Addition of Vitamins and Minerals to Foods
Policy Review and Implementation

Summary Report of Public Consultation

October 2002 - January 2003

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Executive Summary

As part of the policy review process on the addition of vitamins and minerals to foods, Health Canada invited comments on its proposals for implementing the policy recommendations which were originally described in *Addition of Vitamins and Minerals to Foods Proposed Policy Recommendations,* 1999. To facilitate public input, a discussion document was prepared entitled *Health Canada's Addition of Vitamins and Minerals Policy Review and Implementation Consultation Document*, which was posted on the Health Canada website in November 2002. Notification of the posting was sent to over 800 interested parties. Copies were also sent to about 100 representatives of all major stakeholder groups. Fifty-five responses to the document were received from representatives of food industry organizations, individual food manufacturers, from academia and the public health sector as well as from government, non-governmental organizations and other individual health professionals.

Comments on Policies: Respondents indicated that they continue to support several of the policy recommendations. These include nutrient addition to restore losses due to processing, to make a substitute food nutritionally equivalent to the food for which it is substituting, and to correct or prevent nutritional problems of public health concern through mandatory fortification. There was also general support that the Codex General Principles continue to be applied.

Respondents from the public health sector and a provincial consumer organization objected to implementation of the policy of discretionary fortification and one from academia expressed grave concerns about the proposed implementation. Both noted the potential to not only *not* benefit consumers but also to actually do harm by undermining basic principles of healthy eating and confusing consumers. The implementation of the policy can be expected to see manufacturers fortifying food with nutrients that Canadians are currently consuming in adequate amounts to meet requirements. The advertising of such foods would convey the message of an added benefit, and yet there would be no possibility of benefit.

The requirement for a nutritional rationale for discretionary fortification was considered unnecessary by some in the industry sector, but essential by the public health sectors for all nutrient additions including discretionary fortification if it is to be implemented.

Criteria for Food Vehicles: Stakeholder comments identified areas of contention which focused on discretionary fortification, particularly the selection and application of criteria for foods that would qualify. There was general, but not universal, agreement that standardized staple foods should be excluded from discretionary fortification, since there is a recognition that certain staple foods should be available to address public health concerns. However, certain industry respondents objected to the exclusion of standardized staples.

Most notably stakeholders held divergent views on the benefits and limitations of the remaining

criteria proposed for food vehicles for discretionary fortification (limits on saturated and *trans* fat, sodium, alcohol, a nutrient content criterion, and exclusion of bottled water and calorie-free beverages). The food industry respondents as well as one health professional association and one university-based program largely rejected Health Canada's proposed exclusion criteria because applying selection criteria was seen as limiting consumer choice, and as being inconsistent with the total diet approach to healthy eating. Most industry respondents proposed that no exclusion criteria be applied for food vehicles for discretionary fortification.

On the other hand respondents from the public health sector and academia were supportive of Health Canada's proposed exclusion criteria, and in some cases appealed for further restrictions regarding saturated and *trans* fat and sodium in particular. The polarization of stakeholder views was also apparent with regard to water and calorie-free beverages. The major rationale for the public health sector against "no exclusion criteria" was that the policy may foster the consumption of foods that are "inherently bad for health". Other rationales were the potential to mislead consumers about the nutritional value of fortified foods with components associated with increased risk to health (saturated and *trans* fats, sodium content in particular), or with little or no nutritional value. Public health respondents were also concerned about the difficulty in communicating the role of fortified foods of little nutritional value in the context of healthy eating messages. The public health sector was also concerned that consumers would question the adequacy of the food supply more generally.

Regarding the concern for discretionary fortification of foods that are composed mainly of sugars, most respondents considered that there was insufficient scientific evidence to support the exclusion of such foods on the basis of risk to health. However, several in the public health sector noted that increased soft drink consumption has been associated with dental caries and with obesity in children, with replacement of more nutritious drinks, and also with reduced bone mineral density in children.

The 10% Weighted Recommended Nutrient Intake (WRNI) criterion addresses the inclusion/exclusion of foods mainly sugars, and also the policy recommendation (3) that foods of little nutritional value should not be fortified at the discretion of the manufacturer. The majority of the public health respondents along with a few representatives from all other sectors agreed that a food should have a minimum nutrient content for discretionary fortification; one suggested that dietary fibre and protein be added to the WRNI list of nutrients. Food industry respondents did not support this proposed minimum nutrient content requirement and suggested that foods that are intuitively healthy may fail to qualify under this criteria.

