>
</table>

This notice is, therefore, to advise the public of the intention to promulgate an amendment to the Food and Drug Regulations to permit the optional addition of vitamins and mineral nutrients to corn meal at levels which are harmonized with those of the United States.

As a means to improve the responsiveness of the regulatory system while enhancing the nutritional well-being of consumers, an Interim Marketing Authorization (IMA) is being issued to permit the immediate sale of foods containing enriched corn meal, at levels of fortification described above, while the regulatory process to amend the Regulations formally is undertaken.
3. Interim Marketing Authorization to permit the addition of folic acid to goat's milk


Health Canada has received a submission to permit the optional addition of folic acid to goat’s milk to bring the level up that found naturally in cow’s milk. Goat’s milk is deficient in folic acid, having only about one-tenth of the level of folic acid found in cow’s milk. Provision currently exists in the Food and Drug Regulations for the addition of folic acid to evaporated goat’s milk at a higher level consistent with its potential use as an infant formula. Health Canada has completed a safety assessment of the new proposal to add folic acid to goat’s milk and considers this request to be in the public interest. This nutrient addition is consistent with the General Principles for the Addition of Essential Nutrients to Food published in the Codex Alimentarius, under the Joint Food and Agriculture Organization of the United Nations / World Health Organization (FAO/WHO) Food Standards Programme.

This amendment will benefit industry by making it possible to render the nutritional value of goat’s milk equivalent to cow’s milk with respect to folic acid and it will increase the choice and nutritional quality of products available to consumers.

Therefore, it is the intention of Health Canada to recommend the amendment of the Food and Drug Regulations to permit the optional addition of folic acid to fluid or dried whole, skimmed or partly skimmed goat's milk to a minimum level of 5 micrograms and a maximum level of 10 micrograms folate per 100 mL goat's milk when ready-to-serve.

The addition of vitamins to goat's milk continues to be optional. Nevertheless, manufacturers who choose to add folic acid to fluid or dried whole, skimmed or partly skimmed goat's milk are also required to add the vitamins indicated under subsections B.08.029 (1) and (2) and at the prescribed levels.

As a means to improve the responsiveness of the regulatory system while enhancing the nutritional well-being of consumers, an Interim Marketing Authorization (IMA) is being issued to permit the immediate optional addition of folic acid in goat’s milk as indicated above while the regulatory process to amend the Regulations formally is undertaken.
4. Interim Marketing Authorization to permit the optional addition of vitamins and mineral nutrients to vegetable-based or vegetable products and to milk-based products, which resemble cheese

Excerpt from the *Canada Gazette, Part I, Vol. 135, No. 14, April 7, 2001.*

There is no provision in the *Food and Drug Regulations* to permit the addition of vitamins or mineral nutrients to vegetable-based or vegetable and milk protein based products, which resemble cheese, so that these products may contain the important nutrients provided by cheese. Health Canada has received a request to permit the addition of vitamins and mineral nutrients to vegetable-based or vegetable and milk protein based products, which resemble cheese, so that these products may contain the important nutrients provided by cheese for those individuals who do not consume cheese for health or other reasons.

Health Canada has completed a safety assessment of the proposal to permit the addition of vitamins and mineral nutrients to vegetable-based or vegetable and milk protein-based products. Addition of vitamins and mineral nutrients to these products is consistent with the *General Principles for the Addition of Essential Nutrients to Food* published in the Codex Alimentarius, under the Joint FAO/WHO Food Standards Programme. In the 1970’s, similar principles were used as the basis for the development of Regulations under the *Food and Drugs Act* governing the nutritional quality of simulated meat and poultry products, simulated whole egg products and substitutes for fruit juices. In November 1997, a Notice of Interim Marketing Authorization was published to allow for the sale of plant-based beverages as nutritionally adequate alternatives to milk.

The proposed amendment is in the interest of public health because it increases the choice and availability of products with the key ingredients provided by cheese for those individuals who choose not to consume cheese for health or other reasons.

