Demystifying Canada’s Complex Regulations for Vitamin and Mineral Fortification

In Canada, food and beverage type products are classified into many different categories according to Canada’s Food and Drug Regulations. These categories include traditional foods and beverages, “foods for special dietary use” (e.g. meal replacements and nutritional supplements), and “natural health products” (e.g. vitamin supplements, vitamin enhanced water, energy drinks). Within each category, the regulations require, permit, or prohibit the addition of vitamins and minerals in specified amounts. Products in each of these categories are sold and designed for specific purposes and uses, and are all regulated differently in terms of how they are sold, advertised, and labelled.

This fact sheet summarizes the various product categories and explains how the addition of vitamins and minerals is regulated within each category.

Traditional Foods and Beverages

Definition: “Food” includes any article manufactured, sold or represented for use as food or drink for human beings, chewing gum, and any ingredient that may be mixed with food for any purpose.¹

Mandatory and Voluntary Fortification:

Current regulations: A number of foods and beverages must be fortified with specific vitamins and minerals at specific levels. For example, skim milk must contain both vitamins A and D and within a specified range (1200-2500 International Units vitamin A and 300-400 IU vitamin D per 30 fl oz/852 mL). For other foods, fortification is optional such as the addition of B vitamins, magnesium, iron and zinc to breakfast cereals. Again, the permitted amounts to be added must be within a specified minimum and maximum range. Additional examples are shown in Table 1.

Example: Products in beverage-format that are classified as Natural Health Products (NHPs) include energy drinks and vitamin/mineral enhanced waters (e.g., Aquafina Plus™ Vitamin Enhanced Water), iced teas and sports drinks. NHPs in tablet form include vitamin and mineral supplements and a wide range of other substances intended for therapeutic use such as Echinacea, garlic, and ginkgo biloba.

Definition: NHPs are regulated as drugs as part of Canada’s Food and Drug Act. They must be represented for therapeutic use (e.g. to diagnose, treat, or prevent disease; or to maintain or promote health) and are meant for over-the-counter use without a prescription. They may be in any dosage form (e.g., tablet, lozenge, liquid) and include products containing vitamins and minerals, herbal remedies, homeopathic medicines, traditional medicines such as traditional Chinese medicines, probiotics, amino acids and essential fatty acids.

Vitamin and Mineral Content: Products that contain vitamins or minerals and are sold for therapeutic use are classified as NHPs. Amounts of vitamins and minerals in these products may be similar to amounts in traditional foods or beverages or they may be much higher.

Labelling: Health Canada evaluates submissions by manufacturers for safety and efficacy of each individual product, and issues product licences allowing products to be sold and represented within the approved conditions of the license. The licence includes approval of the label. The label of an NHP must include the following information: recommended purpose, recommended dose, intended age group, recommended duration of use, if any; and risk information, including cautions, warnings, contra-indications or known adverse reactions associated with its use. Amounts of medicinal (or active) ingredients, which includes vitamins and minerals, must be listed on the label, in addition to a list of “non-medicinal ingredients,” which may include ingredients such as flavours, colours, sugar, etc.

Some NHPs may provide energy or other nutrients. However, since these products are primarily intended to provide medicinal ingredients for a specific therapeutic purpose, the amounts of nutrients in these products is not required to be labelled. However, this information (e.g., calories, sugars) may be provided on the label voluntarily.

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Traditional Foods and Beverages cont’d…

Labelling: Almost all prepackaged foods and beverages are required to show a Nutrition Facts Table on the label showing calories plus 13 core nutrients per serving size in a standard format. Mandatory vitamins and minerals include vitamin A, vitamin C, calcium and iron shown as % of Daily Value. If additional vitamins or minerals are added, the amounts must be shown in the Nutrition Facts Table.

Government Proposed Regulatory Changes

In 2005, Health Canada released a report of its intentions to broaden the range of foods that can be fortified with vitamins and minerals, also updating requirements on the types and amounts that can be added. These regulations are expected to come into force by approximately 2010.

This new policy would continue to permit the addition of vitamins and minerals for the purposes of nutrient restoration, nutritional equivalence of substitute foods, and addressing or preventing nutritional problems of public health significance. Some of these regulations would be revised, such as those for breakfast cereals, permitting the addition of more vitamins and minerals and at higher levels than currently permitted.

In addition, it would permit a new category called “discretionary fortification,” which would allow the addition of specific vitamins and minerals on a voluntary basis at specific levels in many foods. Table 2 categorizes nutrients by the levels that would be permitted. Because they are pervasive in the food supply, flour, bread, pasta, milk and other similar staple foods will not be eligible for discretionary fortification.

Table 1. Examples of mandatory and voluntary fortification of foods and beverages.

<table>
<thead>
<tr>
<th>Product Type</th>
<th>Mandatory Nutrients</th>
<th>Voluntary Nutrients</th>
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<tbody>
<tr>
<td>Breakfast cereals</td>
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<tr>
<td>Fruit-flavoured drinks</td>
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<td>Margarine and other substitutes for butter</td>
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<td>Simulated meat products</td>
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<tr>
<td>Skim milk, partly skimmed milk, skim milk powder</td>
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<td></td>
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<td>Apple juice, grape juice, pineapple juice</td>
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<tr>
<td>Flour, white flour</td>
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<tr>
<td>Table salt, table salt substitutes</td>
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<tr>
<td>Mineral water, spring water, water in sealed containers</td>
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<td>Meal replacements and nutritional supplements</td>
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Table 2. Proposed discretionary fortification: levels to which vitamins and minerals may be added per reference amount.

<table>
<thead>
<tr>
<th>Risk A nutrients</th>
<th>Example</th>
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<tbody>
<tr>
<td>Thiamine, riboflavin, niacin, vitamin B6, vitamin B12, pantothenate, biotin, vitamin E, vitamin C, beta-carotene</td>
<td>Dole® Apple Juice from Concentrate</td>
</tr>
<tr>
<td>Permitted to be added up to 20% of the Daily Value; products can make “excellent source” claim</td>
<td></td>
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<tr>
<td>Not associated with adverse effects, have a wide margin of safe intakes, or have no serious adverse effects</td>
<td></td>
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<th>Risk B nutrients</th>
<th>Example</th>
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<tbody>
<tr>
<td>Vitamin D, folate, potassium, calcium, magnesium</td>
<td>Dole® Apple Juice from Concentrate</td>
</tr>
<tr>
<td>Permitted to be added up to 10% of the Daily Value; products can make “good source” claim</td>
<td></td>
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<tr>
<td>Have serious adverse effects at excessive levels, but the risk of excessive intakes at the proposed level is low</td>
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<th>Risk C nutrients</th>
<th>Example</th>
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<tbody>
<tr>
<td>Vitamin A, zinc, iron, copper, selenium, manganese, iodine, fluoride, choline, chromium, molybdenum, phosphorus, Vitamin K</td>
<td>Dole® Apple Juice from Concentrate</td>
</tr>
<tr>
<td>Not permitted for discretionary fortification</td>
<td></td>
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<tr>
<td>Have limited safety data or a narrow margin of safety and serious side effects at excessive intake levels and/or current intake levels in vulnerable subgroups exceed the upper level of safety</td>
<td></td>
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</table>

Source: Adapted from Addition of Vitamins and Minerals to Foods, 2005: Health Canada’s Proposed Policy and Implementation Plans.3