A final area of disagreement among stakeholders regarding food vehicles was the proposal that bottled water and calorie-free beverages should not be fortified on a discretionary basis. All public health respondents and a few from the other sectors agreed that bottled water and calorie-free beverages should not be fortified. The majority of respondents who supported the

fortification of these beverages were from the food and beverage industry. As an option, a trade association proposed a new category referred to as Defined Voluntary Fortification for beverages and certain other products that would have been excluded under the proposed criteria.

Proposed risk categorization of nutrients: The public health sector and some respondents from academia supported the approach taken by Health Canada in setting the risk categories, and the placement of nutrients within the categories. However the majority of stakeholders from industry and some respondents from academia suggested that the application of the Tolerable Upper Intake Levels in discretionary fortification should await the findings of the Institute of Medicine's panel on application of the Dietary Reference Intakes to nutrition labelling and discretionary fortification and the International Life Sciences Institute's consultation on understanding Tolerable Upper Intake Levels. Specific suggestions were made to move folic acid to a lower risk category, and to move zinc to a lower risk category, if the same foods were co-fortified with copper.

Proposed levels of nutrient addition: A few of the industry respondents agreed with the proposed levels of Risk Category A nutrients at up to 100 % of the Recommended Daily Intake (RDI), but others indicated that the level was too high and would "provide an inappropriate incentive for manufacturers to add the highest amount permitted." Several respondents proposed that the Estimated Average Requirement should be used for setting the levels of nutrient additions. For nutrients in Risk Category B some respondents agreed with the proposed levels, however other questioned the difference in the levels of vitamin C proposed for foods versus beverages. With regard to Risk Category C nutrients most public health respondents, plus some respondents from other sectors agreed that Risk C nutrients should be subject to pre-market approval. However, others particularly in the industry sector proposed that some level of addition of certain Risk Category C nutrients be permitted with specific mention of calcium, vitamin D, vitamin A, folic acid, zinc, iron, iodine, copper, selenium, manganese. It was further suggested that there be a list of "zero tolerance" nutrients that would not be permitted to be added to the food supply without a specific exemption from Health Canada.

Special purpose foods: Most public health respondents along with a few representatives from the other sectors agreed with the information requirements for fortification of special purpose foods. The description of the requirements was adequate for some respondents while others thought that the level of evidence required, and details on how the evidence would be evaluated needed further explanation.

1. Introduction

Health Canada initiated a comprehensive policy review on the addition of vitamins and minerals to foods in January 1998. The policy review was conducted to take into consideration the public health role of nutrient addition to foods, consumer needs and industry concerns.

Following the release of the *Addition of Vitamins and Minerals to Foods: Proposed Policy Recommendations* in October 1999, stakeholder comments on the proposed policies, along with the publication of the new Dietary Reference Intakes (DRIs) for nutrients which are applicable to the majority of the population in Canada and the United States helped to focus efforts on developing implementation plans.

A consultation workshop to discuss options and a proposal for implementation of the policies as detailed in *Health Canada's Addition of Vitamins and Minerals Policy Review and Implementation Consultation Document* was held on November 29, 2002 in Ottawa. Over 50 representatives of all major stakeholder groups were present including those from consumer organizations, health/disease associations, professional organizations, industry organisations, academia and government. A small group format was used to facilitate discussion and obtain views on the major issues. These views have been summarized in a document which is posted on the Health Canada website:

http://www.hc-sc.gc.ca/food-aliment/english/subjects/dietary_reference_intakes/review_of_hc_policies/e_exec_report_jan200301.html

In addition, a public consultation on the proposals for implementation was conducted at the same time. When *Health Canada's Addition of Vitamins and Minerals Policy Review and Implementation Consultation Document* was posted on the Health Canada's website in November 2003, a notification and invitation to comment was sent out to over 800 interested parties via an electronic mailing list maintained by the Nutrition Evaluation Division. This report summarizes the input from 55 respondents including 29 from food industry associations and individual industries, 8 from the public health sector, 1 from a government agency (Canadian Food Inspection Agency), 8 from non-governmental health and professional organizations, 4 from academia and 5 other individuals in the health sector, referred to as 'other'. The consultation document, as well as describing Health Canada's proposals for implementation of the policies, and outlining options for discussion, also posed questions to help focus input on the areas that stakeholders had identified as contentious or unclear in a previous consultation phase. The questions also highlighted Health Canada's proposed application of the new DRIs to this policy. This report focuses on the responses to the questions and also includes other relevant comments.