Over the years, some stakeholders have expressed concerns regarding the labelling and representation of this type of products. The Canadian Food Inspection Agency has determined that the advertising and labelling of these fortified products are adequately addressed by the related provisions of the *Food and Drugs Act* and the *Consumer Packaging and Labelling Act* and the respective regulations. These provisions prohibit a person from labelling, packaging, treating, processing, selling or advertising a food in a manner that is false, misleading or deceptive or is likely to create an erroneous impression. Furthermore, where a standard for a food has been prescribed, these Acts and Regulations prohibit a person from labelling, packaging, selling or advertising a food in such a manner that it is likely to be mistaken for that standardized food unless it complies with the prescribed standard. These Act and Regulations also prohibit the use of a common name of a standardized food to describe any food unless that food meets the provisions set out in the standard.

The *Food and Drug Regulations* require that a complete list of ingredients and components be declared on the label of almost all prepackaged foods. Accurate and complete ingredient...
labelling of such foods containing milk protein will assist consumers with sensitivities to milk protein to make safe choices from a wide variety of foods in the marketplace.

Health Canada intends to recommend that the *Food and Drug Regulations* be amended to provide that:

(1) Notwithstanding Sections D.01.009, D.01.011 and D.02.009, no person shall sell a vegetable based or vegetable and milk protein based product which is similar to a cheese in appearance, texture, flavour, or odour, to which a vitamin or mineral nutrient has been added, unless the product, when ready-to-serve,
   (a) contains not less than 25 g of protein per 100 g in the case of products intended to have a nutritional value comparable to ripened (mature) cheese, or not less than 15 g of protein per 100 g in the case of products intended to have a nutritional value comparable to fresh cheese,
   (b) has not more than 50 percent of its fat as saturated fat, not more than 10 percent of its fat as trans-fatty acids and not less than 2.5 percent of its fat as linoleic acid and not less than 1.5 percent of its fat as linolenic acid,
   (c) contains not more than 600 mg of sodium per 100 g, and
   (d) has a protein rating of not less than 62 in the case of products intended to have a nutritional value comparable to ripened (mature) cheese or not less than 37 in the case of products intended to have a nutritional value comparable to fresh cheese, as determined by official method FO-1, Determination of Protein Rating, October 15, 1981.

(2) Subject to subsections (3) and (4), the vitamins and mineral nutrients listed in column I of the Table to this section may be added to a product meeting the requirements of subsection (1) provided that the product contains the added vitamins or mineral nutrients in the amounts set out in column II of the Table.

(3) The amount of a vitamin or mineral nutrient that is not an added ingredient in the product may exceed the amount listed in column II of the Table to this section.

(4) The amount of a vitamin or mineral nutrient listed in column II of the Table to this section does not include overages.

(5) The common name of products that meet the requirements in subsection (1) will be “fortified (naming the proteins/naming the oil) [naming the form]” (e.g., fortified casein/soy oil loaf, fortified soy protein/casein/soy oil slices).

(6) The label shall carry the following information, expressed in the following units per serving of stated quantity:
   (a) the energy value of the product, expressed in calories (Calories or Cal) and kilojoules (kilojoules or kJ),
   (b) the protein, fat, linoleic acid and carbohydrate contents expressed in grams,
   (c) the polyunsaturated, monounsaturated, saturated, and trans-fatty acid totals expressed in grams,
(d) the contents of the vitamins and mineral nutrients listed in the Table to this section, expressed as a percentage of the recommended daily intakes specified in column II of Table I to Division 1 and in column II of Table I to Division 2 of Part D of these Regulations for those vitamin and mineral nutrients, and (e) the content of sodium and potassium expressed in milligrams.

