

**Addition of Vitamins and Minerals to Foods
Policy Review and Implementation:
Food Vehicles for Discretionary Fortification**

**Summary report of Stakeholder Consultation
held June 23, 2003
Ottawa**

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Executive Summary

As part of the policy review process on the addition of vitamins and minerals to foods, a consultation workshop on Food Vehicles for Discretionary Fortification was held on June 23, 2003 in Ottawa. Previous consultations had indicated that there remained some outstanding issues to be resolved with regard to discretionary fortification, most notably the food vehicles that could be fortified. Forty-two representatives of all major stakeholder groups were present. Stakeholders discussed four main options for food vehicles that could be fortified at the discretion of manufacturers. A small group format with a mix of the various stakeholder groups represented at each table was used to facilitate discussion and obtain views on the options. This report summarizes the deliberations and preferred option identified by each table.

The options under consideration were:

Option One: no exclusion criteria, except a defined list of standardized staple foods;

Option Two: exclusion on the basis of foods with components associated with risk to health (*excludes foods with saturated and trans fat >2 g combined*§; sodium >480 mg *; alcohol >0.5% (* per reference amount and per serving of stated size or per 100 g if the food is a prepackaged meal) (§ this criterion is intended to be the same as that for the “low in saturated fatty acids” claim which also requires that the food provide 15% or less energy from the sum of saturated fatty acids and trans fatty acids);*

Option Three: exclusions related to health concerns (*excludes foods with saturated and trans fat >2 g combined*§; sodium >480 mg*; alcohol >0.5% (* per reference amount and per serving of stated size or per 100 g if the food is a prepackaged meal) (§ this criterion is intended to be the same as that for the “low in saturated fatty acids” claim which also requires that the food provide 15% or less energy from the sum of saturated fatty acids and trans fatty acids); excludes foods that do not contain 10% Weighted Recommended Nutrient Intake (WRNI) for at least one nutrient);*

Option Four: defined voluntary fortification, by food product category, e.g., beverages, breakfast cereals, with specified levels of addition for each product category.

Participants indicated that certain issues made it difficult for the discussion to move forward on the food vehicles for discretionary fortification. These issues included the need for further understanding of the rationale for the list of excluded standardized foods, the not-yet-available advice from the Institute of Medicine on applying the Dietary Reference Intakes to discretionary fortification, and a concern with the application of the Tolerable Upper Intake Levels (UL) to assess population exposure to excessive intakes, and in setting the Risk Categories for nutrients, with a view that some of the ULs were set based on flawed science.

While there was no overall agreement with any one of the options put forward for discussion, nonetheless, the participants from four table groups supported Option Four either alone or in combination with option 3 or option 1. Option Four was recognized as a means to allow certain food categories which would otherwise be excluded on the basis of the defined criteria to have specified levels of nutrient addition. Option Two was not explicitly supported by any group. Option One was preferred by one table, but with the assumption that some of the higher risk nutrients could be permitted, and that this option would be used in conjunction with Option Four.

A discussion of the pros and cons of each option, and of the preferred option(s) by each table led to an understanding articulated by the facilitator of the meeting that Health Canada's final decision on food vehicles for discretionary fortification, while not satisfying everyone, would be informed and reasonable.

1. Introduction

Health Canada has been conducting a review of Canada's policy on the addition of vitamins and minerals to foods since 1998. The new policy and regulations that will follow will confirm the use of fortification to address public health issues and maintain the nutritional quality of the food supply. The new policy will establish a new category of discretionary fortification and an expanded category of special purpose foods. This will give Canadians more choices in the foods they buy while maintaining Health Canada's responsibility to ensure that the food supply is both nutritious and safe.

Following the publication of the *Addition of Vitamins and Minerals to Foods Proposed Policy Recommendations* in 1999, stakeholders provided feedback on the proposals. Also over the period 1997-2002 the Institute of Medicine (IOM) has published a series of reports on reference values for nutrient intakes, the Dietary Reference Intakes (DRIs), which have provided useful tools and benchmarks in assessing various scenarios of nutrient addition to foods through statistical modelling.

