Health Canada Santé Canada

Addition of Vitamins and Minerals to Foods, 2005

Health Canada's Proposed Policy and Implementation Plans

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Executive Summary

Health Canada's policy review on the addition of vitamins and minerals to foods which was initiated in January 1998 is now completed. The purpose of this document is to inform all interested parties of the proposed policy, as well as plans for implementation. This document proposes more flexible requirements for special purpose foods such as meal replacements and nutritional supplements and also addresses outstanding requests for regulatory amendments from the food industry related to certain substitute foods, breakfast cereals, certain staple grain products.

Consultations have been held throughout the review process providing Health Canada with valuable information highlighting areas of agreement, as well as areas of concern. There has been consistent agreement on the need to continue fortification to address public health concerns (through mandatory and optional fortification of selected and targeted food vehicles), and to maintain the nutritional quality of the food supply (through restoration of nutrient[1] losses due to processing, and ensuring the nutritional adequacy of substitute foods). Stakeholders have held differing views on the proposed policy on discretionary fortification: views differed on the need for a nutritional rationale, on the criteria for foods that would qualify for fortification, on the nutrients to be permitted for addition, and on proposed levels of addition. Consumers have expressed a mildly positive attitude toward greater choice of fortified foods provided that there remain choices of unfortified foods, and that there is clear information on the label identifying fortified foods.

Health Canada is required to respond to the food industry submission for discretionary fortification in order to protect the safety of Canadians from excessive nutrient intakes. Health Canada has set an overarching policy on discretionary fortification to ensure safety by controlling the limits and parameters on discretionary vitamin and mineral nutrient additions to foods.

Over the period of the policy review, the Dietary Reference Intakes reports of the Institute of Medicine (IOM) of the U. S. National Academies have become available. The reports from the IOM have been invaluable to this review as they provided updated estimates of nutrient requirements and a new reference value, the Tolerable Upper Intake Level (UL) which have been key in assessing various options for discretionary fortification. In addition the Institute of Medicine was contracted to provide guidance on the use of the Dietary Reference Intakes in nutrition labelling and most relevant here, in discretionary fortification. Where feasible this guidance has been taken into account in the proposed policy.

The final decisions on discretionary fortification were arrived at after an analysis of several options for discretionary fortification based on input from stakeholders as well as statistical modelling of scenarios which were conducted during the safety assessments. The statistical modelling included various scenarios. These ranged from maximum possible exposure to

[1]Nutrients refer to vitamin and mineral nutrients for the purpose of this policy.

nutrient intakes from foods if all foods that could be fortified were fortified, to simulations in which estimated intakes were based on a fraction of the market being fortified, even if all could be fortified. These latter simulations also assumed that only a fraction of the population would choose a fortified product over an unfortified one if such choices were available. The purpose of regulation for discretionary fortification is consumer protection from exposure to excessive intakes. In addition to safety, the option analysis assessed how well each option addressed criteria related to availability and choice/ innovation, trade and competitiveness, regulatory burden and ease of enforcement. The proposed policy on discretionary fortification is the result of the option analysis.

The *Codex General Principles for the Addition of Essential Nutrients to Foods* will continue to be retained as the reference. Nevertheless, the proposed conditions for discretionary fortification is a more modern approach which will protect Canadians from consuming excessive amounts of vitamins and minerals from foods, and at the same time provide consumers with a choice of a variety of fortified foods.

In proposing these significant changes to the current policy on the addition of vitamins and minerals to foods, Health Canada has adhered to the original guiding principles established at the start of the policy review. The purposes of the proposed policy are to protect consumers from health hazards due to nutrient excess, deficits or imbalance; prevent practices that may mislead, deceive or confuse the consumer; maintain and improve the nutritional quality of the food supply. The policy is based on the best available evidence while being feasible and practical, and sensitive to trade and competitiveness issues. It is recognized that there is a need for appropriate education and communication to guide consumers to enable them to make good choices of food.

PROPOSED POLICY

Vitamin and mineral addition to foods is permitted under the following broad categories, to help protect consumers from nutrient inadequacies and from excessive nutrient intakes:

(a) Vitamin and mineral addition is permitted to maintain and improve the nutritional quality of the food supply through (i) restoration and (ii) nutritional equivalence of substitute foods.

(b) Food fortification programs will continue to be employed to correct and/or prevent nutritional problems of public health significance.

(c) Discretionary fortification, the optional addition of any nutrient from a defined list of vitamins and minerals over defined ranges at the discretion of manufacturers, is expanded to allow for a wider range of fortified products which would provide for more food sources of nutrients without increased risk to health.

(d) The category of special purpose foods is broadened to allow the formulation of a

reater variety of products designed for people who may require them for special nutritional purposes.

IMPLEMENTATION

In implementing the policy, it is proposed that additional regulations would be developed to permit vitamin and mineral addition to foods as follows:

1. **Discretionary fortification**: The implementation of discretionary fortification would be governed as described below.

   i) Eligible foods: All foods are eligible to be fortified at the discretion of manufacturers except: flours, breads, pasta (dry, fresh, frozen, single ingredient), rice, milks, butter, suet, lard, varietal cheeses, sugar and sugar syrups, maple syrup, honey, artificial sweeteners, salt, herbs, spices, dry seasonings, vinegar, flavouring preparations, leavening agents, alcoholic beverages, fresh produce, fresh unprocessed meat, poultry and fish, eggs, nuts, legumes, simulated and extended meat and poultry products, coffee beans, leaf tea, infant foods, formulated liquid diets, breakfast cereals, meal replacements and nutritional supplements.

   ii) Nutrient Risk Categories:
   Risk Category A nutrients: Those vitamin and mineral nutrients for which no UL was set because of no reports of adverse effects, and no concern expressed; and those nutrients for which a UL was set but with a wide margin of safe intake; and those nutrients with a narrow margin of safety, but non-serious critical adverse effects: thiamin, riboflavin, pantothenate, biotin, vitamin B_{12}, β-carotene, vitamin C, vitamin B_6, vitamin E, niacin.

   Risk Category B nutrients: Those nutrients with serious adverse effects, but with low risk of excessive intake at the proposed level of addition for discretionary fortification: calcium, folic acid, magnesium, vitamin D, potassium.

   Risk Category C nutrients (to be excluded from discretionary fortification): Those nutrients with a narrow margin of safety, and with serious adverse effects, and/or with current levels of exposure to intakes above the UL by vulnerable subgroups: vitamin A as retinol, zinc, iron, copper, selenium, manganese, iodine, fluoride. Nutrients in this category are currently permitted or required to be added to a range of foods for purposes of restoration, mandatory fortification, nutritional equivalence of substitute foods or to make a special purpose food such as a meal replacement. New or further additions for these purposes would continue to be subject to regulatory requirements.

Other nutrients for which a risk category has not been assigned include choline, chromium, molybdenum, phosphorus, vitamin K. These nutrients are proposed to be excluded from discretionary fortification for a variety of reasons (see Appendix B).

iii) Level of addition:
Nutrients in Risk Category A may be added such that the total amount (naturally occurring and added) of the nutrient in the food is up to 20% of the Daily Value per reference amount of the food. If the food contains 20% of the Daily Value, the food will qualify for an "excellent source" claim. For Risk Category B nutrients, the total amount (naturally occurring and added) of the nutrient permitted in the food is up to 10% of the Daily Value. If the food contains 10% of the Daily Value the food will qualify for a "good source" claim.

iv) If a nutrient is added, the minimum level of the total amount of the nutrient in the food must be 5% of the Daily Value per reference amount of the food. If the food contains at least 5% of the Daily Value, the food will qualify for a "source" claim.

v) For those vitamins and minerals which have been added, the total amounts of those vitamins and minerals in the food must be declared in the Nutrition Facts table as part of the mandatory nutrition labelling requirements.

vi) Foods with added vitamins and mineral nutrients will be required to indicate on the principal display panel that the food contains an added vitamin(s) or mineral(s).

2. **Special purpose foods** are foods which have been designed to perform a specific function, such as replacing a meal. They necessitate a content of essential nutrients which can be achieved only by the addition of one or more nutrients. Expansion of the options for meal replacements and nutritional supplements is proposed to include foods targeted to consumers with lower or higher energy needs, and to target better the needs for different age groups. The proposed nutrient levels are based on the new Dietary Reference Intakes.

3. The proposed regulations will include a list of acceptable vitamin compounds and mineral salts which may be used for fortification.

4. It is proposed that requirements for analytical testing and record keeping be established for vitamin and mineral addition to foods. Manufacturers would be required to establish procedures for measuring the content of vitamins and minerals in the final product, and to conduct tests to determine the uniformity of distribution of the vitamin or mineral in the food; the stability of the vitamin or mineral nutrient in the food throughout its shelf life; and the expiration date of the food except in the case of foods with best before dates.

Manufacturers and importers would be required to keep records of these tests.

In addition to the proposed policy, this document describes regulatory changes to implement the proposed policy as well as to amend the regulations to make provisions for vitamin and mineral additions that have been permitted through Interim Marketing Authorizations (IMAs) (for fortified plant-based beverages, enriched corn meal, vegetable based or vegetable and milk protein-based products which resemble cheese), and to address requests for fortification or restoration, such as the addition of an expanded list of nutrients and higher levels for some nutrients currently added to breakfast cereals, the enrichment of rice and a reduction in the level of potassium relative to protein content of simulated meat products.

A. Introduction

Health Canada initiated a comprehensive policy review on the addition of vitamins and minerals to foods in January 1998. During the earliest phase of the policy review, stakeholders indicated that the major issues regarding fortification were those in the areas of public health, safety, consumer choice and availability, and trade and competitiveness.

Consultations were held throughout the review process providing Health Canada with valuable information highlighting areas of agreement, as well as areas of concern. There has been consistent agreement on the need to continue fortification to address public health concerns (through mandatory and optional fortification of selected and targeted food vehicles), and to maintain the nutritional quality of the food supply (through restoration of nutrient losses due to processing, and nutritional adequacy of substitute foods). Stakeholders have held differing views on the proposed policy on discretionary fortification: views differed on the need for a nutritional rationale, on the criteria for foods that would qualify for fortification, on the nutrients to be permitted for addition, and on proposed levels of addition. Consumers indicated a mildly positive interest in more choices of foods fortified at the discretion of manufacturers providing that unfortified choices remain available, and providing that Health Canada sets limits to ensure the safety of the levels permitted to be added to the food supply, and requires clear identification of foods with added nutrients.

This document responds to concerns that have been raised during the consultations and indicates how they have been addressed; it sets out the process used in a clear and transparent manner in advance of publication of the regulatory proposals. This document provides an indication of the regulatory framework which is intended to be the basis for regulatory proposals to be published in *Canada Gazette* Part I.

This Phase

This last policy review phase has involved the following steps.

1) Stakeholder Consultations

Throughout the policy review process, several consultations were held and stakeholders were able to provide valuable input at critical stages (see Appendix A for milestones in the review process).

2) Statistical Modelling

Health Canada conducted statistical modelling of the impact of discretionary fortification under mature market scenarios based on information provided by the food industry (see Appendix B).

3) Institute of Medicine (IOM) Reports and their role in the Proposed Policy

The Dietary Reference Intakes (DRI) review process was conducted under the auspices of the IOM of the U.S. National Academies to evaluate the scientific basis for nutrient requirements for the healthy population in Canada and the United States. The results were published in a series of reports over the period 1997 to 2004. The review was initiated in 1995 by the Food and Nutrition Board, IOM and supported by Health Canada and the U. S. government.

Health Canada will be applying the new DRIs in the development of standards and policies in several areas including the Nutrition Recommendations for Canadians, and the policy review on vitamin and mineral nutrient additions to foods

The DRIs are a useful new tool in evaluating the adequacy of nutrient intakes of population groups, and in assessing exposure to excessive intakes, applications that Health Canada has used in developing the revised policy on discretionary fortification.

An additional IOM report, prepared by an expert panel, and published in 2003 (IOM 2003), provides guidance on the application of the DRIs in discretionary food fortification in the North American context. The report details 6 guiding principles (numbered 11-16) towards this application which were considered in developing the proposed policy. One principle[2] recommended that a documented public health need was required for discretionary fortification. In Canada there is a longstanding and widely endorsed policy that government intervene to protect the health of Canadians; as such, numerous mandatory fortification programs have been employed as warranted, to address demonstrated nutritional inadequacies. Discretionary fortification in the Canadian context is aimed to set controls and limits to protect the safety of Canadians against exposure to excessive vitamin and mineral nutrient intakes while allowing the food industry to offer more choices of fortified foods.

i) Application of the ULs

The DRI review process led to the replacement, over the period 1997 - 2004, of the Recommended Nutrient Intakes (RNIs) in Canada and the Recommended Dietary Allowances (RDAs) in the United States with a common set of reference values, the Dietary Reference Intakes (IOM 1997; 1998; 2000; 2002; 2003; 2004). The DRI review process evaluated data on the requirements to prevent nutrient deficiencies and maintain a defined level of nutrient stores. It also examined evidence relating nutrient intakes to the reduction in the risk of chronic diseases. The resulting reference values are the Estimated

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[2]**IOM Guiding Principle 11:** The scientific justification for discretionary fortification of food should be based on documented public health needs, particularly on dietary inadequacy that is determined by assessing the prevalence of nutrient inadequacy in the population.

Average Requirement (EAR)[3], the Recommended Dietary Allowance (RDA)[4], the Adequate Intake (AI)[5] and a new value, the Tolerable Upper Level of Intake (UL) (IOM, 1997). The UL is the highest average daily intake level that is likely to pose no risk of adverse health effect to almost all individuals in the general population. As intake above the UL increases, the risk of adverse effects increases.

Health Canada applied the UL to develop risk categories for nutrients, as detailed below, and to benchmark exposure to excessive intakes in the modelling scenarios.

ii) Development of Risk Categories

The IOM report advises the use of a 3-step process for using intake data together with the Tolerable Upper Intake Level (UL) in a careful modelling approach to explain how current exposure to the nutrient would be altered by discretionary fortification (**Guiding Principle 12**).

- The first step would be determination of dietary inadequacy. The advice is that if there is no inadequacy, then no discretionary fortification is justified.

- In the second step proposed by the IOM committee, if an inadequacy has been identified and a UL has not been set for the nutrient(s) involved because there are no reports of adverse effects, then discretionary fortification to address the inadequacy would be scientifically justified.

- For nutrients with a UL, or with no UL but concerns expressed about safety e.g. chromium, the third step is to model the impact of fortification of those nutrients for exposure analysis on the appropriate populations. Such analysis would consider the severity of the adverse effect (**Guiding Principle 15**) and whether the adverse effect is observed with intakes from foods, or supplements or all sources. If the evidence from the exposure analysis indicates that the fortification poses a

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[3]Estimated Average Requirement: the average daily nutrient intake level estimated to meet the requirements of half of the healthy individuals in a particular life stage and gender group.

[4]Recommended Dietary Allowance: the average daily dietary nutrients intake level sufficient to meet the nutrient requirements of nearly all (97 to 98 percent) healthy individuals in a particular life stage and gender group.

[5]Adequate Intake: the recommended average daily intake level based on observed of experimentally determined approximations of estimates of nutrient intake by a group of apparently healthy people that are assumed to be adequate-used when an RDA cannot be determined.

significant risk of adverse effects to at least one segment of the population, then discretionary fortification at the proposed level would not be justified.