<table>
<thead>
<tr>
<th>Item</th>
<th>Vitamin or Mineral Nutrient</th>
<th>Amount per g protein</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Vitamin A</td>
<td>10 RE</td>
</tr>
<tr>
<td>2.</td>
<td>Vitamin B12</td>
<td>0.06 µg</td>
</tr>
<tr>
<td>3.</td>
<td>Riboflavin</td>
<td>20 µg</td>
</tr>
<tr>
<td>4.</td>
<td>Niacin</td>
<td>0.22 NE</td>
</tr>
<tr>
<td>5.</td>
<td>Calcium</td>
<td>30 mg</td>
</tr>
<tr>
<td>6.</td>
<td>Phosphorous</td>
<td>20 mg</td>
</tr>
<tr>
<td>7.</td>
<td>Magnesium</td>
<td>1 mg</td>
</tr>
<tr>
<td>8.</td>
<td>Zinc</td>
<td>0.15 g</td>
</tr>
</tbody>
</table>

Therefore, it is the intention of Health Canada to recommend that the Food and Drug Regulations be amended to permit the addition of vitamins and mineral nutrients to vegetable based or vegetable and milk protein based products, which resemble cheese, at levels which are consistent with Codex General Principles for the Addition of Essential Nutrients to Foods as indicated above.

As a means to improve the responsiveness of the regulatory system while enhancing the nutritional well-being of consumers, an Interim Marketing Authorization (IMA) is being issued to permit the immediate sale of fortified vegetable based or vegetable and milk protein based products, which resemble cheese, so that these products may contain the important nutrients provided by cheese, while the regulatory process is undertaken to formally amend the Regulations.
5. Interim Marketing Authorization to increase the maximum levels of vitamins A and D in preterm infant formula


The Food and Drug Regulations set out extensive nutritional requirements for human milk substitutes (infant formulas). These include minimum levels for all 13 vitamins and, in the case of vitamins A and D, maximum levels.

Health Canada has received a submission to increase the maximum levels of vitamins A and D in preterm infant formula from the current permitted levels of 500 International Units (IU) for vitamin A and 80 IU for vitamin D per 100 kilocalories (kcal) to 1,420 IU and 300 IU for vitamins A and D, respectively, per 100 kcal. These maximum levels include any overages that may be required to assure that the amounts of the vitamins indicated on the label are present in the food throughout its shelf life.

Health Canada has completed a safety assessment of the proposal to increase the maximum levels of vitamins A and D in preterm infant formula to the levels stated above. Evaluation of the available data supports the safety of these maximum levels of vitamins A and D in preterm infant formula. Preterm formulas with levels of vitamins A and D higher than the currently permitted levels have been sold under Temporary Marketing Authorization Letters for a number of years with no reported adverse effects.

These new maximum levels of vitamins A and D are consistent with the recommendations in Nutrient Needs and Feeding of Premature Infants, published by the Canadian Paediatric Society in 1995 and reaffirmed in 2000. They are also in line with Health Canada’s Guidelines for the Composition and Clinical Testing of Formulas for Preterm Infants, 1995, and the Nutrient Requirements for Preterm Infant Formulas, published in 2002 by the Life Sciences Research Office of the American Society for Nutritional Sciences. All of these reports recommended levels of vitamins A and D in preterm infant formula that are higher than the current maximum levels allowed under section B.25.054 of the Food and Drug Regulations.

The current regulatory requirements for vitamins A and D in infant formulas were based on the requirements of term infants and may not be suitable for the preterm infant.

Therefore, Health Canada intends to recommend that section B.25.054 of the Food and Drug Regulations be amended to provide that a human milk substitute represented solely for use by preterm infants may contain a maximum amount, including overage, of 1,420 IU of vitamin A and a maximum amount, including overage, of 300 IU of vitamin D per 100 available kilocalories.

As a means to improve the responsiveness of the regulatory system, an Interim Marketing Authorization (IMA) is being issued to permit the immediate sale of preterm infant formula with maximum levels of vitamins A and D as indicated above while the regulatory process is undertaken to formally amend the Regulations.
6. Interim Marketing Authorization to increase the maximum level of vitamin D in human milk substitutes (infant formulas)


The Food and Drug Regulations set out extensive nutritional requirements for human milk substitutes (infant formulas). These include minimum levels for all 13 vitamins and, in the case of vitamins A and D, maximum levels.