Stakeholders were consulted on the current status of the policy recommendations and proposals for implementation during November to January 2003. The responses indicated that, although there was general agreement on most of the proposals for implementing the policy recommendations, the food vehicles for discretionary fortification still required discussion. A report of stakeholder comments on the consultation is posted on the Health Canada website http://www.hc-sc.gc.ca/food-aliment/ns-sc/ne-en/nq-qn/e_summary_report_oct-jan01.html

As well, a proposal for defined voluntary fortification for categories of foods that do not qualify under the exclusion criteria proposed in the recent consultation also required discussion with stakeholders.

2. This consultation

2.1 Purpose

The purpose of the consultation, held on June 23, 2003, was to inform Health Canada's final consideration of foods that may be fortified at the discretion of manufacturers. Various options were examined including the option of defined voluntary fortification for those food products that would not qualify under the conditions that had been proposed previously, in October 2002 (http://www.hc-sc.gc.ca/food-aliment/ns-sc/ne-en/nq-qn/e_consultation_oct3001.html)

To help focus the discussion, a Consultation Document entitled *Addition of Vitamins and Minerals Policy Review and Implementation-Food Vehicles for Discretionary Fortification* was sent to all participants prior to the workshop. The document presented four options for criteria for foods for discretionary fortification, each of which would exclude a list of standardized staple foods: Option One: no exclusions; Option Two: exclusions based on components with well-recognized risk to health; Option Three: exclusions related to health concerns; Option Four: defined voluntary fortification, with no overall exclusion applied. The impact of each of the options on food and nutrients and the level which could be added with minimum risk of excessive intakes in the Canadian population was outlined. The document also considered some of the pros and cons of each option from the perspective of each stakeholder group.

2.2 Opening Remarks

Dr. Karen Dodds, Director General, Food Directorate, Health Products and Food Branch at Health Canada provided context for the consultation with regard to the overall fortification policy, as well as to the Government of Canada Regulatory Policy. First, participants were reminded that discretionary fortification is only one aspect of the fortification policy. Fortification in Canada has had a long history of successfully addressing nutrition issues of public health concern, and this approach will continue to be used, should such problems emerge. Second, it was noted that in developing regulatory proposals for discretionary fortification, Health Canada, in keeping with the government's Regulatory Policy, does not want to unduly restrict industry innovation or the benefits that consumers might receive from access to these products, nor impose any unnecessary regulatory burden.

Further, in developing technical regulations such as those dealing with the addition of vitamins and minerals to foods, Health Canada must also take account of the obligations laid out in several international agreements, including the World Trade Organization Technical Barriers to Trade Agreement, the Sanitary and Phytosanitary Agreement and the North American Free Trade Agreement Articles on Technical Barriers to Trade and Sanitary and Phytosanitary Measures.

The systematic risk assessments conducted by the IOM in establishing the ULs provide Health

Canada with benchmarks to guide the assessment of the safety of food fortification options and they will continue to be used in this manner.

There is, however, growing recognition of the potential significant outcomes of closer regulatory cooperation with the United States (US). One relevant reflection of this is the collaboration of Health Canada, the US Food and Drug Administration and the US Department of Agriculture in contracting with the IOM to provide guidance on the use of the DRIs in discretionary fortification. While we have made extensive use of the guidance provided in the DRI reports, including the report on Applications in Dietary Assessment, Health Canada is awaiting the advice to be provided by the IOM by early fall 2003 before finalizing the risk categorization of nutrients.

We have decided that staple foods should not be eligible for discretionary fortification as these foods are pervasive throughout our food supply and a change in their nutrient content could have a profound effect on the nutrient intakes of Canadians. Many of these foods are already fortified to address public health concerns.

Health Canada must make a decision on discretionary fortification that is based on the issues and an understanding of stakeholder perspectives.

