



**POSITION ON DISCRETIONARY FORTIFICATION OF FOODS WITH
VITAMINS AND MINERALS
AND
THE NATURAL HEALTH PRODUCTS/FOOD INTERFACE**

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This brief is submitted on behalf of Dietitians of Canada (DC), the national professional association for just under 6000 dietitians across Canada, who are recognized food and nutrition health professionals serving the public as educators, policy makers, researchers and managers. The mission of Dietitians for Canada is to lead and support members to advance the health and well-being of Canadians through expertise in food and nutrition.

This issue has been under review since 1998 and Dietitians of Canada has consulted with our members in response to Health Canada's earlier call for stakeholder input on the Proposed Policy and Implementations Plans regarding the Addition of Vitamins and Minerals to Foods¹.

More recently, changing market dynamics has resulted in an increased availability and use of Natural Health Products [NHPs] in food format, including juices or water with added vitamin/minerals, vitamin/mineral supplements in candy format and energy drinks, rather than more conventional formats such as capsules, pills or tablets. As this latter issue overlaps with many of the concerns that DC has regarding discretionary fortification, particularly with respect to consumer safety, this brief addresses both topics.

The following are the key elements of Dietitians of Canada's position on these issues:

DISCRETIONARY FORTIFICATION WITH VITAMIN/MINERALS

Dietitians of Canada supports food fortification when there is a clearly documented public health need.

- We recognize the importance of food fortification for its impact on health promotion and chronic disease prevention. Food fortification policy should be guided by public health nutrition principles and only be considered where there is rationale such as a need to fortify foods with nutrients that are of public health concern in preventing illness; where nutrients are difficult to obtain from the food supply, either because they are not available in many

¹ Health Canada. Addition of Vitamins and Minerals to Foods, 2005. Health Canada's Proposed Policy and Implementation Plans. 2005. Available from: http://www.hc-sc.gc.ca/fn-an/nutrition/vitamin/fortification_final_doc_1_e.html

commonly consumed foods, or they are not available in the quantities recommended for optimum health; or where nutrients are not being consumed in adequate amounts. This view is similar to Principle #11 in the Dietary Reference Intakes (DRI) report on Guiding Principles for Nutrition Labelling and Fortification.² This report also asserts that where there is no dietary inadequacy, or the inadequacy is at such a level that it does not constitute a public health risk, discretionary fortification is not scientifically justified.

- In those cases where there is a documented public health need, we support mandatory fortification of needed nutrients, added to foods that would be selected by the population or target group to correct or prevent nutrient deficiencies.
- For the majority of nutrients being proposed for discretionary fortification, there is no evidence of inadequacy in the population and thus no discernable benefit to further nutrient additions³; doing so unnecessarily exposes the population to levels of nutrients they do not need. Consumers cannot be expected to be aware of this, and current labelling practices will make it impossible for them to differentiate potentially valuable nutrient additions [that is, nutrients for which there is documented health risk due to inadequate intakes], from those that are already ample in the Canadian diet. This is an important consideration because a) some of these gratuitous nutrient additions may pose health risks; and b) even where no health risk exists, it is a needless expense to consumers who may purchase these fortified foods believing them to be healthier.

Dietitians of Canada is concerned about the potential of high fat, high energy foods fortified at the discretion of the industry to replace healthier food choices and possibly add to the obesity problem in Canada.

- There is conflicting evidence with regard to how discretionary fortification of foods higher in fat and energy would impact on consumers' food choices. Health Canada's consumer focus group report⁴ indicates that discretionary fortification would not change the way consumers would evaluate food choices. Newer research suggests otherwise. At the end of 2007, Dairy Farmers of Canada commissioned an internet survey of 1,200 adults aged 18+ (n = 1,001) and teens aged 13-17 (n = 199) to assess the potential impact of Health Canada's proposed policy on discretionary fortification of food on Canadians' eating behaviours. The categories of food tested included

² Institute of Medicine. Dietary Reference Intakes. Guiding Principles for Nutrition Labeling and Fortification. The National Academies Press. 2003 Available from: <http://www.nap.edu/books/0309091438/html/126.html>

³ Sacco, J. Assessing the potential population health impact of proposed changes to food fortification in Canada. Abstract for Symposium on Research Results from the CCHS Cycle 2.2. Nutrition Focus. May, 2009.