Health Canada has received a submission to increase the maximum level of vitamin D in infant formula from the current permitted level of 80 International Units (IU) per 100 kilocalories (kcal) to 100 IU per 100 kcal. This maximum level includes any overage that may be required to assure that the amount of the vitamin indicated on the label is present in the food throughout its shelf life.

Health Canada completed a safety assessment of the proposal to increase the maximum level of vitamin D in infant formula to the level stated above. Evaluation of the available data supports the safety of this maximum level of vitamin D in infant formula.

This new maximum level of vitamin D is consistent with the maximum level of 100 IU/100 kcal that was set in 1985 by the United States Food and Drug Administration. It is in line with the Codex Alimentarius for standard infant formula published in 1987, which was reconfirmed in 2003 as part of the ongoing revision of this standard. It is also in line with the report The Revision of Essential Requirements of Infant Formulae and Follow-on Formulae published in 2003 by the European Commission’s Scientific Committee on Food. All of these organizations recommended levels of vitamin D in infant formula that are higher than the current maximum level allowed under section B.25.054 of the Food and Drug Regulations.

Therefore, Health Canada intends to recommend that section B.25.054 of the Food and Drug Regulations be amended to provide that a human milk substitute may contain a maximum amount, including overage, of 100 IU of vitamin D per 100 available kilocalories.

As a means to improve the responsiveness of the regulatory system, an Interim Marketing Authorization (IMA) is being issued to permit the immediate sale of infant formula with a maximum level of vitamin D as indicated above while the regulatory process is undertaken to formally amend the Regulations.
7. Interim Marketing Authorization to exempt formulated liquid diets formulated specifically for patients with renal failure from the application of the minimum requirements of vitamins A and D and the mineral nutrients phosphorus and magnesium


Formulated liquid diets are foods for special dietary use that are sold or represented as nutritionally complete diets and 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. The Food and Drug Regulations set out nutritional requirements for formulated liquid diets. These requirements include minimum levels for 18 vitamins and mineral nutrients and, in the case of vitamins A and D, maximum levels.

Health Canada has received a submission to exempt formulated liquid diets formulated specifically for patients with renal failure from the application of the minimum requirements of vitamins A and D and the mineral nutrients phosphorus and magnesium. The dietary management of vitamins A and D and the mineral nutrients phosphorus and magnesium must be individualized for patients with renal failure based on the specific condition of the patient. Optimal intake levels of these vitamins and mineral nutrients will vary depending on the age and body weight of the patient and the severity of the renal failure.

Health Canada has completed a safety assessment of the proposal to exempt formulated liquid diets for patients with renal failure from the application of the current minimum requirements for the nutrients named above. Evaluation of the available data supports the safety of the exemption of formulated liquid diets for patients with renal failure from the minimum levels for vitamins A and D and for the mineral nutrients phosphorus and magnesium. Patients with renal failure are under strict medical supervision which would ensure the safe use of such products. The Food and Drug Regulations prohibit the advertising of formulated liquid diets to the general public. Formulated liquid diets with lower levels of vitamins A and D and of the mineral nutrients phosphorus and magnesium than the currently permitted levels under the Regulations have been sold under Temporary Marketing Authorization Letters for a number of years with no reported adverse effects.

Health Canada therefore intends to recommend that section B.24.102 of the Food and Drug Regulations be amended to exempt liquid diets formulated specifically for patients with renal failure from the application of the minimum requirements of vitamins A and D and of the mineral nutrients phosphorus and magnesium to meet the specific dietary needs of these patients.