2. Policy Recommendations

2.1 Response to Questions

Q. Do you have any comments on the proposals to accept Policy Recommendations 1a and 1b?

> 1(a) - It is recommended that the policy of addition of vitamins and minerals to foods to maintain and improve the nutritional quality of the food supply through (a) restoration and (b) nutritional equivalence of substitute foods be retained.
>
> 1(b) - It is recommended that the use of mandatory food fortification programs continue to be employed as warranted to correct and/or prevent nutritional problems of public health significance which cannot be adequately addressed through voluntary means.
>
> *Health Canada proposes to retain recommendation 1a and 1b.*

Policy recommendations 1a and 1b were widely supported by all stakeholder groups.

A few respondents requested a better definition of "nutritional equivalence" of substitute foods because differences in the bioavailability of nutrients in these foods calls into question whether they are indeed nutritionally equivalent. A few respondents also requested that criteria be established to ensure that a substitute food has a nutritional profile similar to the food that it replaces.

Respondents from the public health sector and some other sectors identified the need for a monitoring or dietary surveillance system in order to both aid the development of rational implementation of fortification and to also assess the impact once implemented.

Q. Do you concur with Health Canada's proposal for handling Policy Recommendations 2, 3 and 4?

2 - It is recommended that addition of vitamins and minerals not be permitted where no adequate nutritional rationale can be provided.
** Health Canada proposes that discretionary fortification under recommendation 1c not trigger a requirement for nutritional rationale.*

3 - To avoid promoting consumption of foods that might increase the risk factors for certain diseases or that have little nutritional value, it is recommended that criteria be applied to the selection of appropriate food vehicles for nutrient addition.
** Health Canada proposes that this recommendation apply only to discretionary fortification. Do you agree?*

4 - In the context of the policy recommendations, the Codex General Principles should continue to be followed.
**Health Canada proposes that the nutritional need under 1c [policy recommendation pertaining to discretionary fortification] will be interpreted loosely.*

Some respondents from each sector, except public health, supported Health Canada's proposal that discretionary fortification not trigger a requirement for a nutritional rationale. However, respondents from the public health sector and some from industry were of the view that any nutrient addition should require a nutritional rationale. Several questioned the meaning of "adequate nutritional rationale".

Regarding recommendation 3, two respondents from academia and one from each of non-government and government sectors and an 'other' individual supported Health Canada's proposal that the criteria apply only to the selection of vehicles for discretionary fortification.

Support for Health Canada's proposed "loose interpretation" of Codex General Principles for a nutritional rationale when applied to discretionary fortification was limited to a government agency, one respondent each from academia and industry and two 'other' individuals. However, most industry and public health respondents along with two non-government, and one academic respondent did not support the "loose" application of the principles, and stated explicit support the application of Codex General Principles.

3. Food Vehicles

3.1 Response to Questions

Q. Do you agree with the proposed exclusion criteria?

Health Canada proposes the following exclusion criteria be applied to foods subject to discretionary fortification on the basis of risk to health:

1. **a food that contains more than 2 g saturated and *trans* fat combined per reference amount and per 50 g if the reference amount is 30 g or 30 ml or less, and not more than 15 % of energy as saturates and *trans* be used; and**
2. **a food that contains more than 480 mg sodium per reference amount; and**
3. **a food that contains more than 0.5% alcohol; and**
4. **in order to exclude those foods which are mainly added sugars, a food that contains less than 10% Weighted Recommended Nutrient Intake for at least one nutrient per reference amount of the food. The vitamin C added to noncitrus fruit juices would be considered as meeting this requirement.**

Health Canada also proposes the exclusion of white and whole wheat flours, breads, pasta, rice, milk and margarine.

We also propose the exclusion of calorie-free beverages including bottled water from discretionary fortification. Fortification of these products could be considered under the special purpose food category.