2.3 The Process

Attending the consultation were 42 participants representing the public health sector, industry groups and a few individual industries, academia, government, health/disease non governmental organizations and consumer groups, and a member of Health Canada's External Advisory Panel on DRI Implementation. Four former members of the External Advisory Panel on the Addition of Vitamins and Minerals policy review attended.

A presentation was given summarizing the stakeholder response to the October-January 2003 consultation and updating the current status of the policy, in light of these responses. In addition, each of the four options was presented with the results of statistical modelling to illustrate the impact of low to medium levels of fortification with certain nutrients on the intakes of Canadians. A copy of the presentation was given to each participant, and is available upon request.

Stakeholders were asked to consider the pros and cons of each option, and to identify possible solutions to some of the major draw backs. Finally they were asked to identify their preferred option. A facilitated small group format with a mix of the various stakeholder groups represented at each table was used to help focus the discussion.

2.4 This Report

This report summarizes the perspective from each table based on the participants' comments at the table discussion on the four options below. The pros and cons for each option are

summarized. Although each table was intended to have representation from each stakeholder group, this was not always achieved. Thus, the report focuses on the discussion and recommendations of each table.

Food Vehicles for Discretionary Fortification - Options

Note: All options would exclude certain standardized staple foods because of their pervasiveness in the food supply, and the potential for widespread exposure to excessive or imbalanced intakes if these foods were to be fortified at the discretion of manufacturers. Furthermore, because of this feature, they are often the best food vehicles for mandatory fortification to address nutritional problems of public health concern. The list of excluded standardized foods includes flours, breads, pasta, rice, milk and cream, varietal cheeses, butter and margarine, sugar, salt, pepper, other spices, leavening agents, artificial sweeteners.

Option One: No exclusion criteria (except certain standardized staples as above).

Option Two: Exclusion on the basis of foods with components associated with risk to health. *Excludes foods with saturated and trans fat >2 g combined*§; sodium >480 mg*; alcohol >0.5% (* per reference amount and per serving of stated size or per 100 g if the food is a prepackaged meal) (§ this criterion is intended to be the same as that for the “low in saturated fatty acids” claim which also requires that the food provide 15% or less energy from the sum of saturated fatty acids and trans fatty acids)*

Option Three: Exclusions related to health concerns. *Excludes foods with saturated and trans fat >2 g combined*§; sodium >480 mg*; alcohol >0.5% (* per reference amount and per serving of stated size or per 100 g if the food is a prepackaged meal) (§ this criterion is intended to be the same as that for the “low in saturated fatty acids” claim which also requires that the food provide 15% or less energy from the sum of saturated fatty acids and trans fatty acids); excludes foods that do not contain 10% Weighted Recommended Nutrient Intake (WRNI) for at least one nutrient)*

Option Four: Defined voluntary fortification, by food product category, e.g., beverages, breakfast cereals, with specified levels of addition for each product category.

3. Results: Table Discussion, Concerns and Summary of Preferred Options

3.1 Table One

Discussion and concerns

Three concerns affected the deliberations of this table. These were firstly, the exclusion of the standardized foods from discretionary fortification, secondly, the difficulty in evaluating the options in the absence of the IOM report [due early fall] on the application of the DRIs to

discretionary fortification, and thirdly, the view that some of the current ULs are based on flawed science.

Participants commented that industry would not fortify a food unless there was a market for the product, nor would industry implement a sprinkling of a low level of nutrients in the food supply.

Preferred Option

Table One favoured a liberal policy which would be supported by education and labelling to make it effective and not misleading. This Table chose Option One blended with Option Four. The participants made the assumption that Option One would be modified to allow some Risk Category C nutrients such as calcium and trace minerals and that Option Four would “handle” the remaining Category C nutrients [by defining nutrients and levels for each product category]. As well, they recommended the addition of a modified version of the US “Jelly bean rule”, with the intention of excluding candies and snack foods; the modified “Jelly bean rule” would exclude those food products that did not meet a minimum level of nutritional value. It was also recommended that Health Canada use flexibility in setting the levels of addition, based on consumption patterns.