IOM Guiding Principle 12:
In situations where discretionary fortification is scientifically justified, intake data should be used with the Tolerable Upper Intake Level (UL) to provide evidence, using a careful modelling approach, to explain how current exposure to the nutrient in question would be altered by discretionary fortification.

IOM Guiding Principle 15:
The severity of the adverse effect on which the Tolerable Upper Intake Level (UL) is based should be reviewed when considering discretionary fortification with a nutrient using the IOM's conceptual design approach.

Because Health Canada's approach to addressing dietary inadequacy is through other means (e.g. mandatory fortification) than discretionary fortification, Health Canada's alternative to the three step process, was to define risk categories, using the new DRIs and considering the margin between the highest adult RDA or AI and the UL for children, or the most exposed group. Health Canada also took into account the seriousness of the adverse effects due to excessive intakes, and whether the UL was set for total intakes or for supplements only.

iii) Modelling

Health Canada modelled how current intakes of nutrients would be affected by discretionary fortification. The intakes of Canadian adults and children provided the basis for such modelling. Key elements in the assessment were to assign nutrients to risk categories and to identify the levels of exposure to excessive intakes by the most vulnerable segments of the population (see Appendix B).

The IOM 2003 report confirmed the need for a modelling approach to explain how current exposure to the nutrient would be altered by discretionary fortification (Guiding Principle 12).

iv) Levels of Addition

As recommended in the IOM 2003 report, Health Canada proposes that the levels of addition permitted for discretionary fortification would result in a total nutrient content that would meet either 'good source' and 'excellent source' claims for the relevant nutrients according to their risk classification, based on the options analysis (see Appendix B), and the IOM 2003 advice articulated in Guiding Principle 13.

B. Proposed Policy

The *Codex General Principles for the Addition of Essential Nutrients to Foods* will continue to be retained as the reference. Nevertheless, the proposed conditions for discretionary fortification is a more modern approach which will protect Canadians from consuming excessive amounts of vitamins and minerals, and at the same time provide consumers with a choice of a variety of fortified foods.

Vitamin and mineral addition is permitted under the following broad categories

a) Vitamin and mineral addition is permitted to maintain and improve the nutritional quality of the food supply through (i) restoration and (ii) nutritional equivalence of substitute foods.

Restoration of vitamins and minerals lost during processing will be permitted if the amount originally present provided at least 5% of the Weighted Recommended Nutrient Intake (WRNI)[6] per reasonable daily intake of the food (RDI) (see Appendix H) or per reference amount where there is no reasonable daily intake. The amount added should compensate for the loss in processing.

Establishing the nutritional equivalence of substitute foods in terms of vitamin and mineral content, will be permitted provided that the traditional food provides at least 5% of the WRNI per reasonable daily intake (RDI) of the food. The amount added to the substitute food will be the amount required to bring the level of the nutrient to that in the food for which it is a substitute.

b) Food fortification programs will continue to be employed to correct and/or prevent nutritional problems of public health significance.

Health Canada continues to keep abreast of nutritional problems of public health significance. The Canadian Community Health Survey 2.2 (the Nutrition Focus Survey), a nationally representative survey on food consumption and other questions related to healthy living began in January 2004 and results will be available in 2005. These will provide food and nutrient intake data for a large number of Canadians including children. A second survey scheduled to go into the field in January 2006 (the Canadian Health Measures Survey) will look at a number of biochemical as well as physical measures of nutritional status. Based on new information that may emerge from these surveys and

[6] WRNIs became part of the Regulations in 1996. They were calculated by determining the proportion of the population made by each age/sex group using the census data of either 1986 or 1991 and multiplying these percentages by the respective 1990 Nutrition Recommendations. The results for each nutrient were summed to give the WRNI values.

other studies, the nutrients and/or levels permitted to be added to foods, as well as the foods that are used as vehicles for fortification may need revision in the future.

c) Discretionary fortification, the optional addition of any nutrient from a defined list of vitamins and minerals over defined ranges at the discretion of manufacturers, is expanded to allow for a wider range of fortified products which would provide for more food sources of nutrients without increased risk to health.

Analysis of a full range of options regarding eligibility of foods for discretionary fortification and various levels of addition indicates that permitting levels of discretionary fortification of all foods (excluding a defined list of standardized and staple foods, alcoholic beverages, fresh produce and fresh unprocessed meat, fish, poultry, eggs and pulses) without setting additional eligibility criteria satisfies more of the evaluation criteria than other options. The evaluation is presented in Appendix B. Limits are set based on placement of nutrients in risk categories, and on the levels that can be safely permitted within each risk category.

d) The category of special purpose foods is broadened to allow the formulation of a greater variety of products designed for people who may require them for nutritional purposes.

The increased flexibility in discretionary fortification proposed for (c) will allow a broader range of fortified products available to the general population. Policy recommendation (d) is intended for products fortified beyond that permitted under (c) and which are targeted towards specific groups and/or specific nutritional uses. Fortification of these products will require a nutritional rationale and appropriate labelling to ensure that the indications for appropriate and safe use can be given to consumers. Proposals for handling these issues are presented in the section on special purpose foods.

C. Implementation Plans

Because the major changes relate to discretionary fortification, and the special purpose foods category, these are presented first.

1. Discretionary Fortification

Introduction

For discretionary fortification, there are three main questions which need to be answered regarding implementation which, when addressed together, ensure that foods that are fortified under this global policy are safe. The first is which foods are eligible. The second is which vitamins and minerals may be added and the third is to what level may they be added.

Methodology

Proposed options for food eligibility for discretionary fortification were considered ranging from no exclusions, through exclusion of certain standardized and staple foods that are widely consumed, to exclusion of foods of low nutritional value and foods containing important amounts of constituents associated with risk to health, such as saturated and *trans* fats.

Three risk categories of nutrients were proposed. Assessing the safety of the options for discretionary fortification was done through the use of modelling scenarios of exposure of the Canadian population to nutrients in each of the risk categories, under the conditions tested (see Appendix B).

Under each scenario, all qualifying foods were fortified to bring nutrient content to the level evaluated per reference amount. In addition, to evaluate scenarios that more closely reflect actual market practices, a Monte Carlo simulation was subsequently applied. In this case, 33% of foods, chosen randomly from the qualifying foods were fortified, to reflect a mature market in which, according to available data, about one third of consumers indicated that they would buy a fortified product if there was a choice.

It should be noted that in the modelling, no allowance was made for overages of added nutrients. In practice, these overages range from 20 to 200% of the declared value depending on the stability of the nutrient.

Results and Conclusions

a) Which foods may be fortified?

All options for food eligibility have been evaluated assessing the advantages and disadvantages. The key issues of concern in developing the revised policy were safety and consumer protection; availability and choice; and trade and competitiveness.

As more eligibility criteria are applied to foods, consumer choice of fortified foods is limited, the potential for trade is curtailed and, regulatory burden increases. However the ability to manage risks of excessive and imbalanced intakes becomes easier, because fewer foods would be fortified.

The preferred option for implementing discretionary fortification based on the above-noted analysis, and detailed in Appendix B, is one that would see no food exclusions except for:

- a defined list of foods, primarily standardized foods that are pervasive in the food supply (flours, breads, pasta, rice, milk, butter, suet, lard, varietal cheeses, sugars and sugar syrups, maple syrup, honey, artificial sweeteners, salt, herbs, spices, dry seasonings, vinegar, flavouring preparations, leavening agents);
- alcoholic beverages;

- fresh produce, meats, fish, poultry, eggs, pulses, nuts, simulated and extended meat and poultry products, fresh brewed coffee and fresh brewed tea; and,
- infant foods, formulated liquid diets, meal replacements and nutritional supplements (which have defined levels of addition under separate regulations).

The standardized and staple foods listed above are so pervasive in the food supply, that if fortified at the discretion of manufacturers, there is no safe level of addition that could be permitted for many nutrients. Some of the above standardized foods are already fortified under other regulatory provisions.

b) Which nutrients may be added?

The nutrient Risk Categories are being proposed on the basis of exposure considerations under mature market scenarios and take into account the advice of the IOM. The latter includes using the information provided during the development of the ULs for each nutrient, applying the DRIs in dietary assessment (IOM, 2000), as well as the IOM guidance regarding the application of the DRIs to discretionary fortification (IOM, 2003).

The vitamins and minerals which may be added (or excluded) under discretionary fortification have been categorized as follows:

Risk Category A nutrients: Those nutrients for which no UL was set because of no reports of adverse effects, and no concern expressed; and those nutrients for which a UL was set but with a wide margin of safe intake; and those nutrients with a narrow margin of safety, but non-serious critical adverse effects: thiamin, riboflavin, pantothenate, biotin, vitamin B_{12}, β-carotene, vitamin C, vitamin B_6, vitamin E, niacin.

Risk Category B nutrients: Those nutrients with serious adverse effects, but with low risk of excessive intake at the proposed level of addition for discretionary fortification: calcium, folic acid, magnesium, vitamin D, potassium.

Risk Category C nutrients (to be excluded from discretionary fortification): Those nutrients with a narrow margin of safety, and with serious adverse effects, and /or with current levels of exposure to intakes above the UL by vulnerable subgroups: vitamin A as retinol, zinc, iron, copper, selenium, manganese, iodine, fluoride.

Nutrients in this category are currently permitted or required to be added to a range of foods for either purposes of restoration, mandatory fortification, nutritional equivalence of substitute foods or to make a special purpose food such as a meal replacement. New or further additions for these purposes would continue to be subject to the applicable regulatory requirements.

Other nutrients for which a risk category has not been assigned include choline, chromium, molybdenum, phosphorus, vitamin K. These nutrients are proposed to be excluded from discretionary fortification for a variety of reasons (see Appendix B).

c) Levels of Addition

Note: The statistical modelling and the levels of addition were determined using the new Dietary Reference Intakes as described in Appendix B. However, the final levels are expressed in terms of the current labelling reference value in Canada, the Recommended Daily Intake, expressed on the label as Daily Value. Until the common set of labelling reference values are developed for use in both Canada and the U. S., the reference standard for discretionary fortification is the Recommended Daily Intakes set out in Table 1 to Divisions 1 and 2 of Part D of the *Food and Drug Regulations*.

Levels of addition for discretionary fortification are shown in Appendix C. If a nutrient is added, the minimum level of total nutrient (naturally occurring and added) in the food must be 5% of the Daily Value per reference amount of the food (i.e. the food will qualify for a "source" claim). Nutrients in Risk Category A may be added such that the total amount of the nutrient (naturally occurring and added) in the food is up to 20% of the Daily Value per reference amount of the food. If the food contains 20% of the Daily Value the food will qualify for an "excellent source" claim. For Risk Category B nutrients, the total amount of the nutrient (naturally occurring and added) permitted in the food after addition is up to 10% of the Daily Value per reference amount of the food. If the food contains 10% of the Daily Value the food will qualify for a "good source" claim.

For those vitamins and minerals which have been added, the total amounts of those vitamins and minerals in the food must be declared in the Nutrition Facts table as part of the mandatory nutrition labelling requirements. In addition, foods with added vitamins and mineral nutrients will be required to indicate on the principle display panel that the food contains an added vitamin(s) or mineral(s).

d) Reference Values for Discretionary

A reference value or reference standard is required for describing the levels of nutrients permitted for discretionary fortification. The new DRIs and the IOM guiding principles regarding nutrition labelling are an important first step in a process aimed at developing a common set of reference values for nutrition labelling for both Canada and the U. S. Until the common set of reference values are developed, the reference standard for discretionary fortification is the Recommended Daily Intakes set out in Table 1 to Divisions 1 and 2 of Part D of the *Food and Drug Regulations*. These tables were updated in 2002 and are primarily based on the highest RNIs for adults excluding pregnancy and lactation contained in the *1983 Recommended Nutrient Intakes for Canadians.*

e) Nutrient Content Claims

Nutrient content claims with respect to vitamins and minerals are regulated in Part D of the *Food and Drug Regulations*. Sections D.01.004 and D.02 .002 prohibit any statements or claims for a vitamin or mineral other than a statement of quantity unless the food contains at least 5% of the Daily Value (Recommended Daily Intake) in serving of stated size.

The Canadian Food Inspection Agency (CFIA) has criteria for specific claims in the Guide to Food Labelling and Advertising. The claims are as follows: "source": 5% RDI; "good source": ≥15% RDI except ≥30% for vitamin C; "excellent source": ≥25% RDI, except ≥50% for vitamin C.

In view of the proposed levels of vitamin and mineral nutrient additions it is appropriate to revise the nutrient content claims and that these be the subject of regulations under the *Food and Drug Regulations* as follows:

Claim	**% Daily Value***
Source	5
Good Source	10
Excellent Source	20

*per reference amount and serving of stated size.

2. Special Purpose Foods

a) What is a special purpose food?

The Codex definition of special purpose foods is retained: i.e., " foods that have been designed to perform a specific function, such as to replace a meal which necessitates a content of essential nutrients which cannot be achieved except by the addition of one or more of these nutrients. These foods include but are not limited to foods for special dietary use." The *Codex General Principles for the Addition of Essential Nutrients to Foods* state that "Nutrients may be added to special purpose foods, including foods for special dietary uses, to ensure an appropriate and adequate nutrient content. Where appropriate, such addition should be made with due regard to the nutrient density[7] of such foods."

Special purpose foods currently encompass a wide range of products including foods for special dietary uses. These latter are defined in Section B.24.001 of the *Food and Drug Regulations* as follows:

"food for special dietary use" means food that has been specially processed or formulated to meet the particular requirements of a person:

i) in whom a physical or physiological condition exists as a result of a disease, disorder or injury; or

[7]Nutrient density means the amount of nutrients (in metric units) per stated unit of energy (MJ or kcal).

ii) for whom a particular effect, including but not limited to weight loss, is to be obtained by a controlled intake of foods;

Examples of foods for special dietary uses include:

- formulated liquid diets[8] (B.24.102)
- meal replacements[9] (B.24.200)
- nutritional supplements[10] (B.24.201)
- gluten-free foods (B.24.018)
- sodium-reduced foods for sodium-restricted diets (B.24.008)

The current regulations contain detailed nutrient compositional requirements for formulated liquid diets, meal replacements and nutritional supplements.

b) Revisions to current regulations pertaining to special purpose foods

Reference value for compositional requirements for special purpose foods.

The new DRIs will be applied to establish the nutrient compositional requirements for special purpose foods, since one purpose for updating the compositional requirements is to reflect the new nutrient recommendations. The meal replacements and nutritional supplements are formulated based on a defined nutrient contribution to the total daily intake, for example to provide 25% of the recommended daily intake in a serving of the food. The new RDA/AIs are the appropriate reference values for developing such products for targeted individuals. This approach was used in the current regulations for meal replacements and nutritional supplements promulgated in 1995. The nutrient composition was based on the 1990 Nutrition Recommendations and the 1990 Recommended Nutrient Intakes (RNIs).

i) Meal replacements

The current regulatory requirements for meal replacements were established for products which were primarily intended to be used in weight reduction diets. It is for this reason that the minimum energy requirement for meal replacements was set at 225 kcal per serving and nutrient levels providing approximately 25% to 50% (including overages) of the RNI so that four servings (900 kcal) could provide from 100% to as much as 200% of the recommended nutrient intake.