The majority of the respondents from the industry sector as well as a health professional association, a consumer association, a university-based program and an 'other' individual did not agree with Health Canada's proposed exclusion criteria as described. These respondents commented that the criteria were too restrictive and were also inconsistent with the total diet approach. Some respondents added that the criteria would limit consumer choice and access to safe and healthy food.

Support for the proposed criteria came from a government agency and two academic respondents.

A health organization, a consumer association, several respondents from the public health sector and an academic explicitly did not support the principle of discretionary fortification. These respondents were concerned that discretionary fortification had the potential to mislead consumers to believe they needed to choose fortified products in order to obtain essential nutrients, to believe that fortified food products were nutritionally superior to traditional foods resulting in a distrust of the Canadian food supply, and to believe that they needed more nutrients than are recommended. The potential to not only *not* benefit consumers but also to actually do harm by undermining basic principles of healthy eating and confusing consumers.

However, the public health sector respondents commented that if Health Canada were to proceed with discretionary fortification they would agree with Health Canada's proposed criteria and some appealed for even more stringent limits on saturated and *trans* fat and sodium.

Q. Do you think that the scientific evidence is sufficient to exclude foods mainly sugars (10% WRNI criterion) from discretionary addition on the basis of health? Why or why not?

The majority of respondents from industry, as well asa health professional association, a nongovernmental health organization and a consumer association and two from academia thought that there was insufficient scientific evidence to warrant the exclusion of foods high in sugar, on the basis of risk to health.

However some respondents from the public health sector, and one from academia noted that foods high in sugars displace more nutritious foods in the diet and pose a risk such that increased consumption of sugar beverages has been associated with dental caries and with obesity in children. One academic respondent cited evidence suggesting that sugary drinks replace milk consumption and result in lower bone mineral content in children.

Q. Do you agree that foods should be required to have a minimum nutrient content (10% WRNI) before fortification on a discretionary basis as a safety issue? To avoid misleading the consumers about the nutritional quality of a fortified food? Why or why not?

The majority of the public health respondents, along with two respondents from each of academia and industry, along with a health professional association, a nongovernmental health organization and one 'other' individual agreed with the requirement that a food have a minimum nutrient content to qualify for discretionary fortification. Two industry respondents suggested that "food [being] fortified [should] have at least two nutrients at 10% WRNI level." One industry respondent recommended that dietary fibre and protein be added to the list of 17 nutrients on the WRNI list[1]. Most of public health respondents thought that "products with little nutritional value should be excluded from discretionary fortification", to avoid "misleading the consumer as to the nutritional quality of these foods".

However, respondents from industry and one 'other' individual did not agree with the minimum nutrient content criterion and considered it confusing and unnecessary. Some noted that foods which are intuitively healthy such as some fruit and vegetable products may fail to qualify under 10% WRNI criterion.

[1]Weighted Recommended Nutrient Intakes were incorporated into the Food and Drug Regulations in 1996 and are used as a basis for determining the significant nutrients in foods for purposes of restoration and substitute foods.

Q. Do you agree that bottled water and calorie-free beverages should not be fortified on a discretionary basis? Why or why not?

All respondents from the public health sector agreed that bottled water and calorie-free beverages should not be fortified on a discretionary basis. Others concurred: a health professional association, a nongovernmental health organization, a consumer association, a government agency, three industry respondents, one academic and one 'other' respondent. Most of the respondents who supported the fortification of bottled water and calorie-free beverages were from the industry sector, expressing a view consistent with the use of all foods as vehicles for discretionary fortification, including bottled water and calorie-free beverages.

Two respondents, one from industry and one from academia, thought that bottled water should be allowed to be fortified but not calorie-free beverages. One rationale given for this distinction was that a fortified calorie-free soft drink may be seen as a having added nutritional value and this perception may be carried over to non-fortified regular soft drinks.

As an option, a trade association proposed that a category designated as Defined Voluntary Fortification (DVF) be established for beverages. Other respondents from the beverage industry also supported this approach. The association proposed that sub-categories created under DVF would include Fortified Water-Based Beverages, Fruit Juices and Dairy/Soy Based Beverages. Another trade association suggested that a category be created to describe a water product that is fortified with vitamins and minerals as an unstandardized food, but not as a bottled water.