Table One participants suggested that the implementation of Option Four could be done over a fixed time frame in which industry would apply to the government as products were developed.

3.2 Table Two

Discussion and concerns

Table Two expressed some overarching concerns that affected their consideration of all of the options. The main concern was that it was difficult and possibly premature to make decisions about the options in the absence of the forthcoming IOM report on the application of the DRIs to discretionary fortification. The final placement of nutrients in the three Risk Categories was uncertain until the release of the IOM report.

Another concern was the potential for the regulations respecting drugs and natural health products to act as escape routes for fortified products that do not meet the Food Regulations.

Participants also noted that consumer choice may be affected by the availability of fortified foods: the perception that a healthy diet may be achieved by eating natural foods may be skewed by the availability of fortified foods that have little or no other nutritional value and the perception that it is no longer necessary to consume a healthy diet to meet nutritional needs.

Table Two participants commented that industry would not be looking at fortifying foods to 100% [of the RDA] for several reasons, including the fact that formulations would not allow fortification at this level (it would produce unstable colours, for example) and it would be costly to fortify to that level.

Participants at Table Two questioned the risk assessment modelling which presented maximum

exposure of the population to intakes of nutrients under each option. The per cent of the population with intakes over the UL, as well as the shift in the intake distribution curve were presented but benefit was not emphasized. They questioned how risk of excessive intake was weighed against benefit under these scenarios.

Table Two had unanswered questions about the list of excluded standardized foods and wanted to know how the list came about.

Preferred Option

Table Two strongly chose Option Three with the allowance for defined voluntary fortification (Option Four) to include broad categories of products, for example, those which were excluded in the current description of Option Three (e. g., beverages).

3.3 Table Three

Discussion and concerns

As with Tables One and Two, this Table indicated that there were missing pieces needed for the selection of options for food vehicles: the need for the IOM report; more information on the list of excluded standardized foods; and concern for the application of ULs, with the view that some of the ULs are based on flawed science.

Preferred Option

Table Three preferred Option Four with several recommendations for implementation. It was seen as the most flexible regarding qualifying criteria. From the food inspection agency perspective, the option needed to be easily enforceable with clear criteria for food categories. Successful application of Option Four would require clear principles for advertising, labelling, education to ensure that information was truthful and not misleading. As well, this Table thought that some criteria could be applied within food categories, such as levels of saturated and *trans* fats and sodium, and that each category would have its own standard and criteria.

This group also had some concerns associated with choosing this option. They felt that there was a possibility for the creation of an unlevel playing field (i.e., if there was not a category for some foods). As well, the exclusion of some foods of low nutritional value (by applying the 10% WRNI criterion) was seen as positive by some, but negative by others since it could lead to the notion of “healthy/good” versus “unhealthy/bad” foods. Application of the criteria for Option Three would exclude some nutrient dense foods.

3.4 Table Four

Discussion and Concerns

Table Four had a fundamental disagreement among its participants regarding the need for a nutritional rationale when determining whether a food may be fortified (in the context, of course, of discretionary fortification). As well, there was an ideological disagreement among the stakeholders as to the role of Health Canada. Is it to ensure that products are safe or is it about

the protection of Canadians from perceived “deception” or misinformation about what constitutes a healthy product? Participants also raised concerns regarding the assumptions made in the modelling scenarios; they did not reflect realistic penetration of fortified products in the market and interactions between nutrients were also not included in the analysis. They believed that Health Canada should be disclosing all of the data pertaining to the issues being discussed as they could see no point in giving feedback if they only had half of the picture [regarding market penetration and historical time lines of the implementation of fortification by industry].

Preferred Option

Despite these objections, and with strong reservations around the lack of a requirement for a nutritional rationale, there was a greatest agreement around Options Three and Four combined. Further discussion was required on the criteria for the categories under Option Four

3.5 Table Five

Discussion and Concerns

Participants at this table had three issues which framed their discussions of the options. Firstly, they saw a strong need for consistency between the fortification policy and existing nutrition policies. Secondly, they recognized the difficulty in discussing any of the options before the IOM report is released. Thirdly, the need for enforceable and practical regulation was recognized.