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[8]"formulated liquid diet" means a food that (a) is sold for consumption in liquid form, and (b) is sold or represented as a nutritionally complete diet for oral or tube feeding of a person described in paragraph (a) of the definition "food for special dietary use";

[9]"meal replacement" means a formulated food that, by itself, can replace one or more daily meals;

[10]"nutritional supplement" means a food sold or represented as a supplement to a diet that may be inadequate in energy and essential nutrients";

The current Regulations do not impose a maximum energy value on meal replacements thus there is flexibility for the formulation of meal replacements with varying nutrient to energy density. This allows meal replacements to be targeted for different purposes such as weight reduction or for specific population subgroups, such as individuals with low energy requirements.

There is concern, however, that the nutrient density of meal replacements as currently regulated and targeted to individuals with average or high energy requirements is too high. Consumption of several meal replacements to achieve a energy intake of 1800 kcal could provide 400% of the recommended nutrient intake. For some nutrients, this would result in intakes over the UL. It is therefore proposed that the Regulations for meal replacements would allow for two categories as follows:

a) meal replacements with the current minimum of 225 kcal per serving targeted by appropriate indications on the label to individuals on weight loss diets or to those with limited energy intakes for other reasons, e.g. age, infirmity, or disease as described in paragraph (a) of the definition for food for special dietary use.

   Consistent with their role as meal replacements, it is proposed that nutrient content be based on a daily intake of 900 kcal; the minimum protein level will be retained at 20% of energy and the upper level will be set at 35% of energy consistent with the IOM Acceptable Macronutrient Distribution Range (AMDR); the total fat will be retained at a maximum of 35% of energy; linoleic acid at a minimum of 3% of energy, α-linolenic acid at a minimum of 0.5% of energy and the ratio of linoleic to α-linolenic between 4:1 to 10:1; and vitamins and minerals at 25% of the adult male RDA/AI per 225 kcal (see Appendix D).

b) meal replacements with a minimum of 350 kcal per serving targeted by appropriate indications on the label to individuals with average or higher energy requirements (2000+ kcal).

   It is proposed that the nutrient content be based on a daily minimum of 2000 kcal; the protein level be set at 10-35% of energy consistent with the IOM AMDR for protein; the total fat will be retained at a maximum of 35% of energy; linoleic acid at a minimum of 3% of energy and α-linolenic acid at a minimum of 0.5% of energy and the ratio of linoleic to α-linolenic between 4:1 to 10:1; and vitamins and minerals at 12.5% of the adult male RDA/AI per 225 kcal (see Appendix D).

It is proposed that Section B.01.053 which sets minimum levels for protein, 5 vitamins and one mineral for a food represented as an instant or ready breakfast be revoked because these nutritional requirements are inadequate for a meal replacement.

ii) Prepackaged meals

The *Food and Drug Regulations* define a "prepackaged meal" (B.01.001) as "a prepackaged selection of foods for one individual that requires no preparation other than heating and that contains at least one serving, as described in *Canada's Food Guide to Healthy Eating*, of a) meat, fish, poultry, legumes, nuts, seeds, eggs or milk or milk products other than butter, cream, sour cream, ice-cream, ice milk and sherbet, and b) vegetables, fruit or grain products". There are no nutrient compositional requirements set out in the Regulations for prepackaged meals. Specific labelling requirements exist for prepackaged meals that are represented for use in a weight reduction diet.

Interest has been expressed in the fortification of prepackaged meals to ensure that these provide, in a serving, nutrients balanced to their energy value, when such prepackaged meals are represented for the use by a particular population subgroup. This is particularly important for subgroups of the population who may rely on these types of products to provide a major portion of their daily energy and nutrient intake. Examples of such groups include the elderly or others living alone who find prepackaged meals to be convenient and easy to use and organoleptically more acceptable than meal replacements.

It is proposed to make provision in the Regulations for the addition of vitamins and mineral nutrients to prepackaged meals that are positioned as special purpose foods, i.e. targeted to specific groups and appropriately labelled. It is proposed that the nutrient compositional requirements of the meal replacements apply to these foods.

As for meal replacements, it is proposed to require that prepackaged meals targeted by appropriate indications on the label to individuals with low energy requirements provide a minimum of 225 kcal per serving with a serving providing 25% of the adult male RDA/AI (Appendix D). It is proposed that protein level for prepackaged meals intended for individuals with low energy requirements be set at 20% to 35% of energy; the total fat at a maximum of 35% of energy; linoleic acid at a minimum of 3% of energy and α-linolenic acid at a minimum of 0.5% of energy.

Prepackaged meals targeted by appropriate indications on the label to individuals with higher energy intakes would be required to provide a minimum of 350 kcal per serving. A serving would be required to provide 25% of the adult male RDA/AI; 10%-35% of energy from protein; total fat at a maximum of 35% of energy; linoleic acid at a minimum of 3% of energy and α-linolenic acid at a minimum of 0.5% of energy.

iii) Nutritional supplements

Nutritional supplements are defined by the Food and Drug Regulations as products that are a supplement to a diet that may be inadequate in energy and essential nutrients. The energy value of a "nutritional supplement", as provided by protein, fat and carbohydrates, differentiates these foods from vitamin/mineral supplements which provide virtually no energy.

The current regulatory nutrient requirements for nutritional supplements are expressed on an energy basis. The range between the minimum and maximum levels for vitamins and minerals provided for nutritional supplements was intended to allow flexibility in the formulation of products targeted for different needs.

Vitamin and mineral nutrient specifications for nutritional supplements were based on the 1990 Nutrition Recommendations and provide one third to one half of the recommended nutrient intake in 150 kcalories. These supplements were originally intended to be consumed once per day to supplement an inadequate diet. In practice, however, there is a wide variety of nutritional supplements on the markets targeted as snacks, supplements for athletes and supplements for active living. Multiple servings may be consumed in a day. Because the regulations require a high nutrient density, this may result in intakes over the UL from these foods alone.

It is proposed that the regulations for nutritional supplements be amended to bring them in line with the new RDAs/AIs. In addition, in view of the ULs established by the IOM, and, particularly, since in the case of a number of nutrients there is overlap between the RDAs/AIs for some age groups and the ULs for others, e.g. children, for some micronutrients, it is proposed to amend the Regulations for nutritional supplements as indicated below (and tabled in Appendix E).

It is proposed that:

- Specific labelling regarding indications for use and targeting be required for informed and appropriate safe use of the special purpose food.

- Specific vitamin and mineral levels would be established for nutritional supplements targeted to different population subgroups (see Appendix E). The DRI report of 2002 provided estimated energy requirements (EERs) for the various age and sex groups; the RDAs/AIs for the respective age and sex groups were considered in establishing the proposed vitamin and mineral levels which are expressed per 100 kcal.

- The minimum energy requirement for nutritional supplements would be decreased from 150 kcal per serving to 100 kcal per serving for products targeted to children.

- The current requirements for protein, fat and fatty acids remain unchanged.

- All 8 B vitamins be required; the remaining micronutrients would be optional: i.e., vitamins A, D, C, E and calcium, phosphorus, iron, iodide, copper, zinc, manganese, selenium, chromium and molybdenum.

- Non-targeted nutritional supplements would provide vitamins and minerals in relation to energy based on the recently established RDAs/AIs for adult males aged 19-30, except for calcium which is based on RDA/AI for males aged 14-18 years. Non-targeted nutritional supplements would provide the RDAs/AIs for micronutrients in 1500 kcal; the regulatory requirements for vitamin and minerals for non-targeted nutritional supplements would be expressed on a per 100 kcal basis (Appendix E-Adults, adolescents and children). Nutritional supplements formulated to these requirements would also be appropriate for supplements targeted to active individuals/athletes.

- Nutritional supplements targeted to young children (1 to 3 years of age) would provide levels of vitamins and minerals based on an intake of 1000 kcal providing the IOM RDA/AI for this age group and expressed on a per 100 kcal basis (Appendix E-Toddlers).

- Nutritional supplements targeted to women of childbearing years would be required to provide iron, folate, calcium and vitamin D, in addition to nutrients required for energy utilization, the B vitamins, at minimum levels consistent with the new IOM RDAs/AIs; levels are established based on 1) 900 kcal providing the RDA/AI for women 19-30 years for those on energy restricted diets and requiring a higher nutrient density (Appendix E-Women of child bearing years on energy restricted diet) ; 2) 1500 kcal providing the RDA/AI for women 19-30 years (Appendix E-Women of child bearing years); and would be expressed on the basis of 100 kcal. Provision is made for additional formulations for nutritional supplements containing higher levels of calcium, vitamin D, folic acid, vitamin B_{12} and iron (see Appendix E).

- Nutritional supplements targeted to adults over 50 would provide levels of vitamins D, B_6 and B_{12} and of iron, and nutrients required for energy utilization, consistent with the IOM RDAs/AIs for men aged 51-70 years, except for vitamin D which is based on the AI for adults over 70 years (Appendix E-Older adults).

c) ***For special purpose foods not included in the provisions above***

Requests for regulatory amendments to make provision for special purpose foods that are not in the provisions above must be accompanied by information to support the nutritional composition of special purpose food. A rationale for the nutrient additions would be required in the case of these foods. Information supporting the rationale for targeting a special purpose food to a specific group would include:

i) evidence that the nutrition needs for the target group(s) are different from the general population, how and to what extent; this may require demonstration of inadequate intake or evidence of increased requirements. Intake data and /or requirement data for the target group would provide the necessary evidence for nutrition needs;

ii) evidence supporting that the proposed levels of fortification contribute to meeting the identified needs. Modelling data to show how the product, when used as intended, contributes to intakes in the context of the total diet would be appropriate evidence; and

iii) evidence that the proposed levels of fortification are safe and do not exceed the UL in the context of the total diet for the target group. This condition is an extension of the item b) above in which upper levels of the intake distribution would be identified.

iv) specific labelling regarding indications for use and targeting for informed and appropriate use of the special purpose food.

3. Substitute Foods

The following are modifications to the current Regulations.

i) Fruit Flavoured Drinks

Sections B.11.150 and B.11.151 currently permit the addition of vitamin C, thiamine, folic acid iron and potassium to drinks that are sold as a substitute for a fruit juice or as a breakfast drink provided that they are not carbonated or represented or commonly known as a soft drink or thirst-quenching or refreshment drink. The nutrient levels were based on those contained by apple juice and orange juice.

It is proposed that Sections B.11.150 and B.11.151 be revoked, however, that provision be made for the addition of vitamin C to fruit-flavoured drinks to provide a minimum of 60 mg per reference amount and a maximum level of 130 mg per reference amount (the level present in raw orange juice). In addition, these fruit drinks would be eligible for discretionary fortification with the B vitamins, vitamin D, vitamin E, beta-carotene, calcium, magnesium and potassium.

ii) Simulated meat products

The current requirements for addition of vitamin and minerals nutrients for simulated meat products are set out in the Table to Division 14. These requirements are proportional to protein content of the product, i.e. the amount of vitamin and mineral nutrients per gram of protein. As the protein content increases, the levels of vitamins and minerals increase. Minimum protein levels are set for various simulated meat products in Sections B.14.085 - 14.090 and range from 9 to 25%. The higher protein content of some simulated meat products results in vitamin and mineral levels including potassium that are higher than in the corresponding meat product. In the case of potassium, this results in unacceptable texture and flavour.

It is proposed that Division 14 be amended to require that the amount of potassium contained by a simulated meat product be 20.0 mg potassium per gram of protein up to the amount corresponding to the minimum amount of protein for that simulated meat product, with no further addition of potassium required for products containing more than

the minimum amount of protein. This proposal is consistent with the *Codex Alimentarius General Principles for the Addition of Essential Nutrients to Foods*.

The following items are products that were allowed for sale under an Interim Marketing Authorization (IMA) and which we propose to incorporate as new regulations.

iii) Plant-based beverages

An IMA was issued on November 20, 1997 to authorize the sale of soy and other plant-based beverages as an alternative to milk. (Appendix F). This IMA sets out the requirements for manufacturers who want to voluntarily fortify their products. If fortified, these beverages must contain specified amounts of calcium, zinc, vitamins A, D, B_{12}, and riboflavin. As well, one or more of the following nutrients are permitted at defined levels: vitamin B_6, vitamin C, thiamin, niacin, folacin, pantothenic acid, phosphorus, potassium, and magnesium. Such beverages must contain not less than 2.5 g protein of a nutritional quality equivalent to not less than 75% casein per 100mL; 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, as indicated in the IMA.

iv) Vegetable- based or vegetable- and milk-protein based product which resemble cheese

An IMA was issued on March 29, 2001 to authorize the 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 (Appendix G). This IMA sets out the requirements for manufacturers who want to voluntarily fortify their products. If fortified, these products must contain vitamin A, vitamin B12, riboflavin, niacin, calcium, phosphorus, magnesium and zinc in the amounts listed in Appendix G. Other requirements regarding protein quality and content, fat and sodium content are detailed in Appendix G. The amendment resulting from this IMA is consistent with the *Codex Alimentarius General Principles for the Addition of Essential Nutrients to Foods*.

4. Restoration of nutrients

Current regulatory provisions for the restoration of vitamins and minerals in specific foods will be retained, e. g. corn meal. It is proposed that a general provision would allow restoration of vitamins and minerals lost in processing, storage and handling if the amount originally present provided at least 5% of the Weighted Recommended Nutrient Intake of the nutrient in a reasonable daily intake of the food or the reference amount where there is no reasonable daily intake. The amount of vitamins and minerals added should compensate for that lost due to processing, storage and handling. It is proposed that Schedule K to the *Food and Drug Regulations* will be revised to eliminate duplication with the reference amounts (in Schedule M) where the reasonable daily intake is the same (see Appendix H).

5. Specific Cases

The following foods may be fortified to achieve one or more objectives of this proposed policy.

i) Breakfast Cereals

It is proposed that Section B.13.060 of the Food and Drug Regulations be amended to provide for the addition to breakfast cereals of more vitamin and mineral nutrients and at higher levels. The proposals for breakfast cereals listed below are based in part on an effort to allow greater trade harmonization in this product category while ensuring safety. The proposals also recognize the traditional role of breakfast cereals as a significant source of nutrients in the Canadian diet which has long been recognized through regulations specific to this product category (B.13.060).

In assessing breakfast cereals, the following nutrients were modelled: calcium, folic acid, zinc, retinol, iron. For further details see Appendix B. The risk assessment indicated that the levels proposed below would result in minimal exposure of the population to intakes over the UL. In the case of folic acid, to mitigate any risk of masking vitamin B_{12} deficiency, any breakfast cereal fortified at 200 µg folic acid, which may result in a small percent of children and adults with intakes over the UL, will be required to be fortified with vitamin B_{12} at 2.4 µg. In the case of zinc, about 12% of Canadian boys aged 6-8 years, the youngest age group for which data are available, have intakes over the UL, but do not approach the level at which copper-deficiency anemia was seen in infants.