Q. Are there any other considerations regarding food vehicles for discretionary fortification that we have missed?

Some industry respondents indicated that the application of criteria to food vehicles was not consistent with the practices in the United States, and that this was "inconsistent with Canada's trade objectives".

It was further noted that the proposed criteria for vehicles would only serve to make "healthy Canadians even healthier" and would not reach those who might benefit from fortification of a full range of products. One industry respondent stated that "fortification policies must be designed to improve the consumption of nutrients across a full range of eating patterns."

Concern about the bioavailability of nutrients in fortified foods was expressed by some respondents. Further, a government agency urged Health Canada to set out specifications and identify forms or sources of vitamins and minerals that may be added to foods and to set these out in the Food and Drug Regulations.

3.2 - Optional Criteria for Foods - Discretionary Fortification

#1: All food may be fortified - No exclusion criteria.

Six industry respondents including a major trade association explicitly supported the option that all foods may be vehicles for discretionary fortification.

Three public health respondents, a nongovernmental health organization and a government agency explicitly did not support this option.

#2 : Excludes only foods containing defined amounts of nutrients or substances with known health risk. ie. Excludes those foods containing >2 g saturated and *trans* fat; >480 mg sodium; >0.5% alcohol.

The majority of respondents from industry, a university-based program, a health professional association and one 'other' individual did not agree with excluding foods containing >2 g saturated and *trans* fat, >480 mg of sodium and >0.5% of alcohol indicating that the criteria were too restrictive. The proposed restriction of saturated and *trans* fat would delete a number of commonly consumed foods, including certain dairy products and margarines. Some industry respondents also were concerned that the proposed sodium level was too restrictive and would exclude foods such as canned vegetables, soups and vegetable-based beverages from discretionary fortification.

On the other hand, most of the public health sector respondents proposed that the exclusion criteria for fatty acids be lowered from 2 grams of saturated and *trans* fat per reference amount to 0.4 grams combined. An academic respondent also suggested that "the saturated and *trans* fat criteria be revised to exclude products with anything more than a trace amount of these nutrients". The public health respondents suggested that "the exclusion criteria for sodium should be at the level for the low sodium claim, 140 mg sodium per reference amount." The majority of the respondents agreed with the exclusion of alcohol.

Two respondents, one from industry and a government agency questioned why an exclusion for cholesterol was not addressed.

#3: Excludes foods that are not consistent with healthy eating recommendations (excludes sugary foods such as candies and desserts). ie. Excludes those identified in number 2 and those with <10% WRNI for at least one nutrient.

There was agreement among respondents from the public health sector, along with one from

industry and one from academia, on the exclusion of foods that are composed mainly of sugars. One public health respondent suggested that Health Canada consider an additional requirement such that "if a food contains sugars added in processing, the added sugars contribute less than 25% of Calories."

Respondents from industry did not agree that the sugar content of foods should be a factor in food vehicles for discretionary fortification. Some industry representatives thought that the criterion lacked consistency with Health Canada's position on sugars for mandatory nutrition labelling. Industry respondents also noted that the exclusion of foods consisting mainly of sugars sends the wrong message to consumers about good food / bad food. A university-based program also stated that this criterion would eliminate obvious foods consumed by target groups [at risk of inadequate intakes]. This respondent also commented that the current levels of sugar intake do not pose a risk to health, and are well below the maximum upper level suggested by the Institute of Medicine report on *Dietary Reference Intakes for Energy, Carbohydrate, Fibre, Fat, Fatty Acids, Cholesterol, Protein and Amino Acids*.

#4: Excludes certain standardized staple foods. ie. Flours, breads, pasta, rice, milk, margarine. This may stand alone or be applied in combination with number 2 or 3.

There was general support among respondents from all sectors, except some industry groups, to exclude the standardized staple foods. Of the seven respondents from the industry sector who were opposed to this criterion, six represented manufacturers of standardized staple foods, who expressed the desire to have the opportunity to apply discretionary fortification to these foods. The foods that they would like to have available for discretionary fortification were flours, breads, pastas, rice, milk, cheese, other dairy products and margarine. One stakeholder commented that "the fortification of staple foods does not present a significant risk".

Two non-government representatives recommended that the "exclusion of standardized foods as vehicles for discretionary fortification should be reviewed on a case-by-case basis".

#5: Excludes water and zero calorie beverages. This may be applied in combination with number 2, 3 or 4.