As a means to improve the responsiveness of the regulatory system, an Interim Marketing Authorization (IMA) is being issued to permit the immediate sale of liquid diets formulated specifically for patients with renal failure and exempted from the application of the minimum requirements of vitamins and mineral nutrients, as indicated above, while the regulatory process is undertaken to amend the Regulations formally.
8. Interim Marketing Authorization to permit a higher maximum level for vitamin D in formulated liquid diets


Formulated liquid diets are foods for special dietary use that are sold or represented as nutritionally complete diets and 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. The Food and Drug Regulations set out nutritional requirements for formulated liquid diets. These requirements include minimum levels for 18 vitamins and mineral nutrients and, in the case of vitamins A and D, maximum levels.

Health Canada has received a submission to increase the maximum levels of vitamin D in formulated liquid diets from the current permitted level of 400 International Units (IU) per 1 000 kilocalories (kcal) to 800 IU per 1 000 kcal where the recommended intake is 2 500 kcal per day or less, and from 200 IU per 1 500 kcal to 400 IU per 1 500 kcal where the recommended intake is greater than 2 500 kcal per day.

Health Canada has completed a safety assessment of the proposal to increase the maximum amount for vitamin D in formulated liquid diets. Evaluation of the available data supports the safety of these modifications. Permitting higher levels of vitamin D in formulated liquid diets would assist persons relying on these products as their sole or major source of nutrition, in maintaining adequate vitamin D intakes. The revised upper level would also benefit manufacturers by allowing the production of a single formulation for marketing in Canada and the United States.

Therefore, Health Canada intends to recommend that the table of section B.24.102 of the Food and Drug Regulations be amended to allow a higher maximum level of vitamin D in formulated liquid diets, that is, 800 IU per 1 000 kcal for recommended intake of up to 2 500 kcal per day, and 400 IU per 1 500 kcal for recommended intake of greater than 2 500 kcal per day, including overages.

As a means to improve the responsiveness of the regulatory system, an Interim Marketing Authorization (IMA) is being issued to permit the immediate sale of formulated liquid diets, with an increased maximum level of vitamin D, as indicated above, while the regulatory process is undertaken to formally amend the Regulations.
9. Interim Marketing Authorization to permit the addition of calcium, with or without vitamin D, to orange juice, or orange and tangerine juice sold as such, in fluid, concentrated, or reconstituted forms


The addition of nutrients to foods sold in Canada is regulated under the Food and Drug Regulations. An Interim Marketing Authorization (IMA) was published in the Canada Gazette, Part I, on April 22, 2006, to permit the addition of calcium, with or without vitamin D, to orange juice, or orange and tangerine juice sold as such, in fluid, concentrated, or reconstituted forms, while the regulatory process to amend the Regulations formally was undertaken.

The present notice replaces the IMA of April 22, 2006, and amends the labelling requirements for orange juice and orange and tangerine juice with added calcium, with or without added vitamin D, in order to ensure consistency with the intention of the Temporary Marketing Authorization Letters issued by Health Canada between 1999 and 2006.

Therefore, it is the intention of Health Canada to recommend that the Food and Drug Regulations be amended to permit the addition of calcium, with or without vitamin D, to orange juice, or orange and tangerine juice sold as such, in fluid, concentrated, or reconstituted forms. The requirements for the sale of these foods containing these added nutrients are as follows:

(1) if calcium is added, the product must contain 310 milligrams (mg) of calcium per reference amount of 250 millitres (mL) not including overage;

(2) if vitamin D is added with calcium, the product must contain 2.5 micrograms (µg) of vitamin D per reference amount of 250 mL not including overage;

(3) the product would have to bear a Nutrition Facts table in accordance with the nutrition labelling requirements set out in sections B.01.401 and B.01.402 of the Regulations;

(4) the common name of the product must be modified to include one of the following phrases: (i) if calcium is added, “with added calcium”, “calcium enriched”, “enriched with calcium”, or “plus calcium”; or, (ii) if calcium and vitamin D are added, “with added calcium and vitamin D”, “calcium and vitamin D enriched”, “enriched with calcium and vitamin D”, or “plus calcium and vitamin D”;