Nutrient	Minimum per reference amount	Maximum per reference amount
Vitamin A/retinol (µg)	50	155
Vitamin D (µg)	0.25	1.0
Vitamin C (mg)	3	6
Thiamin (mg)	0.6	0.6
Riboflavin (mg)	0.08	0.4
Niacin (mg)	1.4	5
Vitamin B_6 (mg)	0.2	0.5
Folate µg	20	200 *
Vitamin B_{12} (µg)	0.4	2.4 (*2.4 is required if folic acid is 200)
Calcium (mg)	55	110
Phosphorus (mg)	55	200
Magnesium (mg)	50	60
Iron (mg)	4	9
Zinc (mg)	1.0	1.5

ii) Enriched rice

The enrichment of rice recognizes its importance as a staple food by many Canadians. Several nutrients are lost in milling, and at the present time in Canada, if pre-cooked rice is represented as enriched, it must contain added thiamin, niacin and iron; the addition of vitamin B_6, folic acid and pantothenic acid is optional. In the United States, thiamin, riboflavin, niacin, folic acid and iron must be added to enriched rice; the addition of calcium and vitamin D is optional. In line with the Canadian policy to harmonize the mandatory nutrients in enriched grains, it is proposed to expand the ranges of the permitted nutrient levels (see Appendix I), and to make provision for the addition of calcium. The enrichment of rice with calcium is consistent with the permitted fortification of flour with calcium in Canada. The maximum levels for nutrients in the U.S. standard are twice the minimum to allow for variability in the enrichment process, and it is proposed that these ranges be adopted.

iii) Enriched corn meal

The enrichment of corn meal with certain vitamins and minerals at levels harmonized with those in the U. S. has been permitted since 1997 under an IMA). The Regulations

will be amended in accordance with the IMA and as seen in Appendix J. It is further proposed that corn meal may not be presented as "enriched" unless it contains added thiamin, riboflavin, niacin, folic acid and iron.

iv) Processed cheese products and cottage cheese
Provision will be made to permit the addition of calcium to processed cheese products to a level of 30 mg calcium per g protein; this ratio is within the range found in varietal cheeses. Provision will also be made for cottage cheese permitting calcium addition up to the level of 300 mg per reference amount (Schedule M to the *Food and Drug Regulations*), equivalent to the amount of calcium in the reference amount of milk.

6. Milks

Vitamin D is a mandatory ingredient in all standardized milks. It is added to provide 300- 400 IU (7.5 - 10 µg) in a reasonable daily intake of 852 mL or 35 - 47 IU (0.9 - 1.2 µg) per 100 mL. Canada's Food Guide to Healthy Eating recommends children consume 2 - 3 servings of milk products daily. A Food Guide serving of milk is 250 mL. It is proposed that the reasonable daily intake for milk be changed to 750 mL (Schedule K, Appendix H) and the levels of vitamin D be changed to 1.0 - 1.3 µg (40 IU - 53 IU) per 100 mL It is proposed that the level of vitamin D in goat's milk also be increased to 1.0 - 1.3 µg per 100 mL.

The levels of vitamin A and folic acid (amounts per 100 mL), where added, will not be affected by the change in the reasonable daily intake.

7. Schedule K to the *Food and Drug Regulations*

Proposed Revisions to Schedule K (see Appendix H)

Schedule K to the *Food and Drug Regulations* lists the reasonable daily intake (RDI) of a variety of foods. RDIs have been used:

- to determine the nutritional contribution/significance of a food for purposes of restoration of vitamin and mineral losses due to processing, packaging or storage, or for purposes of determining the need to add nutrients to a substitute food.

- as the basis for protein claims

- as the basis for determining the significant nutrients in a novel food.

As in the past, it is proposed that for restoration of processing losses, the original unprocessed food must contain at least 5% of the Weighted Recommended Nutrient Intake per reasonable daily intake of the food as set out in Schedule K. Where there is no reasonable daily intake then the reference amount (Schedule M of the *Food and Drug Regulations*) will apply. The

vitamin(s) and mineral(s) which have been lost due to processing may be added to the level in the original unprocessed food. Similarly, where consideration is being given to the addition of vitamins and mineral nutrients to substitute foods, the original food must contain at least 5% of the Weighted Recommended Nutrient Intake per reasonable daily intake of the food or per reference amount where there is no reasonable daily intake listed. The vitamin(s) and mineral(s) which may be added to the substitute food must be added to the level in the food for which it is substituting.

Schedule M to the *Food and Drug Regulations* contains reference amounts for foods which were derived from the average quantities of foods consumed at a single eating occasion. It is proposed that Schedule K be amended to include only those foods which are likely to be consumed more than once per day, for example, bread. The reference amount for bread is 50 g (estimated as one to two slices). The reasonable daily intake is 150 g which is about 3 to 5 slices. In the case of fruits and vegetables, these are consumed several times per day but it is unlikely that the same fruit or vegetable is consumed more frequently than once per day.

With the proposed revisions to Schedule K, nutrient content claims for protein (in the table following Section B.01.513, items 8-10 of the Regulations) will continue to be based on the reasonable daily intake, or where there is no reasonable daily intake listed, on the reference amount in Schedule M.

8. Requirements for Analytical Testing and Record Keeping

The addition of vitamins and mineral nutrients to foods must be carefully controlled, because vitamins and minerals are biologically active compounds that are required in small amounts, and are added to foods in very small quantities. In addition to the control of the amounts added, the vitamins and minerals must be uniformly dispersed throughout the food. Vitamins are also unstable and are subject to destruction by heat, oxidation, light, etc. Reasonable overages[11] of vitamins and mineral, within the limits of good manufacturing practice, must be present to ensure that the required levels of the vitamins and minerals are maintained throughout the shelf-life of the food under customary conditions of distribution and storage. Since excessive overages could lead to inadvertent excesses, overages for most minerals need only be sufficient to compensate for variations in dispersion.

Since vitamins and minerals are usually sold as premixes, these should come with certificates of analysis, and if stored, should be re-analysed at intervals to verify their potency.

[11] "Overage" means the amount of a vitamin and mineral nutrient that is, within the limits of good manufacturing practice, added to a food in excess of the amount declared on the label, in order to ensure that the amount of the vitamin or mineral nutrients declared on the label is maintained throughout the durable life of the food (Division 1 to Part B).

It is proposed that manufacturers will be required to establish procedures for verifying the content of the vitamins and mineral nutrients in the final product. To accomplish this, it is proposed that the manufacturer be required to conduct tests to determine:

i) the uniformity of distribution of the vitamin or mineral in the food;
ii) the stability of the vitamin or mineral in the food;
iii) the minimum amount of overage required to maintain the level of the vitamin or mineral in the food throughout its shelf-life ;
iv) for foods with a durable life of more than 90 days, the date after which the manufacturer does not recommend that the food be consumed because the declared levels of vitamins and minerals may no longer be present. This date must be shown on the label.

Manufacturers and importers would be required to keep records of the tests.

9. Regulated List of Vitamin Compounds and Mineral Salts

To ensure that the source of vitamins and minerals added to foods meet appropriate specifications for identity and purity of vitamins and minerals, a proposed list of permitted vitamin compounds and mineral salts is presented in Appendix K. A vitamin compound or mineral salt must comply with specifications in a relevant monograph in:

the fifth edition of the *Food Chemicals Codex* published by the National Academy of Sciences and the National Research Council of the United States of America in Washington, D. C. (2003) including supplements; or

If not in the *Food Chemical Codex*, then in the Food and Nutrition Paper 52 Compendium of Food Additive Specifications Volumes 1 and 2, as amended from time to time, published by the Food and Agriculture Organization of the United Nations in Rome (1992); or

If there is no monograph applying to a substance under 9. a) and 9. b), the substance must comply with a relevant monograph published in one of the following secondary sources:

i) *British Pharmacopoeia*, 2003. The Stationery Office, Norwich; or
ii) *The United States Pharmacopeia*, 27th Revision and *The National Formulary*, 22nd Edition. Official from January 1, 2004. United States Pharmocopeial Convention Inc. Rockville Md. (2004); or
iii) *The Pharmaceutical Codex*, 12th Edition, Council of the Pharmaceutical Society of Great Britain. The Pharmaceutical Press, London (1994); or
iv) *Martindale The Extra Pharmacopoeia*, 31st Edition, JEF Reynolds (Ed) The Royal Pharmaceutical Society of Great Britain. London (1996); or

v) *European Pharmacopoeia* 4th Edition, Council of Europe, Strasbourg Cedex, France (2001) and supplements; or

vi) *The International Pharmacopoeia* 3rd Edition, Volumes 1, 2, 3, 4, and 5. World Health Organization, Geneva (2003).

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Appendix A: Milestones in the Review Process (1998-2005)

January 1998	Launch of review of Health Canada's policies on the addition of vitamins and minerals to foods and establishment of External Advisory Panel.
March 1998	Consultation on issues, guiding principles.
November 1998	Consultation workshop to evaluate potential food fortification approaches.
October 1999	Publication of Health Canada's policy recommendations for comment to December 1999.
July 2000	Publication of stakeholders comments on the policy recommendations.
October-November 2002	Consultation with stakeholders on proposed policy and implementation plans.
January 2003	Publication of report of November 2002 workshop.
May 2003	Publication of summary report of public consultation on proposed policy and implementation plans of October 2002 - January 2003.
June 2003	Consultation workshop with stakeholders on food vehicles for discretionary fortification
July 2003	Publication of summary report of stakeholder consultation held June 23, 2003.
Fall 2004	Publication of final policy and implementation plans.
2005	Publication of proposed regulations in *Canada Gazette* Part I.
2005	Publication of final regulations in *Canada Gazette* Part II.

Appendix B - Options Analysis

Introduction

For discretionary fortification, there are three main questions which need to be answered regarding implementation. The first is which foods are eligible. The second is which vitamins and minerals may be added and the third is to what level may they be added.

The options for eligible foods range from no exclusions, through exclusion of certain standardized and staple foods that are widely consumed, to exclusion of foods which contain important amounts of constituents associated with risk to health, such as saturated and *trans* fats. These options (see Table One) have been evaluated on the basis of criteria reflecting the key issues of concern identified by the External Advisory Panel and stakeholders during the earliest phase of the policy review:

a) consumer protection;
b) availability and choice / innovation;
c) trade and competitiveness.

Furthermore, the implications of each option based on stakeholder comments have been considered in terms of education / information / risk communication; monitoring; regulations and enforcement.

Table One: Options for Eligibility Criteria for foods which may be fortified at the discretion of manufacturers

Option 1	a)	No exclusions other than the foods from the general exclusions list
	b)	Mature market scenarios-no exclusions other than the general exclusions, except milk and margarine; assumptions made that only certain product categories would be fortified (eg. breakfast cereals, instant breakfast powders, 'bars' (cereal bars, sports bars, including confectionery), beverages including milk, fruit and vegetable juices and drinks, carbonated beverages and water, soy beverages and products, ketchup, wieners and processed meats, frozen dinners. Snack foods such as potato chips were also included. One third of choices were assumed to be fortified.
Option 2		In addition to foods from the general exclusion list, excludes foods with components associated with risk to health, i. e. those with: ▸ saturated and *trans* fat >2 g combined and the food provides >15% energy from the sum of saturated and *trans* fatty acids; ▸ sodium >480 mg (per reference amount or serving of stated size or per 100 g if the food is a prepackaged meal); or ▸ alcohol >0.5%

Option 3	In addition to foods from the general exclusion list, excludes foods with components associated with risk to health and foods of low nutritional value, i. e. those with: ▸ saturated and *trans* fat >2 g combined and the food provides >15% energy from the sum of saturated and *trans* fatty acids; ▸ sodium >480 mg (per reference amount or serving of stated size or per 100 g if the food is a prepackaged meal; ▸ alcohol >0.5% ▸ <10% Weighted Recommended Nutrient Intake (WRNI) for any nutrient
Option 4	No exclusion other than the foods from the general exclusion list. Defined voluntary fortification, for specifically defined food product categories, with specified levels of addition for each product category, e.g. beverages, breakfast cereals.

Methods:

A. The Issues and Decision-Making Criteria

The key issues of concern in developing the revised policy were population health; consumer protection; safety and effectiveness; availability and choice; trade and competitiveness. These were identified during stakeholder consultations in the earliest phase of the policy review. These were developed into decision-making criteria to evaluate the policy options proposed in 1999. These criteria have been retained and further elaborated in the present evaluation of discretionary fortification, and are described as follows.

1. Consumer protection

This criterion is a measure of the extent to which the options are consistent with Health Canada's primary role in protecting the health and safety of Canadians. This criterion addresses the impact of ad libitum consumption of foods, if fortified at the discretion of manufacturers, on risk of excessive or imbalanced intake. Further, this criterion addresses the issue of potential promotion of foods containing constituents well recognised as increasing risk to health, on the basis that they are fortified.

For discretionary fortification, the potential for health benefit for individuals exists, if the individual with an inadequate intake chooses a food fortified with the nutrient lacking in his or her diet. However, benefit on a population basis cannot be addressed, nor can it be statistically modelled, because it is not known who will select a fortified product, given the choice, or his or her nutritional status. In general, the Canadian population has a low prevalence of inadequacy for most nutrients, except for magnesium, and for adults, vitamin C, and for older adults vitamin B_{12} and vitamin B_6. Some groups also have

median intakes of calcium below the Adequate Intake suggesting some potential for inadequacy. Thus it is expected that on a population-wide basis, benefit from discretionary fortification would be quite low. Therefore the issue of discretionary fortification is not one of establishing benefit, but one of managing risks, primarily risk of excessive intake.

1.1 Safety Assessment of Discretionary Fortification Options

1.1.1 Risk Assessment Methodology

1.1.1.1 Risk Categorization of Nutrients

The safety assessment of the options for discretionary fortification is assisted in part through the use of the risk categories of nutrients, which were proposed by the Food Directorate, using the new DRIs. The categorization was based on the margin between the highest adult RDA or AI and the UL for children or the most exposed group. It also took into account the seriousness of the adverse effects due to excessive intakes, and whether the UL was set for total intakes or for supplements only. The highest adult RDA was selected as the lower boundary because of the practice in the U. S. of fortifying foods to a per cent of the Daily Value which is based on the highest adult RDA. Thus a food that is fortified to 100 % of the RDA for certain nutrients (e.g. zinc, folic acid , retinol-vitamin A, niacin) would provide an intake over the UL to a child in a single serving of the food. Three risk categories of nutrients were proposed and discussed with stakeholders in November 2002.

The Risk Categories below were used between 2002 and 2003 for statistical modelling and consultation purposes. The response to the initial categorization, together with the modelling, helped in the development of the final risk categories which are presented in Health Canada's Proposed Policy and Proposed Implementation, p 6.

Risk Category A: thiamin, riboflavin, vitamin B_{12}, pantothenic acid, biotin.
Risk Category B: vitamin B_6, vitamin E, vitamin C, niacin.
Risk Category C: calcium, folic acid, vitamin A as retinol, zinc, vitamin D, iodine, iron, copper, selenium, manganese, magnesium (UL for supplementary magnesium only).
Other nutrients for which an RDA or AI has been established, but for which a risk category has not been assigned, include choline, chromium, fluoride, molybdenum, phosphorus and vitamin K. For a variety of reasons which are briefly described here, these nutrients are proposed to be excluded from discretionary fortification. Choline has very limited evidence available to set an AI and a UL and has a 2-fold range of safety. Data for chromium are too limited to set a UL. Molybdenum has limited animal data used to set a UL. Phosphorus has a narrow range of safety and is increasingly used as a food additive and

vitamin K has insufficient data to set a UL, but is used in supplements (by prescription only) due to its role in blood coagulation.