As seen from the earlier question (on page 9) regarding the fortification of bottled water and calorie-free drinks on a discretionary basis, there were comments for and against this exclusion. The proposal from a trade association for beverages to have their own category and the subsequent support from the beverage industry for this recommendation was noted.

4. Risk Categories

4.1 Response to Questions

Q. Do you agree with the three proposed risk categories for nutrient addition to foods?

The majority of respondents from the public health sector, three from non-government organizations including a health professional association, one academic, a government agency, one from industry and an individual from the 'other' group indicated agreement with the three proposed risk categories, but in some cases with qualifications. Most public health respondents and a consumer association added that they would like to see a consideration of a health rationale, not just safety, to be included for all three risk categories.

Disagreement with the categorization of nutrients into the three risk groups was widespread in responses from the industry sector particularly on the basis of the methods used in their derivation.

Q. Do you agree with the method used to determine the risk categories?

Agreement with the method used came from some respondents from each stakeholder group. These included the a government agency, a health professional association, a consumer association, a nongovernmental health organization, a few respondents from industry, two academic respondents, one from public health and an "other" individual.

Respondents from the industry sector largely disagreed with the method used to determine the risk categories. Several respondents commented that the ULs used to determine the risk categories were based on limited research data for most nutrients, and that the ULs had been accepted prematurely.

One industry group commented that the method "only considers risk in determining the categories", and that "a risk/benefit analysis, rather than risk only analysis, should be conducted".

The public health sector respondents thought that there should be scientific consensus among experts in the field concerning the method used to determine risk categories.

Q. Do you agree with the placement of the nutrients within the categories?

While there was partial support for the placement of the nutrients within the categories, by 2 or 3 respondents from each sector, those from the public health sector thought that scientific consensus among experts in the field about such placement was needed. One industry respondent indicated that more information on other risk assessment methods would be necessary before giving agreement.

Eight industry respondents disagreed with the placement of the nutrients within the categories, and one suggested that the placement "should be based in a risk/benefit analysis, rather than a risk only analysis". Three respondents also noted that the proposed placement of the nutrients in their respective risk categories was linked to the proposed levels of addition. (Addition of Risk Category C nutrients would be subject to individual regulation.) Thus the placement of nutrients in Risk Category C would prevent their discretionary addition. Beverage manufacturers noted that this categorization would prevent them from adding minerals such as calcium, zinc and vitamins such as A, D and folic acid .

4.2 Comments on placement of the nutrients within the individual risk categories.

Few commented on the placement of the nutrients within the individual categories, except regarding Risk Category C, having noted their concerns as above.

> **Those nutrients with lowest risk, ie. those nutrients with evidence indicating no UL, are categorized as Risk A: thiamin, riboflavin, vitamin B12, pantothenic acid, biotin.**

One 'other' individual respondent suggested that β carotene should be included in Risk Category A.

> **Those with a known low degree of risk, ie. those with a UL, but with a wide margin of safety (>10 fold) between UL for children or most vulnerable group and RDA (AI) for adults, or those with a narrow margin of safety (0-5 fold), including some overlap between children's UL and adult RDA (AI), and a non-serious critical adverse effect were categorized as Risk B: vitamin B6, E, C, niacin.**

One US trade association suggested that vitamin C and niacin should be moved to Risk Category A.

> **Those with a high degree of risk, ie those with a UL, and with serious adverse effects, and either a narrow margin of safety or an overlap between children's UL and adult RDA were categorized as Risk C: calcium, folic acid, vitamin A, zinc, vitamin D, iodine, iron, copper, selenium, manganese, magnesium.**

The majority of comments concerning the Risk Category C came from the industry sector but there were also a small number from the other sectors. Some industry respondents wanted the option to fortify with some of the nutrients in Risk Category C. Calcium addition was of

particular interest to several industry groups. Two industry respondents suggested that margarine fortified with calcium would meet the needs of consumers who are looking for non-dairy alternative sources of calcium. Another industry respondent recommended that if Health Canada maintains its current structure for the risk categories, vitamin D and calcium be moved to at least the Risk B Category, to allow discretionary fortification of foods consumed by vulnerable groups (those at risk of osteoporosis). A trade association also did not agree that calcium and folic acid should be placed in Risk C Category, due to their demonstrated health benefits and the "absence of conclusive evidence" of either a narrow margin of safety or serious side effects. An industry and an 'other' respondent also suggested that folic acid be moved to a more lenient category while another respondent suggested that folic acid addition be paired with vitamin B_{12} and moved to Risk Category A. It was suggested by an academic respondent that zinc and copper be added to foods together since high intakes of copper can ameliorate the adverse effect of excessive zinc on copper status. An industry representative also suggested that iron be permitted for discretionary fortification. However, one public health respondent commented that it is necessary to consider the needs of people with hemochromatosis (who absorb and store too much iron), noting that iron is already abundant in the food supply because of high levels of iron in fortified grain products.