Preferred Option

There was no consensus within this group as to the most preferred option. There was no support for Option One as stated. However, there was some support if significant additions of Risk Category C nutrients were allowed. Option Two was seen as sensible, except that the sodium criteria would exclude some otherwise nutritious products (e.g. soup). Option Three was acceptable if it was modified to include beverages and other products not included under the option, as currently written. There was no support for Option Four as presented, and a representative of the proponents of defined voluntary fortification commented that it was not intended as a stand-alone option. Others noted that Option Four did not meet key public health issues.

4. Summary and Conclusions

Some of the issues that made it difficult for participants to move forward on the food vehicles for discretionary fortification were noted, including the need for further understanding of the rationale for the list of excluded standardized foods, the anticipated advice from the IOM on applying the DRIs to discretionary fortification, and a concern with the application of the ULs to assess population exposure to excessive intakes, and in setting the Risk Categories for nutrients, with a view that some of the ULs were set based on flawed science.

While there was no overall agreement with any one of the options put forward for discussion, nonetheless, the participants in four table groups supported Option Four either alone or in

combination with Option Three or Option One. Option Four was recognized as a scheme to allow certain food categories which would otherwise be excluded on the basis of the exclusion criteria to have specified levels of nutrient addition. Option Two was not explicitly supported by any group. Option 1 was preferred by one table, but with the potential to add some of the nutrients in Risk Category C, in conjunction with Option 4.

A discussion of the pros and cons of each option, and of the preferred option(s) by each table led to an understanding articulated by the facilitator of the meeting that Health Canada's final decision on food vehicles for discretionary fortification, while not satisfying everyone, would be informed and reasonable.

Annex 1-Pros and Cons of each Option

Annex One
Pros and Cons and Solutions to Discretionary Fortification Options

Option One - No Exclusions (except the named standardized foods)	
Pros	Cons
For Consumers	
<ul style="list-style-type: none"> • maximizes consumer choice of nutrient sources in the diet • discretionary fortification of foods in the other category of Canada's Food Guide to Healthy Eating (CFGHE) may provide nutrient sources to those segments of the population who regularly consume a large proportion of their diet from the "Other Foods" category • maximizes sources of Risk Category A & B nutrients • increases options of fortified products • as more fortification - more awareness - consumers will want to find out more - will engage the market • by fortifying any and all foods, you'll be able to reach all populations 	<ul style="list-style-type: none"> • may increase consumption of foods with components associated with increased risk to health with the perception that these are healthier than the unfortified food counterparts • may question the adequacy of the food supply if this policy results in a greater proliferation of fortified foods • may be misled about the nutritional quality of certain fortified foods • may be confused about healthy food choices • may receive limited nutritional benefit because only Risk Category A , and modest levels of Risk Category B nutrients could be added, and most of these are nutrients not lacking in the diets of most Canadians • because nutrients that are supposed to be together are not - are they going to be added together? • even with low cal options - consumers still cannot make a proper choice • don't see advantage of maximizing consumer choice • levels too low to make a difference
For the Public Health Sector	
<ul style="list-style-type: none"> • consistent with notion that all foods have a place in a healthy diet 	<ul style="list-style-type: none"> • challenge for educators • Makes nutrient intake analysis more complex • doesn't address major public health issues, e.g. obesity • may increase prevalence of chronic diseases • may spend resources educating the public on fortified foods for which there is little or no inadequacy in the Canadian diet • increased difficulty in telling people about their food choices based on nutrient additions • some foods are more nutritious than others • will not increase nutritional benefit
For Government	
<ul style="list-style-type: none"> • minimal regulatory burden • aids NAFTA negotiations • reducing technical trade barriers 	<ul style="list-style-type: none"> • potentially inconsistent re:role in health protection • inconsistent with policy recommendation 3 (to avoid promoting the consumption of foods that might increase risk factors for certain diseases or that have little nutritional value), a policy derived from earlier stakeholder consultations • increased burden to address Risk Category B & C nutrients

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Shaded sections indicate the comments provided by the consultation participants.