While stakeholders indicated some agreement with the above risk categorization in response to the October 2002 consultation document, many stakeholder groups recommended waiting for the report of the IOM on the application of the DRIs to nutrition labelling and discretionary fortification, which was to become available in late 2003. Nonetheless, risk categorization has demonstrated its utility in assessing the safety of defined levels of nutrient addition under a range of scenarios. The IOM report became available in December 2003. This report set out a series of Guiding Principles. With reference to applying the ULs, Guiding Principle #15 states that "The severity of the adverse effect on which the UL is based should be reviewed when considering discretionary fortification with a nutrient using the conceptual decision approach presented" (in the report). An important consideration in using the ULs is the heterogeneity of the severity of adverse effect of excessive nutrient intakes, and in the case of some nutrients, the limited data available to set the UL. Other considerations in interpreting the risk of adverse effects due to high exposure are the sources of nutrient on which the adverse effects were identified in setting the ULs. This is a practical recommendation which Health Canada has taken into account in setting out the final risk categories of nutrients.

1.1.1.2 Exposure Assessment

The exposure assessments are key elements of the risk assessment. Assessing the safety of the options for discretionary fortification was through the use of modelling scenarios of exposure of the Canadian population to nutrients in each of the risk categories, under the conditions tested.

The data from three Federal/ Provincial surveys (British Columbia, Manitoba and Ontario) were pooled to provide a sample of 4489 to generate the adult results, and the data from the Quebec survey of children and youth (n= 1932) were used to generate the children's results. All participants in these surveys provided a 24 hour recall and about one third of participants provided a second recall, permitting adjustment to reflect usual intakes. All intakes were calculated based on the 1999 Canadian Nutrient File.

Under each scenario, all qualifying foods were fortified to bring nutrient content to the level evaluated per reference amount. However, to evaluate scenarios that more closely reflect actual market practices, a Monte Carlo simulation was applied. In this case 33% of foods chosen randomly from the qualifying foods were fortified, to reflect a mature market in which, according to data provided by an industry group, about one third of consumers indicated that they would buy a fortified product (e.g. beverages, cereals, bread, bars) if there was a choice. Under the mature market simulations, all ready-to-eat cereals were fixed to the stated

level of nutrient addition because of consumer brand loyalty to one or a limited number of cereals.
It should be noted that in the modelling, no allowance was made for overages of added nutrients. In practice, these range from 20 to 200% of the declared value depending upon the stability of the nutrient.

The fortification scenarios listed in **Table One** (Options 1, 2, 3, 4 for the June 2003 consultation and Option 1- mature market scenarios afterwards) were tested.

2. Availability and choice/ innovation

This criterion speaks to the extent to which the option would allow more food choices and wider distribution of nutrients in the food supply. Innovation is addressed through the extent to which the development of new fortified products potentially filling niche markets is fostered.

3. Adherence to /Application of Codex General Principles and the new Dietary Reference Intakes

Early in the policy review process, stakeholders supported Health Canada's recognition of the *Codex General Principles for the Addition of Essential Nutrients to Foods*. However, there was also recognition that these principles do not include discretionary fortification, i.e. fortification without a defined nutritional rationale. Consequently, the Codex General Principles will apply to all purposes for addition except discretionary fortification.

However, the appropriate application of the new Dietary Reference Intakes in both risk assessment (IOM 2000, 2003), in setting levels of addition (IOM, 2003) and eventually, in the longer term, in labelling is applicable to all discretionary fortification options.

4. Trade and Competitiveness

This criterion addresses the extent to which the options would facilitate fortified food and beverage products to be marketed with our major trading partners. The extent to which Canadian manufacturers would develop fortified products for export, and Canada would be able to import more products from our major trading partners is considered.

4.1 Situation in the US.

In the United States, all fortification is at the discretion of the manufacturer. Mandatory fortification is not required for any food product. Every standard of identity for an enriched food is coupled with a standard of identity for an unenriched version of the same food.

The US Code of Federal Regulations contains a Fortification Policy (21CFR§104.20) which sets out situations and conditions in which fortification of foods is considered appropriate: correction of inadequate intakes of nutrients; restoration of nutrient losses; balancing nutrient content in proportion to caloric value (nutrient density); and prevention of nutritional inferiority of substitute foods. The FDA's Fortification Policy is expressed as a series of guidelines which manufacturers are urged to follow if they elect to add nutrients to a manufactured or processed food. With the exception of the requirements for nutrients classified as food additives, and those linked to nutrient content claims and related label statements, the FDA does not regulate discretionary fortification of unstandardized foods and is not involved in decisions taken by companies to fortify these.

4.2 Situation in the European Union

In Europe, responsibility for regulating fortified foods rests with the Member States. As of 1998, regulatory or legislative controls varied widely ranging from virtually unrestricted addition as long as no health hazards existed (e. g. Austria, U. K.) to addition allowed only if approved by the Ministry of Health (e. g. Italy).

The White Paper on Food Safety, adopted by the Commission of the European Communities on January 12, 2000, proposed in its Action Plan on Food Safety "to lay down provisions for marketing foods to which nutrients such as vitamins and minerals have been added". It was intended for the provisions to be adopted by the Commission in September 2000 and by the Council/Parliament in September 2001. Adoption of a proposal has been delayed and the Commission has released a *Proposal for a Regulation for the European Parliament and of the Council on the addition of vitamins and minerals and of certain other substances to food*, November 10, 2003, for comment. The document focuses on voluntary (discretionary) addition. The proposal includes a positive list of vitamins and minerals that may be added. The Commission also proposes to set maximum safe levels that can be added to foods, taking into account intakes from other dietary sources, and the upper safe levels (ULs) established by the Scientific Committee on Food of the European Commission. The only foods excluded are fresh produce including fruits, vegetables, fish and meats, and beverages containing alcohol greater than 1.2% by volume. To address concerns that products that do not have a "desirable" nutrient profile such as candies, high salt and high fat snacks should not be allowed to be fortified, it is proposed that the nutrient profile of a food be a criterion for allowing a fortified food to carry claims (nutrition or health claims).

4.3 Situation in Australia and New Zealand

Food Standards Australia and New Zealand (FSANZ) has a specific standard (Standard 1.3.2-Vitamins and Minerals) which prohibits the addition of vitamins and minerals to general purpose foods unless the addition of that vitamin or mineral is specifically permitted (levels of addition are also defined). Regulatory Principles were derived from the *Codex General Principles for the Addition of Essential Nutrients to Foods.*

B. Implications of Each Option

Stakeholders commented on the advantages and disadvantages of each option at a consultation in June 2003. Taking this input into account, the implications of each option for discretionary fortification were also considered from the additional perspectives of :

- **Education / Information / Risk Communication -** The issues include the type and characteristics or nature of public health messages required to decrease potential risk of the option.

- **Monitoring** - The issues include the type of monitoring required to assess the impact of the implementation of the option as well as the responsibility for monitoring.

- **Regulations and enforcement** - The issues include the regulatory burden on Health Canada associated with the option, the ease of enforcement.

C. Evaluating the Options for Discretionary Fortification

Four major options, plus mature market scenarios under Option 1, presented in the table below, were weighed against the decision-making criteria. A mature market scenario assumed that only certain product categories would be fortified based on data provided by industry and that one third of choices were assumed to be fortified. Representative nutrients from risk categories B and C presented on p 3 of this Appendix were modelled. The levels were based on the new IOM Recommended Dietary Allowances (RDA) and Adequate Intakes (AI).

General exclusions

All modelling scenarios and options excluded fresh unprocessed meat, poultry, fish, eggs, fruits and vegetables, coffee beans, leaf tea. Infant foods were also excluded. **All modelling scenarios and options also excluded certain standardized and staple foods** from discretionary fortification because of their pervasiveness in the food supply and the potential for widespread exposure to excessive or imbalanced intakes if these were to be fortified at the discretion of manufacturers. The list of excluded standardized foods for November 2002 modelling was flours, breads, pasta, rice, milk, margarine. The list of standardized and staple

foods was expanded for the June 2003 modelling to also exclude varietal cheeses, sugar, honey, maple syrup, molasses, salt, pepper, other spices, leavening agents and artificial sweeteners. It is proposed that alcoholic beverages also be excluded. **In further explorations of Option 1, under mature market scenarios, milk as a beverage and margarine were included in the modelling** to assess the impact of an industry proposal that these two standardized staple foods be allowed discretionary fortification.

The options for food vehicles for discretionary fortification were the subject of a consultation workshop on June 23, 2003. The further analysis of the application of mature market conditions to Option 1 were completed in December 2003 and are now being shared with stakeholders.

Rationale for Exclusion criteria:
The increasing market for fortified foods suggests that fortification does lead to increased consumption of the fortified vehicles. Restricting discretionary fortification to foods that meet nutritional criteria was suggested for options which would increase the availability of fortified foods while preventing promotion of fortified foods with components associated with risk to health or foods of low nutritional value. *Under Option 2*, the first criterion is intended to be the same as for the "low in saturated fatty acids" claim. According to the DRI report (IOM 2002), "any incremental increase in saturated fatty acid [and trans fatty acid] intake increases CHD risk".

Establishing a level of sodium >480 mg remains consistent with Health Canada's *Nutrition Recommendations... A Call for Action* (1990) to lower sodium intake. This level also meets the requirement for foods which may bear the sodium and hypertension health claim.

Under Option 3, the 10% WRNI criterion was included to ensure that foods to be fortified would have an inherent nutritional value and to exclude those foods composed mainly of sugars. It should be noted that no UL was set for sugars intake in the DRI report, however, the report recommended that added sugars should not make up greater than 25% of energy.

As proposed by the industry sector, options with no exclusion criteria were also considered. Under Option 1, all product categories are treated similarly. Under Option 4, each product category would have specific allowable levels of nutrient addition. An underlying assumption regarding the implementation of both Options 1 and 4 is that not all product categories would be fortified, and also that of those product categories that may be fortified, only a segment would be fortified.

Results

1. Consumer Protection

Of all the options, Option 3 offers maximal consumer protection under discretionary fortification, both with regard to the foods that could be fortified, and potential for exposure to excessive intakes if all qualifying foods were fortified. The exposure to excessive intakes from foods is

limited because the number and types of foods that may be fortified are restricted. However, individuals who already follow healthy eating recommendations are those most likely to be at risk of excessive intakes under Option 3.

> Option 3: Statistical modelling indicated that addition of Risk Category B nutrients to 50% of RDA to all qualifying foods presented minimal exposure to excessive intakes. For the Risk C nutrients tested, additions to 10% of RDA to all qualifying foods resulted in low exposure to excessive intakes (less than 5% of the most exposed members of the population had intakes over the UL). For example, the addition of calcium to a level of 10% of AI to all qualifying foods resulted in an estimated 5% of adolescent boys with an intake over the UL. Folic acid addition to 10% of RDA resulted in less than 1% with intakes over the UL, but addition to 25% of RDA resulted in an estimated 16 % with intakes over the UL in children aged 6 to 8 years.

Option 2 ranks second in terms of consumer protection and is consistent with Health Canada's role in health protection, as this option would reduce the potential for promotion of fortified foods with constituents recognized to be associated with increased risk to health. The levels of Risk Category A and B nutrients that could be added without risk are similar to the levels under Option 3, but only low levels of Risk C nutrients could be added, and only with an assumption that not all foods that could be fortified would be fortified.

> Option 2: Statistical modelling indicated that for Risk Category B nutrients, addition to 50% of RDA resulted in low exposure to excessive intake. The modelled addition to a level of 50 % of RDA to all qualifying foods under this option resulted in less than 1% of children with intakes over the UL. However, for Risk C nutrients, modest levels of fortification, to 10% of RDA or AI to all qualifying foods, resulted in some exposure to intakes over the UL (6% of children over the UL for folic acid; 25% of boys over the UL for calcium).

Under Option 4, consumer protection would be difficult to ensure because of the continually changing exposure to nutrients from Defined Voluntary Fortification (DVF) as more product categories were approved. An alternative would be to define all possible DVF categories at the outset with maximum levels of addition. This alternative would be a highly burdensome exercise to complete, involving many possible permutations and combinations of fortification on a product category- by- product category basis, and with stakeholder involvement at each step. The danger in taking this approach would be in setting an absolute mechanism which would be unable to adapt to changes in scientific knowledge and the food supply. Based on the levels of nutrient addition proposed by industry, to date, DVF has the potential for the greatest exposure to excessive intakes. This is because of the widespread consumption of the DVF categories of

beverages and breakfast cereals, and the requested levels of Risk Category C nutrients. If only a fraction of food products were to be fortified, as the industry has proposed, then the exposure to intakes over the UL may be reduced but the potential would always be there for a high proportion of a category to be fortified as is the case with breakfast cereals.

Option 4: Statistical modelling of an example of maximal exposure under DVF, for vitamin C addition to all beverages at 100% of the RDA and to all other vehicles at 25% of RDA, an estimated 2% of children aged 6-8 years would have intakes over the UL. Vitamin C addition to all beverages at 100% of RDA and 50% of RDA to all other vehicles resulted in an estimated 14% with intakes over the UL. These results illustrate the potential impact of DVF (for beverages) combined with Option 1 (all other vehicles).

For DVF of three product categories, the addition of calcium according to the following requests - at- hand was modelled: ready-to-eat cereals at 110 mg per reference amount; beverages at 308 mg per cup (the amount already in the market through approved TMAL applications); processed cheese products at 216 mg per reference amount. If all three DVF categories were approved at the requested levels, and all manufacturers chose to fortify these products, over 50% of adolescent boys could be exposed to calcium intakes over the UL, based on current consumption patterns of Canadians.

As a second example of a Risk Category C nutrient, folic acid addition to two DVF categories, ready-to-eat breakfast cereals (RTE), and beverages was modelled. The amount of 100 µg folic acid per reference amount was added to all RTEs and 100 µg folic acid per 250 ml was added to all beverages. With just these two food categories, at these levels of folic acid addition, if all manufacturers were to implement these additions, an estimated 21% of children aged 6-8 years could have folic acid intakes over the UL of 400 µg. Intake at the 99th percentile was 740 µg.

As with the statistical modelling of the other options, where exposure was assessed under the assumption that all qualifying foods would be fortified if they were permitted, the same approach was also initially taken with Option 1. Results under this scenario indicated no risk of exposure with amounts of Risk Category A nutrients of up to 100% RDA (because no UL has been set for these nutrients, and no concern expressed) and amounts of Risk B nutrients of up to 25% RDA with no risk of exposure to intakes over the UL ***from foods*** . However, with the same assumption, there was no safe level of addition of Risk Category C nutrients.

Under Option 1, Risk B nutrients (e.g. vitamin C) added to a level of 25% of RDA to all qualifying foods, if they did not already contain that amount or more, based on actual food consumption patterns of Canadians, resulted in none of the most exposed group to intakes over the UL. With a level of 50% of RDA, an estimated 5% of children could have intakes over the UL.

Option 1, like Option 4, has great potential to result in imbalanced or excessive intakes of Risk Category C nutrients, depending upon the ranges permitted. If all qualifying foods were to be fortified under Option 1, even to a level of 5% of the RDA/AI, exposure to Risk C nutrients would result in intakes over the UL. For example, with calcium, the most exposed group is adolescent boys. If calcium was permitted at 5% of AI (65 mg calcium/reference amount) to all qualifying foods, an estimated 21% had intakes over the UL. At 10% of AI, over 70% had intakes over the UL. Similarly for girls, at 10% of AI, about 22% had intakes over the UL. For folic acid, addition to 5% of RDA to all qualifying foods resulted in 5% of children aged 6-8 years with intakes over the UL. Additions to 10% of RDA resulted in 61% with intakes over the UL.