One industry respondent recommended that the nutrients in Risk Category C should include only those nutrients "with a clear scientific basis of safety and serious adverse effects grounded in a substantial number of clinical studies." Another commented that under the current proposal, the nutrients in the proposed Risk Category C would be "unnecessarily restricted".

One industry respondent agreed with Health Canada's proposal that the "that Category C nutrients should not be included under discretionary fortification."

4.3 Additional comments on risk categories

A number of the industry respondents and a university-based program suggested that Health Canada "await consideration of the reports from Health Canada's Expert Advisory Committee on Dietary Reference Intakes, the Food and Nutrition Board's Subcommittee on Interpretation and Uses of the DRIs, International Life Sciences Institute (ILSI) North America's Committee on ULs (Tolerable Upper Levels)" before making any decision on the risk categories.

Several respondents from industry and 'other' individuals suggested that the Estimated Average Requirement (EAR) be used in place of the Recommended Dietary Allowance (RDA) in setting levels of addition, and also in setting the risk categories. Some respondents believe that "additional categories and movement between categories may be warranted and scientifically justified."

5. Levels of Addition

5.1 Response to Questions

Q. Do you agree with the proposed level of addition of Risk A nutrients to qualifying foods for discretionary addition? Why or why not?

Nutrients which may be added to qualifying foods are those nutrients with evidence indicating to UL: thiamin, riboflavin, vitamin B12, pantothenic acid, biotin. These nutrients may be added up to the amounts below, per reference amount. These amounts are approximately 100% of the Recommended Daily Intake (RDI) currently used for labelling purposes.

thiamin 1.2 mg; riboflavin 1.3 mg; pantothenate 5 mg; biotin 30 mcg; vitamin B_{12} 2.4 mcg

The proposed level of addition of Risk Category A nutrients was supported by respondents from three industry groups, two academic and two respondents from the category 'other'.

However, others in the industry sector did not support the proposed levels. One industry respondent did not agree with any food being fortified up to 100% RDI of any nutrient, and suggested the maximum should be 50%. The majority of the public health respondents also did not see a rationale for adding 100% of the RDI to single food items without evidence that the specific nutrient is lacking in the Canadian food supply. Further, it was noted by several respondents that the possibility that many foods could contain 100% RDI for several nutrients may mislead consumers with respect to the nutritional quality of foods, the nutritional differences between foods, or cause them to no longer believe that eating a variety of foods is still desirable. One academic respondent noted that fortifying single foods with up to 100% of any reference value "works to undermine the nutrition education messages about the importance of variety and balance".

Some industry groups including a major trade association, along with a health professional association, a consumer association, a governmental public health group and an 'other' individual suggested that the EAR be used as a benchmark for setting the levels of nutrient additions. The EAR was suggested as a level having the maximum potential for benefit and least potential for waste and for misleading consumers .

Q. Do you agree with the proposed levels of Risk B nutrients such if all qualifying foods had the proposed levels of addition, the risk of excessive

intakes from foods is less than 1% for the most exposed group, usually young men? Why or why not?

Nutrients which may be added to qualifying foods are those nutrients with a UL and a wide margin of safety (>10 fold), or a narrow margin of safety (0-5 fold) and a non-serious adverse effect. Nutrients in this category are vitamin E, B_6, C and niacin. These nutrients may be added up to the amounts below, per reference amount. The amounts are approximately 50% of the Recommended Daily Intake. In addition all qualifying beverages may be fortified with vitamin C up to 150% RDI.

vitamin E 7 mg; vitamin B_6 0.65 mg; vitamin C 45 mg for foods, 90mg for beverages; niacin 8 mg

Most respondents to this question commented on the proposed levels of risk B nutrients, rather than the exposure question specifically. However one academic and three public health respondents commented that they were unable to assess that the degree of exposure from the proposed level of addition was less than 1%, and that this needed to be evaluated by scientific experts

The proposed levels of Risk B nutrients were seen as acceptable by three industry respondents, a health professional association, a government agency, and an 'other' individual. An academic also agreed with the proposed levels with a few modifications, to add zinc, copper and magnesium to this category.