Annex One
Pros and Cons and Solutions to Discretionary Fortification Options

<ul style="list-style-type: none"> • forces industry to regulate itself • consistent with government's regulatory policy and smart regulations approach • supports the Agricultural Policy Framework - increasing value added products 	<ul style="list-style-type: none"> • no health promotion element to balance health protection • enforceability of maximum levels will be challenging • will require increased resources [for education and inspection]
For Industry	
<ul style="list-style-type: none"> • level playing field for all industry stakeholders (except those who produce standardized foods) • increased marketing opportunities • decreased costs for 'special' Canadian market - closer to US model, closer to EU • increased research & development • increased investment in Canada • increased product availability • more local jobs • encourages companies to sell their products under the food regulations rather than under the drug regulations. • reduces regulatory costs 	<ul style="list-style-type: none"> • may spend resources fortifying foods with nutrients for which there is little or no inadequacy in the Canadian diet • may be seen as misleading consumers about the nutritional quality of some fortified foods • limited levels of nutrients from Risk Category B could be permitted under this scenario to avoid possible exposure to excessive intakes; no room for addition of Risk Category C nutrients under this scenario • limits innovation, jobs, R&D • doesn't level playing field for those who produce standardized foods • forces industry to self-regulate • reactive approach - if problems arise more resource intensive to resolve • lack of oversight • smaller manufactures won't have necessary level of QA or QC • opportunities are marginal
In general/Questions	
<ul style="list-style-type: none"> • Hard to enforce • Low benefit to consumers and industry • Do we have data to support the "Pro" statements? • Pros are more "would" statements - Cons are more "may" - more hypothetical • Should we be basing this [nutrient addition under Option One] on inadequacy? 	
Option Two - Revised Exclusion Criteria - "Safety Only" (and excluding the named standardized foods)	
Pros	Cons
For consumers	
<ul style="list-style-type: none"> • no increased risk to health with consumption of fortified foods meeting these exclusion criteria, except for concern re: dental caries • some potential benefit to consumers because nutrients of public health interest (some of those in Risk Category C) may be added at low levels, as well as moderate levels of Risk B nutrients 	<ul style="list-style-type: none"> • may be misled about the nutritional value of some fortified foods • this would restrict consumer access to certain foods because of safety criteria • conflicting message that foods to fortify are also those already in a healthy diet • prevents fortification of some foods that consumers want - disadvantages consumers

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Annex One
Pros and Cons and Solutions to Discretionary Fortification Options

- eliminates certain types of foods, like canned soups, vegetables impacting certain consumers

For public health sector	
<ul style="list-style-type: none"> • education messages will be consistent with current nutrition recommendations • potentially creates a stronger public health stance 	<ul style="list-style-type: none"> • an educational challenge about the role of fortified foods in a healthy diet • creates belief that there are healthy/unhealthy (which could still be nutrient dense) foods • will divert scarce resources to areas where there are not clear benefits
For government	
<ul style="list-style-type: none"> • reduced regulatory burden • reduced regulatory burden compared to options 3 & 4 • supports the Agricultural Policy Framework 	<ul style="list-style-type: none"> • clear exclusion criteria will be required for enforcement so that assessment of foods by inspectors can be done easily on a category basis rather than on a case-by-case basis • potential technical trade barrier • increased burden to address risk category 'C' nutrients • sheer number of potential products - lead to enforcement challenges - need clear criteria for enforcement
For industry	
<ul style="list-style-type: none"> • will be able to add nutrients of interest to the public to a wide range of foods • industry can respond to consumer demand 	<ul style="list-style-type: none"> • some limits on the products that may have discretionary fortification • potential perception of an unlevel playing field • non-harmonized with US, EU, and possibly more • amount limits for nutrient additions is unappealing • perception of unlevel playing field among eligible foods • eliminates some good nutrient dense foods that industry may want to improve • difficult to develop palatable foods at these levels • does the evidence support the levels that have been set? • dependence on regulatory policy
In general	
<ul style="list-style-type: none"> • false assumption that consumers will change their eating habits in response to more choice of fortified foods <p>Can maximum allowance of sodium be raised higher than 480 mg?</p>	
Option Three - Exclusions related to health concerns (and excluding the named standardized foods)	
Pros	Cons
For consumers	
<ul style="list-style-type: none"> • no identified increased risk to health with consumption of fortified foods meeting these exclusion criteria • some potential benefit to consumers because nutrients of public health interest (some of those in Risk Category C) may be added at low levels, as well as moderate levels of Risk Category B nutrients 	<ul style="list-style-type: none"> • limited choice of fortified foods • some consumers who do not regularly eat according to CFGHE would not benefit from discretionary fortification under this option