Industry stakeholders have advised us that modelling based on the assumption that all foods would be fortified, if permitted by the regulations, overestimates exposure because the assumption is unrealistic. An industry stakeholder group provided data to Health Canada indicating that in a mature market in which discretionary fortification predominates, such as seen in the U. S., only a fraction of product categories are fortified, and even within those categories, not all products are fortified, and not all to the maximum permitted level. Further, data were provided indicating that about one third of consumers would be interested in buying a fortified product i.e. “with added functional components” (beverage- 32% of consumers would consider buying; cereals- 47% would consider buying; bars-20% would consider buying) if available.

Thus additional modelling was undertaken under Option 1 to simulate “mature market” scenarios (referred to here as Fixed Market Penetration (FMP)) to explore up to what levels of Risk Category C nutrients could be added with low exposure to excessive intakes. As indicated by the industry group, the main commodities that would be voluntarily fortified in a mature market would include breakfast cereals, instant breakfast powders, ‘bars’ (cereal bars, power bars, including confectionary), beverages including milk, fruit and vegetable juices and drinks, carbonated beverages and water, soy beverages and products, ketchup, wieners and processed meats and frozen dinners. Snack foods such as potato chips were also included. Only a very small per cent of other categories such as 8% of baked goods, 2% of soups would be expected to be fortified (data provided by an industry group). Under the mature market simulations, all ready-to-eat cereals were fixed to the stated level of nutrient addition because of consumer brand loyalty to one or a limited number of cereals.

Statistical modelling under the Option 1 scenario referred to as Fixed Market Penetration including Milk and Margarine (FMP-CkdCer+Milk), and with ready-to-eat (RTE) cereals at a fixed level (the inclusion of cooked cereals does not affect the results, but were excluded from this example as less likely to be fortified), indicated that calcium addition to a level of 5% of AI per reference amount resulted in about 10% of boys aged 14-16 years with intakes over the UL if all fortified. Under the same scenario but with Monte Carlo simulation of one third of choices being randomly fortified to 5, 10 or 25% of AI, an estimated 5, 8 and 30% would have intakes over the UL. (Figure 1).

Under the Monte Carlo "FMP-Cooked Cereals + Milk" simulation of folic acid addition to 5, 10 or 25% of RDA to 33% of randomly selected choices, and all RTEs fixed at 200 µg folic acid, an estimated 2, 4 and 33% respectively could have intakes over the UL (Figure 2).

For zinc, the Monte Carlo simulation of addition to 5, 10 and 25% of RDA to 33% of foods, and all RTEs fixed at 1.5 mg resulted in an estimated 25, 40 and 85% of 6-8 year old children, respectively with intakes over the UL (Figure 3).

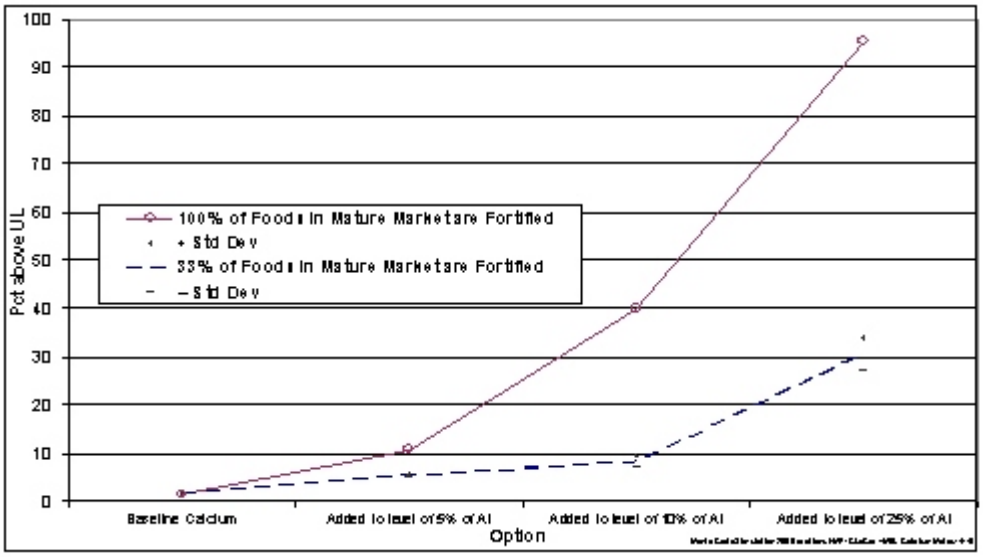

Figure 3 Option 1: Percent of boys aged 14-16 years with intakes over the UL for calcium under mature market conditions, with 100% of choices fortified (solid line) or with 33% of choices fortified (dashed line). Current baseline is shown at left of scenario "FMP - Cooked cereals + milk" fortified to levels of 5%, 10% or 25% of AI for calcium, but all RTEs fixed at 110 mg calcium.

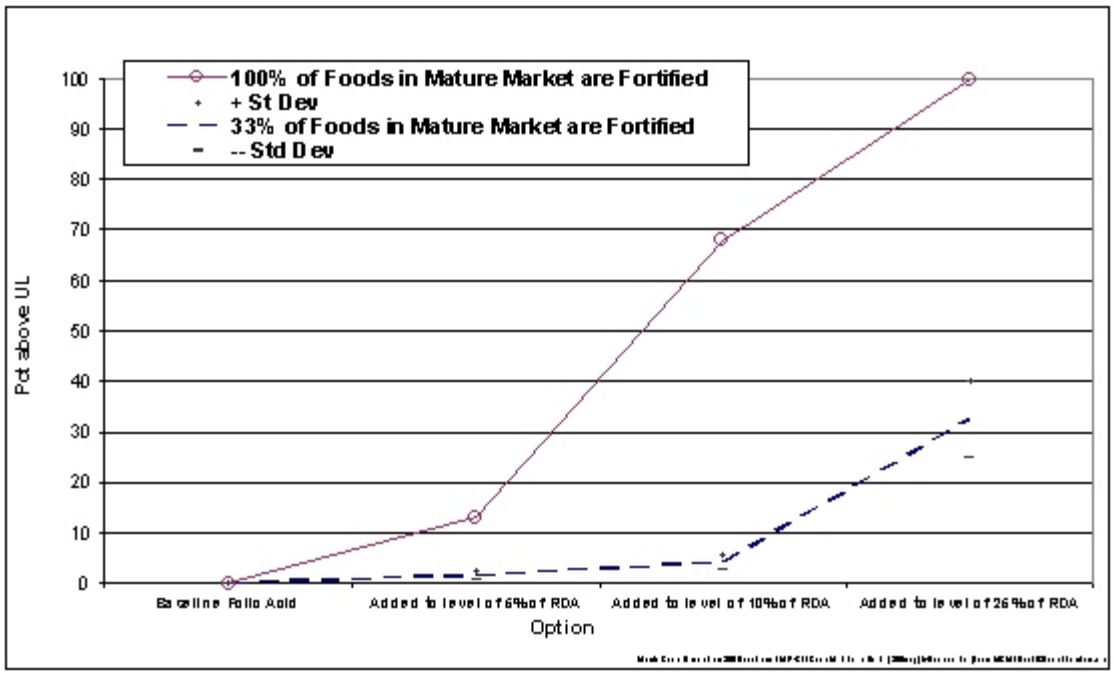

Figure 2 Option 1: Per cent of children aged 6-8 years with intakes over the UL for folic acid under mature market conditions with 100% of choices fortified (solid line) and with 33% of choices fortified (dashed line). Current baseline is shown at left of scenario "FMP-Cooked cereals + milk" fortified to levels of 5%, 10% or 25% of RDA for folic acid, but 200 µg folic acid to all RTE cereals.

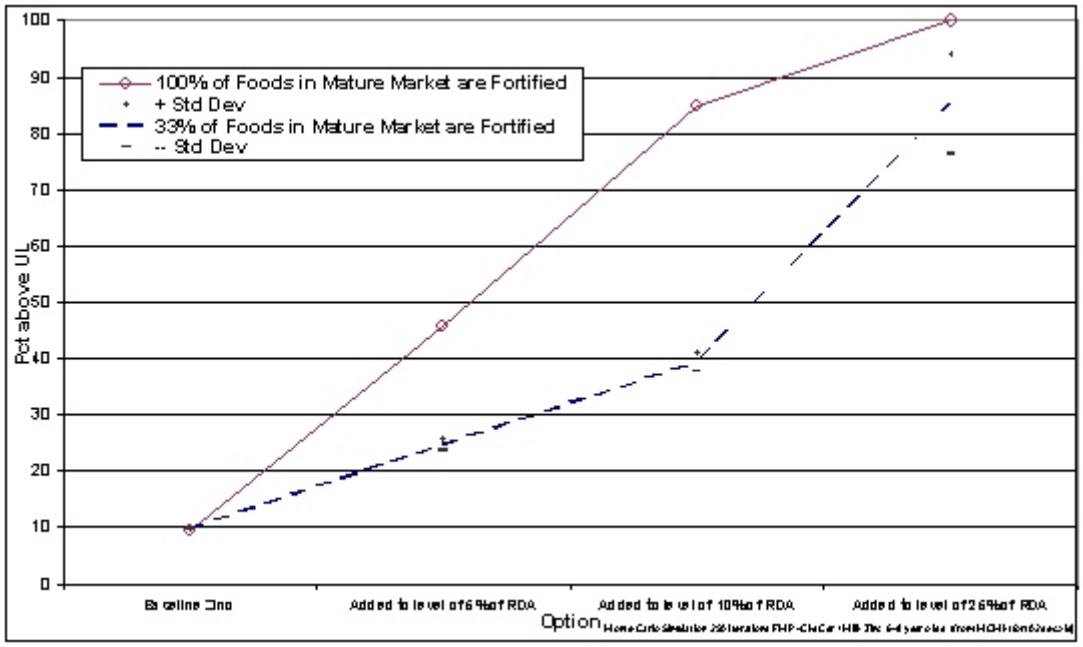

Figure 5 Option 1: Per cent of children aged 6-8 years with intakes over the UL for zinc under mature market conditions with 100% of choices fortified (solid line) and with 33% of choices fortified (dashed line). Current baseline is shown to left of scenario "FMP-Cooked Cereals + Milk" fortified to 5%, 10% or 25% of RDA for zinc, but 1.5 mg zinc to all RTE cereals.

In summary, under all options, there is no risk of excessive intake of the nutrients in Risk Category A (p 36- this Appendix) from foods because there is no UL, and no concern expressed by the IOM expert panels. Under all options except Option 4, there is no exposure to excessive intakes of Risk Category B nutrients (p36- this Appendix) from foods, even if all foods were to be fortified at 25% of RDA or AI; however fortification of all qualifying foods to 50% of RDA or AI results in intakes over the UL. For Risk Category C nutrients (p36- this Appendix), Option 3 was the only option that resulted in a small exposure (<10%) to intakes over the UL (except for nutrients where intakes are currently over the UL, e. g. zinc), if all qualifying foods were fortified to a level of 10% RDA or AI.

Thus consumer protection is best addressed through Options 2 and 3, with regard to the risk of excessive intakes and the potential for promotion of fortified foods with components associated with risk to health. The former is particularly relevant to Risk Category C nutrients which could be added at moderate levels. The modelling under Option 1 with assumptions of mature market conditions indicates that for some nutrients in Risk Category C (page 36- this Appendix), such as calcium and folic acid, but not zinc, addition up to 10% of RDA or AI could be permitted with minimal risk of excessive intake.

2. Availability and choice/ innovation

Option 1 allows for the greatest number of fortified food choices and wider distribution of nutrients in the food supply because any and all foods, with the exception of a list of standardized and staple foods, and fresh, unprocessed meats, fish, eggs and produce, and infant foods, may be fortified. This option also has the highest potential for innovation. The extent of the potential for innovation will be influenced by decisions on the levels of Risk Category C nutrients permitted.

Option 2 would result in some restrictions on choice of fortified foods, based on saturated and *trans* fat content and sodium content. As well, innovation would be limited to those foods that meet these criteria. A number of commonly consumed foods, e.g. peanut butter, processed cheese products, soups and vegetable juices, luncheon meats, wieners, would be excluded from fortification. Stakeholders have objected to this exclusion as these foods are widely consumed and can contribute to a healthy diet.

Option 3 is the most restrictive in that it limits fortified food choices to those that are already healthy choices. It would not result in a wider distribution of nutrients in the food supply. Innovation would be hampered because the marketing options for the food industry would be limited.

Option 4 would see wider distribution of nutrients within product categories, and innovation within the approved categories. However, as more DVF categories use up the safe levels of Risk Category B and C nutrients, choices of fortified foods or other foods as sources of nutrients in the rest of the food supply would be limited.

3. Trade and Competitiveness

Option 1 would allow the greatest potential for flexibility in trade. Of all of the options, this allows for much greater trade flexibility because this option does not exclude any foods from potential fortification (except a list standardized and staple foods, alcoholic beverages, infant foods and fresh produce, see p 40).

Options 2 and 3 would result in fairly extensive curtailment of trade due to the exclusion of certain products from fortification. Option 3 in particular results in very few eligible food vehicles for fortification.

Option 4 would see lower concerns about trade in the approved product categories, however, the levels of Risk Category C nutrients permitted would be a limitation to trade. The nutrients and the levels permitted would be influenced by the number of product categories manufacturers wish to fortify with a given nutrient. There is potential for a “first in the door” approach to obtain all of the nutrients of marketing interest, creating an unlevel playing field and limit any future innovation or changes.

Implications

1. Education / Information / Risk Communication

The risk communication may be most challenging under Option 1 since it does not require eligibility criteria for foods permitted fortification, and promotion of fortified foods may result in consumers switching to fortified foods containing constituents with recognized risk to health or with little or no nutritional benefit as opposed to any unfortified but otherwise healthy food choice. To date there is no evidence that such switching of food choices occurs, but neither has this been systematically investigated. To prevent this switching of choices, consumers need to be aware of healthy eating guidelines, and have increased knowledge about the composition of foods. As well, the food industry would need to fortify responsibly and would need to develop appropriate messaging to inform and educate consumers of the risks.

Under Option 2, Health Canada would retain credibility through consistency in public health messaging about saturated and *trans* fat and sodium. The fortification of foods with little nutritional value (foods mainly sugars, carbonated beverages) would be permitted under this option, a situation that is not supported by the public health sector. However, the potential risk to health under this option would be mainly from excessive nutrient intakes, which can be controlled by the levels permitted.

Under Option 3, risk communication would be simplest, since messages about healthy eating would be consistent with other Health Canada nutrition promotion activities. However, messages will still remain difficult regarding explanation of why already healthy food choices are being fortified. Of all of the options for discretionary fortification, this is the one that the public health sector supports, if discretionary fortification must be implemented.