Some industry representatives disagreed with the proposed levels, but only commented with respect to the use of the EAR rather than the RDA to set the amounts. One industry respondent disagreed with the 50% level and suggested that the level should be reduced to 25% RDI.

Regarding the addition of vitamin C to foods and beverages, some were unclear as to why there was a difference in the levels of this vitamin to be allowed in foods as opposed to beverages.

Q. Do you agree with the addition of any Risk C nutrients should be subject to pre-market review and regulation?

There was agreement among some respondents from all sectors that the addition of any Risk C nutrient should be subject to pre-market review and regulation. These respondents included almost all from the public health sector, two from each of academia, industry, 'other' individuals as well as a health professional association and a government agency. One industry respondent suggested that the addition of any Risk C nutrient should be reviewed on a case-by-case basis by Health Canada.

Because the addition of Risk Category C nutrient would be restricted by this mechanism, Refreshments Canada considered that the addition of nutrients in this category would be "unnecessarily restricted under this proposal". Some industry representatives disagreed with the

proposed levels, but only commented with respect to the use of the EAR to set the amounts.

Q. Have we missed some issues that should be addressed under discretionary fortification?

Most of the public health sector respondents, along with one industry respondent, a health professional association and a consumer association questioned the lack of reference to post-market evaluation, and emphasized the importance of measuring if the proposed policy changes result in improvement in the nutritional health of Canadians, and in reducing the burden of disease.

Concerning the use of the EAR rather than the RDA in setting levels of addition, a few industry members noted that the RDA was intended as a goal for daily intake by individuals, whereas the EAR should be used in establishing dietary goals for groups. Since the fortification policy will be addressing population goals, these respondents thought that the EAR would be a more useful tool as a bench mark for setting levels of addition. Public health representatives also suggested that fortification should be based on the most recent evidence from the Dietary Reference Intakes and not the [older] RNIs (Recommended Nutrient Intakes).

6. Special Purpose Foods

6.1 Response to Questions

Q. Do you agree with the information requirements for fortification of special purpose foods? Why or why not?

Most respondents from public health, a few from industry, two from academia, a non-governmental respondent and an 'other' individual agreed with the information requirements for fortification of special purpose foods. Several industry groups expressed support for the concept of special purpose foods tailored to the nutritional needs of specific sub-groups. However, one industry respondent also commented that under a flexible system of discretionary fortification, the need for future special purpose foods would be limited.

Two industry respondents required clarification about the information requirements and evidence needs for the fortification of special purpose foods. In particular Roche Vitamins Canada Inc. proposed that Health Canada develop standards of evidence in support of special purpose foods. In addition the a nongovernmental organization noted that "high evidentiary standards would be required for any claim of benefits or efficacy of products as well as claims for safety".

Three public health respondents and a health professional association noted that submissions for special purpose foods should provide evidence that special groups (athletes, people with chronic conditions, etc.) can not acquire [particular] nutrients through the existing food supply and provide evidence of inadequate intake of the nutrients in question.

Others commented that evidence must show that the special purpose food will reach the intended target group. Further, the implications of the product being consumed by others outside the target group must be addressed.

Q. Are the information requirements adequately described for your implementation?

Several industry respondents commented that the information requirements were not described adequately. More detail was required regarding the quantity and quality of evidence needed to support the "rationale for targeting a special purpose food to a specific group". Details on how the evidence would be evaluated were also needed.

Q. Have we missed some issues for this product category?

The need for labelling of special purpose foods to clearly identify the target groups and to discourage consumption of the food by other population sub-groups at risk was noted by the a government agency as well as a health professional association, a consumer association, a respondent from public health and one from academia. An industry respondent commented that the labelling of special purpose foods must be strictly regulated.

Two industry representatives stated that the Interim Marketing Authorization was the appropriate regulatory vehicle to enable development and launch of a special purpose food.