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Annex One
Pros and Cons and Solutions to Discretionary Fortification Options

<ul style="list-style-type: none"> • minimizes confusion about healthy eating messages 	<ul style="list-style-type: none"> • only benefits consumers who are already consuming nutrient dense foods
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For public health

<ul style="list-style-type: none"> • education messages will be consistent with current nutrition recommendations and healthy eating messages 	<ul style="list-style-type: none"> • none apparent • promote good food/bad food not whole diet • may disadvantage those with low socio-economic status and others most in need • increased complexity in teaching about fortified foods in a healthy diet • some risk for certain populations
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For government

<ul style="list-style-type: none"> • some reduction in regulatory burden, but potential for increased submissions for special purpose foods 	<ul style="list-style-type: none"> • clear exclusion criteria will be required for enforcement so that assessment by food inspectors can be done easily on a category basis rather than a case-by-case basis • added burden - special purpose foods • technical trade barrier • less harmonized - widens NAFTA gap • inconsistent with smart regulations approach and establishment of international trade
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For industry

<ul style="list-style-type: none"> • will be able to add nutrients of interest to the public to a range of foods recognized as healthy • would be seen as providing fortified foods consistent with healthy eating guidelines 	<ul style="list-style-type: none"> • considerable limits on the products that may have discretionary fortification • potential perception of unlevel playing field • increased use of special product regulations - more cost • doesn't value/evaluate hydration as nutritional/valuable • less harmonization with trading partners • there are some foods that have <10% WRNI but that are good foods, e.g. fruits and vegetables • limited scope of products • excludes some products that may have benefit • creates unlevel playing field
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In general

<ul style="list-style-type: none"> • lowest level of risk • should fibre and protein be added because of added nutritional value - greater range of "good" foods would be included in the proposal. 	<ul style="list-style-type: none"> • are these criteria (2g trans/sat & 480 mg sodium) consistent with current nutrient recommendations? - should be using FREE instead of LOW . 10% WRNI rule re:sugar not consistent with current nutrition recommendations • criteria should be lowered • debatable whether there is a benefit to adding Risk Category A & B nutrients - con for all options - not as great a drawback for Option Three as for Options One & Two.
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Questions

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Annex One
Pros and Cons and Solutions to Discretionary Fortification Options

- Whose exclusion criteria were used?
- What is meant to be achieved with 10% WRNI?