The implications of DVF are the same as for Option 1, but the issue of risk communication/messaging is the most complex. In addition to the issue of mixed messages/ confusion regarding the consumption of foods with components recognized to be associated with risk to health, of greater concern is the potential exposure of subgroups to high levels of Risk C nutrients, i.e. the risk of excessive intakes is potentially much greater than under Option 1 because as more food categories are approved, each with its defined levels of Risk Category C nutrients the chance of exposure to these nutrients increases. Safe implementation of this option would require consumer knowledge of ULs and the contribution of foods to those levels.

2. Monitoring Impact

Monitoring needs depend on the foods that are fortified, the extent of fortification of the food supply, and the nutrients and levels of addition. The monitoring needs are greatest under Option 1, since the entire food supply would be affected. There is a potential increased health risk of consumption of foods with components of known risk to health which will need to be monitored, as well as exposure to excessive nutrient intakes. At a minimum, consumption patterns across the entire food supply will need to be assessed. The Canadian Community Health Survey 2.2 (the

Nutrition Focus Survey), a nationally representative survey on food consumption and healthy living initiated in January 2004 may help provide a good baseline. A second survey scheduled to go into the field in January 2006, during which blood and urine samples will be collected to look at a number of biochemical measures as well as physical measures of nutritional status will provide an important addition to the baseline assessment.

Monitoring under Option 1 particularly will also require the industry participation to coordinate effective and efficient means of collecting and analysing pertinent data. Access to marketing data, consumption patterns and other market trend information by government would significantly aid in this process. If the implementation of Option 1 differs from what the industry has stated they would reasonably do, then changes to the regulations can be made to ensure that the risks to health are minimized.

Under Option 2, although monitoring requirements are similar to those of the other options, the urgency of implementation is less because there is lower risk of consuming foods with risk to health and therefore, no potential increase in coronary heart disease, hypertension, etc. due to this option.

Under Option 3, the urgency for monitoring the impact is the lowest of any option due to the fact that potential increases in chronic diseases (hypertension, heart disease, etc.) are not expected because foods with constituents associated with risk to health would not be fortified. As well, risks of excessive intake are minimal as the number of allowable fortified foods is very limited. Requirements for establishing monitoring mechanisms are also lessened under this option, as the segment of the food supply which would include fortified products would be small. Industry's and government's roles in monitoring the impact of the fortified foods allowed under this option would be more manageable due to the smaller scale of discretionary fortification.

Monitoring needs under Option 4, DVF, or with DVF in combination with any other option would be similar to those in Option 1. The monitoring would have the added complexity of a constantly shifting market place as more DVF categories would be approved over time. This option has the potential to affect the entire food supply over time.

3. Regulations and Enforcement

Regulatory burden under Option 1 is the lowest amongst all of the options. Requirements involve specifying ranges for nutrients in the different risk categories.

Effective enforcement of acceptable levels of nutrients will require significant resources, both in terms of manpower and technical and analytical capacity. Cooperation between the industry and government would be required to share enforcement mechanisms needed for this option.

Under Options 2 and 3, the regulatory burden increases for Health Canada in setting out eligibility criteria for food vehicles as well as the ranges of addition. However, the major burden is that of enforcement which would require the assessment of saturated and *trans* fat content and

sodium content, as well as assessing the total nutrient content of the products for compliance under Option 3. This in itself would require considerable resources to establish and maintain. Essentially, without a practical enforcement plan, industry will become self-regulating under this option.

The regulatory burden of DVF is greater than for the other options as each new product category and its levels of addition would be approved on a sequential basis in discussion with relevant stakeholders. Because the product categories would be defined over time, Health Canada would be unable to plan for safe levels of addition in future applications, and could be seen as inefficient and unprepared. Although CFIA may be better able to enforce compliance with defined product categories and defined levels of addition, the changing market place as new products are approved would be an increasing burden over time.

Table 1: Options and Fortification Levels Nov 27 03

Option	Excluded	Special Inclusion	Fortification levels per reference amount			
			Vitamin C RDA=90 mg/d	**Calcium** AI=1300 mg/d	**Folic Acid** RDA=400 mcg/d	**Zinc** RDA=11 mg/d
Option 1 SSF Criteria	SSF (June list)	none	5%, 10%, 25%, 40%, 50% of RDA	5%, 8%, 10% of AI	5%, 10%, 20%, 25%, 40% of RDA	5, 10, 25% of RDA
Option 1A SSF with Bevs @ 100%	SSF	All beverages	100% RDA All other fortifiable foods 25%,50% of RDA			
Option 1 FMPa	SSF and Market Exclusion list	Market inclusion and Water, carbonated bev	----	5, 10, 25% of RDA Cereals 110 mg	5, 10, 25% of RDA Cereals 100, 200 mcg Soups 12 mcg	5, 10, 25% of RDA Cereals 1.5 mg
Option 1 FMPb (FMP +Milk)	SSF and Market Exclusion list	Market inclusion Milk & Margarines; Water & carbonated bev	----	5, 10, 25% of RDA Cereals 110 mg	5, 10, 25% of RDA Cereals 100, 200 mcg Soups 12 mcg	5, 10, 25% of RDA Cereals 1.5 mg
Option 1 FMPc (FMP–CkdCer)	SSF, Market Exclusion list and Cooked Cereals	Market inclusion Water & carbonated bev	----	5, 10, 25% of RDA Cereals 110 mg	5, 10, 25% of RDA RTEs 100, 200 mcg Soups 12 mcg	5, 10, 25% of RDA Cereals 1.5 mg
Option 1 FMPd (FMP – CkdCer + Milk)	SSF and Market Exclusion list and Cooked Cereals	Market inclusion Milk & Margarines; Water & carbonated bev	----	5, 10, 25% of RDA Cereals 110 mg	5, 10, 25% of RDA RTEs 100, 200 mcg Soups 12 mcg	5, 10, 25% of RDA Cereals 1.5 mg
Option 1 FMPe (FMP –CkdCer +Milk - SftDrks)	SSF and Market Exclusion list, Cooked Cereals and Soft drinks	Market inclusion Milk & Margarines	----	5, 10, 25% of RDA Cereals 110 mg	5, 10, 25% of RDA RTEs 100, 200 mcg Soups 12 mcg	5, 10, 25% of RDA Cereals 1.5 mg
Option 2 SSF with Safety criteria	SSF and Exclusion criteria for sat & trans fats, alcohol, sodium	none	5%, 10%, 25%, 40%, 50% of RDA	5%, 8%, 10% of AI	5%, 10%, 20%, 25%, 40% of RDA	---

Option	Excluded	Special Inclusion	Fortification levels per reference amount			
			Vitamin C RDA=90 mg/d	**Calcium** AI=1300 mg/d	**Folic Acid** RDA=400 mcg/d	**Zinc** RDA=11 mg/d
Option 3 **SSF with Safety and Nutrient Content criteria**	SSF and Exclusion criteria for sat & trans fats, alcohol, sodium and Exclusion criteria for nutritional content (8% RDA)	none	5%, 10%, 25%, 40%, 50% of RDA	5%, 8%, 10% of AI	5%, 10%, 20%, 25%, 40% of RDA	---
Option 4 **Defined Voluntary Fortification**	SSF	RTE Cereal	---	110 mg	100 mcg	---
		Beverages	100% of RDA	308 mg	100 mcg	---
		Process Cheese	---	216 mg per 30 g ref. amount	----	---
		All other fortifiable	25% of RDA 50% of RDA	----	----	---

FMP = Fixed Market Penetration, CkdCer = Cooked Cereals, SSF = Standardized and Staple Foods, SftDrks = Soft Drinks

Appendix C - Discretionary Fortification: Levels to which Vitamins and Minerals may be Added per Reference Amount

		MINIMUM[1]	MAXIMUM[2, 3, 4]
Risk Category A[2]			
Thiamin	mg	0.07	0.3
Riboflavin	mg	0.08	0.3
Niacin	mg (NE)	1.2	5
Vitamin B_6	mg	0.09	0.4
Vitamin B_{12}	µg	0.1	0.4
Pantothenate	mg	0.35	1.4
Biotin	µg	1.5	6
Vitamin E	mg	0.5	2
Vitamin C	mg	3	12
β-Carotene	RE	50	200
Risk Category B[3]			
Vitamin D	µg	0.25	0.5
Folate	µg	11	22
Potassium	mg	175	350
Calcium	mg	55	110
Magnesium	mg	11.5	25

1. The minimum for **Risk Category A** and **Risk Category B** nutrients is the level that meets the "Source" claim, 5 % of RDI.

2. The maximum for **Risk Category A** nutrients is the level that meets the "Excellent Source" claim, 20 % of RDI.

3. The maximum for **Risk Category B** nutrients is the level that meets the "Good Source" claim, 10 % of RDI.

4. The maximum does not include overage.

Appendix D - Proposed Revisions for the Nutrient Composition of Meal Replacements

MEAL REPLACEMENTS			
NUTRIENT	**CURRENT per serving**	**PROPOSED for energy restricted diets per 100 kcal[1]**	**PROPOSED for non-energy restricted diets per 100 kcal[2]**
energy	minimum energy per serving: 225 kcal	minimum energy per serving: 225 kcal	minimum energy per serving: 350 kcal
protein	15%-40% of energy (minimum of 20% for products for weight reduction)	20%-35% of energy	10%-35% of energy
fat	maximum 35% of energy (maximum 30% if sole source of nutrition)	maximum 35% of energy (in the case of meal replacements that are the sole source of nutrition maximum is 30% of energy)	maximum 35% of energy (in the case of meal replacements that are the sole source of nutrition maximum is 30% of energy)
saturated and trans fat	maximum 10% of energy as saturates (if sole source of nutrition)	maximum 10% of energy as saturates and trans for meal replacements that are sole source of nutrition	maximum 10% of energy as saturates and trans for meal replacements that are sole source of nutrition
linoleic acid	minimum 3% of energy	minimum 3% of energy	minimum 3% of energy
α-linolenic acid	minimum 0.5%	minimum 0.5%	minimum 0.5%
linoleic/α-linolenic	4/1 to 10/1	for meal replacements 4/1 to 10/1	for meal replacements 4/1 to 10/1
vitamin A	250-630 RE	100 RE	50 RE
vitamin D	1.25-2.50 µg	0.5 µg	0.25 µg
vitamin C	10-20 mg	8.4 mg	4.2 mg
vitamin E	2.5-5.0 mg	1.7 mg	0.8 mg
vitamin B6	400-750 µg	144 µg	72 µg
vitamin B12	0.25-0.75 µg	0.27 µg	0.13 µg
thiamine	300-750 µg	133 µg	66 µg
riboflavin	400-800 µg	144 µg	72 µg
niacin	6-12 NE	1.8 NE	0.9 NE

MEAL REPLACEMENTS			
NUTRIENT	**CURRENT per serving**	**PROPOSED for energy restricted diets per 100 kcal[1]**	**PROPOSED for non-energy restricted diets per 100 kcal[2]**
folate	60-120 µg	44 µg	22 µg
pantothenic acid	1.25-2.50 mg	0.55 mg	0.28 mg
biotin	25-75 µg	2.6 µg	1.3 µg
β-carotene	as part of vit A	as part of vit A	as part of vit A
calcium	200-400 mg	144 mg	74 mg
phosphorus	250-500 mg	138 mg	69 mg
iron	2.5-5.0 mg	1.7 mg females 1.2 mg males	0.85 mg females 0.6 mg males
iodide[3]	40-120 µg	17 µg	8.5 µg
magnesium	60-120 mg	44 mg	22 mg
copper	0.5 - 1.0 mg	0.10 mg	0.05 mg
zinc	3-6 mg	1.1 mg	0.55 mg
potassium	375 mg	522 mg	235 mg
manganese	1-2 mg	0.2 mg	0.1 mg
selenium	10-20 µg (optional)	6.2 µg	3.1 µg
chromium	10-20 µg (optional)	3.5 µg	1.8 µg
molybdenum	20-40 µg (optional)	4.9 µg	2.5 µg

[1]Proposed regulatory requirements per serving are based on IOM RDAs/AIs for adult men 19-30 years in 900 kcal, and on 4 servings per day (i.e. a serving provides 1/4 of the daily RDAs/AIs). Energy retained at 225 kcal/serving.

[2] Proposed regulatory requirements per serving are based on IOM RDAs/AIs for adult men 19-30 and on the RDA/AI in 2000 kcal. Minimum energy retained at 225 kcal /serving.

[3] Requirement applies only to meal replacements represented for use as sole source of nutrition.

Appendix E - Nutritional Supplements - Proposed Nutrient Compositional Requirements

NUTRIENT	CURRENT REGULATIONS	Adults, adolescents and children [3]	Adults on energy restricted diets [4]	Toddlers 1 to 3 years [5]	Women on energy restricted diet (childbearing age) [6]	Women (childbearing age)[7]	Older adults on energy restricted diets (50+ years of age) [8]	Older adults (50+ years of age) [9]
		PROPOSED per 100 kcal						
energy	minimum energy per serving: 150 kcal	minimum energy per serving: 225 kcal	minimum energy per serving: 150 kcal	minimum energy per serving: 100 kcal	minimum energy per serving: 150 kcal	minimum energy per serving: 150 kcal	minimum energy per serving: 150 kcal	minimum energy per serving: 150 kcal
protein	15-40% of energy	no change	no change	no change	no change	no change	no change	no change
fat	maximum 35% of energy in products with ≥225 kcal	no change	no change	no change	no change	no change	no change	no change
linoleic acid	minimum 3% of energy from linoleic acid in products with ≥225 kcal	no change	no change	no change	no change	no change	no change	no change
α-linolenic acid	minimum 0.5% from α-linolenic in products with ≥225 kcal	no change	no change	no change	no change	no change	no change	no change
linoleic/α-linolenic	4/1 to 10/1	no change	no change	no change	no change	no change	no change	no change
vitamin A RE	100-250	60	100	30	78	47	100	60
vitamin D µg	0.25-1	0.33	0.6	0.5	0.6★	0.3★	1.7	1
vitamin C mg	38116	6	10	1.5	8	5	10	6
vitamin E mg	1.0-2.0	1	1.7	0.6	1.7	1	1.7	1
vitamin B6 µg	180-350	90	140	50	140	90	190	110
vitamin B12 µg	0.1-0.3	0.16	0.27	0.1	0.27★	0.16★	0.27	0.16

NUTRIENT	CURRENT REGULATIONS	Adults, adolescents and children [3]	Adults on energy restricted diets [4]	Toddlers 1 to 3 years [5]	Women on energy restricted diet (childbearing age) [6]	Women (childbearing age)[7]	Older adults on energy restricted diets (50+ years of age) [8]	Older adults (50+ years of age) [9]
thiamine µg	140-350	80	130	500 (50)	120	70	130	80
riboflavin µg	180-360	90	140	50	120	70	140	90
niacin NE	38051	1.1	1.8	0.6	1.6	0.9	1.8	1.1
folic acid µg	30-60	27	44	15	22★	27★	44	27
pantothenic acid mg	0.6-1.2	0.3	0.6	0.2	0.6	0.3	0.6	0.3
biotin µg	12-35	2	3.3	0.8	3.3	2	3.3	2
β-carotene	CAN BE ADDED AS PART OF VITAMIN A							
calcium mg	100-175	87	144	50	111★	67★	133	80
phosphorus mg	100-175	47	77	47	78	47	78	47
iron mg	1.0-2.0	0.5	0.9	0.7	2.0★	1.2★	0.9	0.5
iodide µg	15-45	10	17	9	17	10	17	10
magnesium mg	20-40	27	44	8	34	21	47	28
copper mg	0.15-0.30	0.6	0.1	0.3	0.1	0.1	0.1	0.1
zinc mg	1.4-2.0	0.7	1.2	0.3	0.9	0.5	1.2	0.7
potassium mg	175	175	175	175	175	175	175	175
manganese mg	0.45-0.90	0.2	0.3	0.1	0.2	0.1	0.3	0.2
selenium µg	98	3.7	6.1	2	6.1	3.7	6.1	3.7
chromium µg	98	2.3	3.9	1.1	2.8	1.7	3.3	2
molybdenum µg	227	3	5	1.7	5	3	5	3

[3] Proposed requirements per 100 kcal are based on 1500 kcal providing the IOM RDA/AI for men 19-30 years, except for boys 14-18 for calcium where the value was higher.