(5) if calcium and vitamin D are added, the label of the product must display the statement “Fortified with calcium and vitamin D for people who do not drink milk” or “Specially designed as a source of calcium and vitamin D for people who do not drink milk” on the principal display panel of the label, prominently displayed and in close proximity to the most prominent claim for calcium or vitamin D content or, if no claim for calcium or vitamin D content is present, in close proximity to the common name and, in both cases, in letters of at least the same size as the letters...
used in the numerical portion of the declaration of net quantity as required under section 14 of the Consumer Packaging and Labelling Regulations;

(6) if calcium is added without added vitamin D, the label of the product must display the statement “Fortified with calcium for people who do not drink milk” or “Specially designed as a source of calcium for people who do not drink milk” on the principal display panel of the label, prominently displayed and in close proximity to the most prominent claim for calcium content or, if no claim for calcium content is present, in close proximity to the common name and, in both cases, in letters of at least the same size as the letters used in the numerical portion of the declaration of net quantity as required under section 14 of the Consumer Packaging and Labelling Regulations. In addition, the label must display the statement “This product does not contain vitamin D. A source of vitamin D may be required”, clearly visible, either grouped together with the Nutrition Facts table or on the principal display panel in close proximity to the most prominent claim for calcium content or, if no claim for calcium content is present, in close proximity to the common name and, in both cases, in letters of at least the same size as the letters used in the numerical portion of the declaration of net quantity as required under section 14 of the Consumer Packaging and Labelling Regulations;

(7) the product must not be represented for consumption by children under the age of 12 years.

As a means to improve the responsiveness of the regulatory system, an Interim Marketing Authorization is being issued to permit the immediate sale of orange juice, and orange and tangerine juice, with added calcium, with or without added vitamin D, as indicated above, while the regulatory process is undertaken to formally amend the Regulations.
10. Interim Marketing Authorization to permit the optional addition of vitamin D2-yeast to yeast-leavened bakery products


The addition of nutrients to foods sold in Canada is regulated under the Food and Drug Regulations (the Regulations). The current regulatory provisions list the types of foods that can be fortified, which nutrients can be added and the levels permitted in the particular food. Provision currently exists in the Regulations for the addition of vitamin D to products such as skim milk, partly skimmed milk, margarine and liquid whole eggs.

Health Canada has received a submission to permit the optional addition of vitamin D2-yeast to yeast-leavened bakery products at a level of 90 I.U. (2.25 µg) per 100 g. Health Canada has completed the safety assessment of the proposal to fortify yeast-leavened bread and unstandardized yeast-leavened bakery products such as pizza crust, bread mix, donuts, croissants and bagels. Evaluation of available data has demonstrated that the addition of vitamin D to the foods described above at a level of up to 90 I.U. (2.25 µg) per 100 g of product, as consumed, is safe. The evaluation also concluded that the source of vitamin D need not be limited to a yeast source.

The addition of vitamin D to yeast-leavened bread and unstandardized yeast-leavened bakery products will benefit consumers by providing additional sources of vitamin D thereby permitting higher intakes of this vitamin. It will also benefit industry by allowing the production of a broader range of products fortified with vitamin D.

Therefore, it is the intention of Health Canada to recommend that the Regulations be amended to permit the optional addition of vitamin D to bread, enriched bread, raisin bread, whole wheat bread, brown bread and unstandardized yeast-leavened bakery products at a level of up to 90 I.U. (2.25 µg) per 100 g of bakery product, as consumed.

As a means to improve the responsiveness of the regulatory system, an Interim Marketing Authorization (IMA) is being issued to permit the immediate optional addition of vitamin D to bakery products while the regulatory process is undertaken to amend the Regulations. The standardized foods described above are exempted from the application of sections 6 and 6.1 of the Food and Drugs Act, paragraphs B.01.042(a), B.13.022(c) and sections B.13.021, B.13.025, B.13.026, B.13.027, D.01.009 and D.03.002 of the Regulations only with respect to the optional addition of vitamin D. The unstandardized foods are exempted from sections B.13.029, D.01.009 and D.03.002 of the Regulations only with respect to the optional addition of vitamin D.