Option Four - Defined Voluntary Fortification	
Pros	Cons
For consumers	
<ul style="list-style-type: none"> • increased choice of certain categories of fortified foods • consumers who do not regularly follow CFGHE may benefit from the fortification of some of the foods and beverages they do consume 	<ul style="list-style-type: none"> • may consume foods with components associated with increased risk to health (e.g. saturates and trans) with the perception that these are healthier than the unfortified food counterparts • may question the adequacy of the food supply if they see a great proliferation of fortified foods • may be misled about the nutritional quality of certain fortified foods • may be confused about healthy food choices • loss of targeting messages to guide appropriate use, e.g. calcium-fortified orange juice for people who do not drink milk • may consume imbalanced nutrient intakes
For public health	
<ul style="list-style-type: none"> • potential to focus nutrition education on these food categories 	<ul style="list-style-type: none"> • potential educational challenge • nutrient intake analysis more complex
For government	
<ul style="list-style-type: none"> • consistent with current positive listing approach • opportunity for harmonization 	<ul style="list-style-type: none"> • high regulatory burden • evaluation framework needed • implementation issues - process for identifying groups and evaluation - needs to be clarified - first come first serve? - needs to be done upfront • no exclusions
For industry	
<ul style="list-style-type: none"> • increased marketing potential for the defined categories • level playing field within product categories • access to some Risk Category C nutrients of interest to consumers for some products • potentially less money required to achieve approval for whole category • allows some specificity • does allow some flexibility for evaluation • more liberal - as categories of food not specific foods • This is not a stand alone option - should/could be combined with others 	<ul style="list-style-type: none"> • unlevel playing field across all product categories • Risk C Category nutrients may be restricted to only certain product categories and not available to other categories • difficult to accommodate changes to product definitions - new products • don't see possibility of new future categories
Questions	
<ul style="list-style-type: none"> • Will nutrients be added together or in isolation? E.g. if calcium added, do you have to add Vitamin D? Will this be mandatory? Voluntary? - Fortified OJ with calcium "without Vitamin D" 	

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Annex One
Pros and Cons and Solutions to Discretionary Fortification Options

- What would the process be? e. g. Special Purpose Foods?
- Will you have to fortify to a specific level or will it be a "sliding scale" of fortification?

Significant Con/Drawback	Solution
Limited choice and unlevel playing field (if Option Three is chosen)	<ul style="list-style-type: none"> • modify foods that are fortifiable by adding foods under Option Four - would need to subsequently modify levels of nutrient addition • combine Option Three and Option Four
Separation of nutrients that are usually added together - can be confusing for consumers because of the nutrition labelling regulations - only information on the nutrient added would be included - not for all the nutrients (if Option One is chosen)	<ul style="list-style-type: none"> • when a product is fortified with one nutrients, list all nutrients so consumers know what they are getting and what they are not getting
Regulatory/Enforcement burden to categorize foods	<ul style="list-style-type: none"> • establish clear criteria for product categories and clear enforcement guidelines
Consumers may be misled about the nutritional quality of fortified foods	<ul style="list-style-type: none"> • if all foods are included in a category - would there be exclusion criteria as well e.g. for health reasons? • have to have clear advertising • establish principles/labelling/education that is truthful NOT misleading • mandatory labelling may mitigate misleading information
Option Two	<ul style="list-style-type: none"> • increase maximum allowable level of sodium from 480 mg • have some flexibility at 480 mg and other criteria surrounding rules for addition of nutrients • ensure that policies are looked at regularly and revised as necessary according to new and emerging science
Burden on Manufacturers re: New and Unique Foods - Some foods are excluded if there is no category for them - results in an unlevel playing field	<ul style="list-style-type: none"> • Ensure that categories are created to include these foods, e.g. beverages, confectionaries, etc. This would level the playing field
Preferred Options	
Option One with Option Four	<ul style="list-style-type: none"> • Option One modified to allow some of the Risk Category C nutrients like calcium and trace minerals; Option Four will then handle other Risk Category C nutrients • Add modified version of US "jelly bean" rule
Option Three with Option Four	<ul style="list-style-type: none"> • levels the playing field • not more complex than any other option

** Please Note: The Un-shaded text was previously composed by Health Canada and discussed and agreed upon by the consultation participants.

Shaded sections indicate the comments provided by the consultation participants.

Annex One
Pros and Cons and Solutions to Discretionary Fortification Options

Option Five-new option, addition based on health benefit or rationale	<ul style="list-style-type: none">• some participants felt that there should only be discretionary fortification to address some health benefit; they are comfortable with adding nutrients to foods for people who can't eat them in their "traditional" form, e.g. lactose intolerance - calcium and Vitamin D in orange juice; vegans - nutrients in soy-based products, etc.• shouldn't be adding nutrients in a free-for-all
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