[4] Proposed requirements per 100 kcal are based on 900 kcal providing the IOM RDA/AI for men 19-30 years, except for boys 14-18 for calcium where the value was higher.

[5] Proposed requirements per 100 kcal are based on 1000 kcal providing the IOM RDA/AI for children aged 1-3 years.

[6] Proposed requirements per 100 kcal are based on 900 kcal providing the IOM RDA/AI for women 19-30 years.

[7] Proposed requirements per 100 kcal are based on 1500 kcal providing the IOM RDA/AI for women 19-30 years.

[8] Proposed requirements per 100 kcal are based on 900 kcal providing the IOM RDA/AI for men 51-70 years, except for men > 70 years for vitamin D where the value was higher.

[9] Proposed requirements per 100 kcal are based on 1500 kcal providing the IOM RDA/AI for men 51-70 years, except for men >70 years for vitamin D where the value was higher.

* for these vitamins and calcium, the values in the table are the minimum nutrient density for addition (nutrient/100 kcal). Formulations may be altered such that: (a) Supplements from women of childbearing age may contain calcium up to 250 mg at the lower kcal level (150 kcal), but at this level of calcium addition, must also contain vitamin D at 1.25 µg. (b)These levels would apply until the nutrient/kcal ratio exceeded these amounts, ie., for iron, the RDA is 18 mg. In a 900 kcal diet, this would provide 2 mg/100 kcal. A supplement of <450 kcal would thus contain up to 9 mg, but above 450 kcal, the amount would increase in proportion to kcal, e.g. 2 mg/100 kcal x 450 kcal=9 mg. 2 mg/100 kcal x 500 kcal=10 mg.

Appendix F - Interim Marketing Authorization for Amendments to Plant-based Beverages

GOVERNMENT NOTICES - DEPARTMENT OF HEALTH
FOOD AND DRUGS ACT
Food and Drug Regulations - Amendments

Interim Marketing Authorization

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 for 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 for 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:

> **5.1** "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 Regulations* and the *Guide to Food Labelling and Advertising*.

Health Canada intends to recommend that the Regulations be amended to provide 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

TABLE I

	Column I	Column II
Item	Vitamin or Mineral Nutrient	Amount per 100 mL ready-to-serve
1	vitamin A	40 RE
2.	vitamin D	0.85 ug
3.	vitamin B12	0.4 ug
4.	riboflavin	0.15 mg
5.	calcium	125 mg
6.	zinc	0.4 mg

TABLE II

	Column I	Column II
Item	Vitamin or Mineral Nutrient	Amount per 100 mL ready-to-serve
1.	vitamin B6	0.04 mg
2.	vitamin C	1.0 mg
3.	thiamine	0.04 mg
4.	niacin	0.85 NE
5.	folacin	5.0 µg
6.	pantothenic acid	0.35 mg
7.	phosphorus	100 mg
8.	potassium	150 mg
9.	magnesium	12 mg

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 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.

November 20, 1997

J.Z. LOSOS, M.D.
Deputy Minister
Health Protection Branch

Appendix G - Interim Marketing Authorization for Amendments to vegetable-based or vegetable and milk based products

GOVERNMENT NOTICES - DEPARTMENT OF HEALTH
FOOD AND DRUGS ACT
Food and Drug Regulations - Amendments

Interim Marketing Authorization

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 of 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,

1. 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,

2. has not more than 50% of its fat as saturated fat, not more than 10% of its fat as trans-fatty acids and not less than 2.5% of its fat as linoleic acid and not less than 1.5% of its fat as linolenic acid,

3. contains not more than 600 mg of sodium per 100 g, and

4. 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:

1. The energy value of the product, expressed in calories (Calories or Cal) and kilojoules (kilojoules or kJ),

2. the protein, fat, linoleic acid and carbohydrate contents expressed in grams,

3. the polyunsaturated, monounsaturated, saturated, and trans-fatty acid totals expressed in grams,

4. 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

5. the content of sodium and potassium expressed in milligrams.

TABLE

	Column I	Column II
Item	**Vitamin or Mineral Nutrient**	**Amount per g. protein**
1.	Vitamin A	10 RE
2.	Vitamin B_{12}	0.06 µg
3.	Riboflavin	20 µg
4.	Niacin	0.22 NE
5.	Calcium	30 mg
6.	Phosphorus	20 mg
7.	Magnesium	1 mg
8	Zinc	0.15 mg

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.

DATE: March 29, 2001

Diane C. Gorman
Assistant Deputy Minister
Health Products and Food Branch

Appendix H - Proposed Revised SCHEDULE K

REASONABLE DAILY INTAKE FOR VARIOUS FOODS

Name and Description	*Current Reasonable Daily Intake (RDI)*	*Reference Amount*	*Proposed New Reasonable Daily Intake*
Beverage bases for addition to milk	**454 mL**	**-**	**amount required to make 500 mL ready-to-serve**
Bread	**150 g**	**50 g**	**150 g**
Butter	**57 g**	**10 g**	**50 g**
Buttermilk	**852 ml**	**250 mL**	**750 mL**
Cereals, infant	**28 g**	**-**	**30 g**
Cheese (other than cottage cheese)	**57 g**	**30 g**	**60 g**
Condensed milk	**426 mL**	**15 mL**	**60 mL**
Cream, whipping	**57 g**	**15 mL**	**60 mL**
Evaporated milks	**426 mL (853 mL reconstituted)**	**15 mL**	**375 mL (750 mL reconstituted)**
Flours including corn meal	**-**	**30 g**	**100 g**
Fruit juices: lemon or lime	**28 mL**	**5 mL**	**25 mL**
Infant formulas, Prepared (ready-to-serve)	**(as directed by label)**		**(as directed by label)**
Grains such as rice or barley	**-**	**45 g dry**	**90 g dry**
Margarine	**57 g**	**10 g**	**50 g**
Mayonnaise	**-**	**15 mL**	**30 mL**
Meat product extenders	**100 g**	**-**	**100 g⋆**

SCHEDULE K - (Concluded)

Name and Description	*Current Reasonable Daily Intake (RDI)*	*Reference Amount*	*Proposed New Reasonable Daily Intake*
Milk (flavoured)	**852 mL**	**250 mL**	**750 mL**
Milk powder	**852 mL (reconstituted)**	**250 mL (reconstituted)**	**750 mL (reconstituted)**
Milks	**852 mL**	**250 mL**	**750 mL**
Peanut butter	**28 g**	**15 g**	**30 g**
Poultry product extenders	**100 g**	**-**	**100 g⋆**
Simulated meat products	**100 g**	**100 g**	**100 g⋆**
Simulated poultry products	**100 g**	**100 g**	**100 g⋆**
Skim and partly skimmed milk	**852 mL**	**250 mL**	**750 mL**
Skim and partly skimmed milk, flavoured	**853 mL**	**250 mL**	**750 mL**
Sterilized milk	**852.0 mL**	**250 mL**	**750 mL**
Vegetable juices	**114 mL**	**250 mL**	**500 mL**
Vegetable oil	**-**	**10 mL**	**60 mL**
Yeast	**14.0 g**	**-**	**14.0 g**

⋆ Retained because of Regulations in Division 14 & Division 22

Appendix I -

Proposed Nutrient Levels for Enriched Rice

Nutrient	Levels (per 100 g of milled rice or pre-cooked rice)
Thiamin (mg)	0.44-0.88 (mandatory)
Riboflavin (mg)	0.26-0.52 (mandatory)
Niacin (mg)	3.5-7.0 (mandatory)
Folic acid (mg)	0.150 - 0.300 (mandatory)
Iron (mg)	2.9 - 5.7 (mandatory)
Calcium (mg)	110-220 (optional)
Vitamin B_6 (mg)	0.6 (optional)
Pantothenic acid (mg)	1.2 (optional)
Magnesium (mg)	140 (optional)

Appendix J - Proposed Nutrient Levels for Fortification of Corn Meal

Nutrient	Levels (per 100 g of corn meal)
Thiamin (mg)	0.44- 0.66
Riboflavin (mg)	0.26- 0.40
Niacin (mg)	3.5- 5.3
Folic acid (mg)	0.15- 0.22
Iron (mg)	2.9- 5.7
Calcium (mg)	110
Vitamin D (μg)	not permitted

Appendix K - Proposed Regulated List of Vitamin Compounds and Mineral Salts

Vitamin compounds and mineral salts which may be added to foods as nutrient sources

Unless otherwise noted, specifications are set out in the *Food Chemicals Codex,* Fifth Edition, 2003 published by the National Academy of Sciences, Washington, D. C., United States, as amended from time to time.

Vitamin compounds

1. VITAMIN A
    - 1.1 all trans retinol
    - 1.2 retinyl acetate
    - 1.3 retinyl palmitate

2. PROVITAMIN A
    - 2.1 beta-carotene

3. VITAMIN D
    - 3.1 Vitamin D3 = cholecalciferol

4. VITAMIN E
    - 4.1 D-alpha-tocopherol
    - 4.2 DL-alpha-tocopherol
    - 4.3 D-alpha-tocopherol acetate
    - 4.4 DL-alpha-tocopherol acetate
    - 4.5 D-alpha-tocopherol acid succinate

5. VITAMIN K
    - 5.1 Phytomenadione (2-methyl-3-phytyl-1,4-naphthoquinone / phylloquinone)

6. VITAMIN B_1
    - 6.1 thiamin hydrochloride
    - 6.2 thiamin mononitrate

7. VITAMIN B_2

7.1 riboflavin

7.2 riboflavin-5'-phosphate sodium (*United States Pharmacopeia*, 2004; *Pharmacopoeia Europoeia*, 2002)

8. NIACIN

8.1 nicotinic acid amide (nicotinamide)

8.2 nicotinic acid

9. VITAMIN B_6

9.1 pyridoxine hydrochloride

10. FOLIC ACID

10.1 N-pteroyl-L-glutamic acid

11. PANTOTHENIC ACID

11.1 calcium-D-pantothenate

11.2 D-panthenol/ DL-panthenol

12. VITAMIN B_{12}

12.1 cyanocobalamin

12.2 hydroxocobalamin (*United States Pharmacopeia*, 2004; *Pharmacopoeia Europoeia*, 2002)

13. BIOTIN

13.1 D-biotin

14. VITAMIN C

14.1 L-ascorbic acid

14.2 calcium-L-ascorbate

14.3 6-palmitoyl-L-ascorbic acid (ascorbyl palmitate)

14.4 sodium-L-ascorbate

Mineral substances

1. CALCIUM

1.1 calcium carbonate

1.2 calcium chloride

1.3 tricalcium dicitrate (calcium citrate)

1.4 calcium gluconate

1.5 calcium glycerophosphate

1.6 calcium lactate

1.7 calcium hydroxide

1.8 calcium oxide

1.9 calcium dihydrogen phosphate (calcium phosphate, monobasic)

1.10 calcium hydrogen phosphate (calcium phosphate, dibasic)

1.11 tricalcium diphosphate (calcium phosphate, tribasic)

1.12 calcium sulphate

2. MAGNESIUM

2.1 magnesium hydroxide carbonate (*United States Pharmacopeia*, 2004)

2.2 magnesium chloride

2.3 magnesium gluconate

2.4 magnesium glycerophosphate (*Pharmacopoeia Europoeia*, 2002)

2.5 magnesium hydroxide

2.6 magnesium L-lactate

2.7 magnesium oxide

2.8 magnesium hydrogen phosphate (magnesium phosphate, dibasic; magnesium salt of orthophosphoric acid)

2.9 trimagnesium diphosphate (magnesium phosphate, tribasic; magnesium salt of orthophosphoric acid)

2.10 magnesium sulphate

2.11 magnesium citrate

3. IRON

3.1 ferrous fumarate

3.2 ferrous gluconate

3.2a ferrous glycinate

3.3 ferrous lactate

3.4 ferrous sulphate

3.5 ferric ammonium citrate

3.6 ferric citrate

3.6 ferric diphosphate (pyrophosphate)

3.7 hydrogen reduced iron

3.8 electrolytic iron

3.9 carbonyl iron

3.10 ferric orthophosphate

3.11 sodium ferric diphosphate

3.12 ferrous citrate

3.13 ferric saccharate

4. COPPER

4.1 cupric citrate

4.2 cupric gluconate (copper gluconate)

4.3 cupric sulphate (copper sulphate)

5. ZINC

5.1 zinc acetate (*United States Pharmacopeia*, 2004; *Pharmacopoeia Europoeia*, 2002)

5.2 zinc chloride (*United States Pharmacopeia*, 2004; *Pharmacopoeia Europoeia*, 2002)

5.3 zinc citrate

5.4 zinc gluconate

5.5 zinc oxide

5.6 zinc sulphate

6. MANGANESE

6.1 manganese (II) chloride

6.2 manganese (II) citrate

6.3 manganese (II) glycerophosphate

6.4 manganese (II) sulphate

6.5 manganese (II) gluconate

7. SELENIUM

7.1 sodium selenite (*The United States Pharmacopeia* on line 2003)

7.2 sodium selenate (*The United States Pharmacopeia* on line 2003)

8. MOLYBDENUM

8.1 sodium molybdate dihydrate (*Pharmacopoeia Europoeia*, 2002)

8.2 ammonium molybdate

9. POTASSIUM

9.1 potassium carbonate

9.2 potassium hydrogen carbonate (potassium bicarbonate)

9.3 potassium chloride

9.4 tripotassium citrate (potassium citrate)

9.5 potassium gluconate

9.6 potassium glycerophosphate

9.7 potassium L-lactate

9.8 potassium dihydrogen phosphate (potassium phosphate, monobasic)

9.9 dipotassium hydrogen phosphate (potassium phosphate, dibasic)

9.10 potassium hydroxide

10. IODINE

10.1 potassium iodide

10.2 potassium iodate

10.3 sodium iodide (United States Pharmacopeia, 2004; Pharmacopoeia Europoeia, 2002)

11. FLUORIDE

11.1 sodium fluoride

12. SODIUM

12.1 sodium carbonate

12.2 sodium hydrogen carbonate (sodium bicarbonate)

12.3 sodium chloride

12.4 trisodium citrate (sodium citrate)

12.5 sodium gluconate

12.6 sodium lactate

12.7 sodium dihydrogen phosphate (sodium phosphate, monobasic)

12.8 disodium hydrogen phosphate (sodium phosphate, dibasic)

12.9 trisodium phosphate (sodium phosphate, tribasic)

12.10 sodium hydroxide

13. Chromium

13.1 chromium chloride hexahydrate (*The United States Pharmacopeia* on line 2003)

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