<http://events.onlinebroadcasting.com/statcan/053009/index2.php?page=launch>

⁴ Health Canada Canadian Consumer Perspectives on Food Fortification. Executive Summary, 2006. [Cited 2007 31 Oct]; Available from: http://www.hc-sc.gc.ca/fn-an/nutrition/vitamin/focus_test_final_exec_summary-resume_exec_final_test_type_e.html

cereal bars, energy bars, flavoured bottled water, frozen desserts, fruit drinks, fruit juice, salty snacks, soda pop, sports drinks, sweet baked goods and sweets. The survey revealed that the proposed policy will likely increase the consumption and category penetration of most foods tested among both adults and teenagers and that it could also negatively impact milk product consumption.⁵

- The challenge of body weight and the importance of preventing obesity were considered carefully in the preparation of Eating Well with Canada's Food Guide (CFG). To address this challenge, CFG has tailored guidance on amounts and types of foods to consume and limit, and it promotes daily physical activity. Research conducted during the development of *Eating Well with Canada's Food Guide* clearly indicated that people who are least active need to minimize foods eaten outside of the four food groups to prevent weight gain.⁶ It is clear that many Canadians presently over consume "extra" foods in place of more nutritious choices, contributing to the obesity epidemic. The fortification of foods which have low nutrition density, that is foods that supply calories but relatively small amounts of micronutrients⁷, reinforces an obesogenic diet [see Appendix – Foods Eligible for Discretionary Fortification]. Dietitians of Canada supports action to encourage Canadians to reduce, not maintain or increase, their intake of these "extra" foods.
- Market research indicates that many consumers are looking for lower energy substitutes for nutritious foods such as 100% fruit juice, selecting "lighter" juices [5% juice with added nutrients]⁸ or calcium fortified orange juice in place of milk. Clearly these foods, regardless of their fortification levels, are not nutritionally equivalent to the products they may be replacing in the diet. It underscores the need for better research to determine the impact that discretionary fortification would have on Canadians' diets and their health.
- The discretionary fortification of foods will lead to manufacturers making health and/or nutrition claims and positioning these foods as being "healthier" because they have been fortified. It would therefore be misleading to the public to allow these fortified foods to be marketed as "healthier" since research shows that consumers do use the information on packaged foods to help them make choices; 47% use labels to find foods that claim to be good for their health⁹.
- Foods that are higher in fat, sugar and energy and low in vitamins and minerals are often priced competitively against healthier beverages such as

⁵ For further details contact Isabelle Neiderer, Director of Nutrition. Dairy Farmers of Canada.

⁶ Bush MAA, Martineau C, Pronk JA and Brulée D. Eating Well with Canada's Food Guide. A Tool for the Times." *Can J Diet Pract Res* 2007; 68:92-96.

⁷ American Dietetic Association. Practice Paper of the American Dietetic Association: Nutrient Density: Meeting Nutrient Goals within Calorie Needs. *JADA* 2007(5): 860-869.

⁸ Strategic Marketing Institute – MSU Product Center. The Market for Orange Juice – Challenges and Opportunities. Working Paper 2-102605.

⁹ Canadian Council of food and Nutrition. Tracking Nutrition Trends V1. August 2006.

milk and fruit juice.¹⁰ This is especially prevalent in northern and remote communities. Allowing these lower nutrient dense products to be fortified on a discretionary basis is likely to add to their appeal, especially for those on tight budgets.

- Shifts in the pattern of eating as might occur with discretionary fortification, making higher fat, higher energy foods more appealing, may promote the development of chronic diseases such as diabetes, heart disease and certain kinds of cancer. Socio-cultural changes, including changes in diet of Canada's First Nations population, provide a good example of how such a shift can result in an increased incidence of obesity and type 2 diabetes¹¹ in vulnerable population groups. We know it is not just the individual nutrients in foods that are important to health, but their presence within the context of the complete food that contribute health benefits. This premise is borne out by research on the DASH Diet¹², the synergistic effect of fruits and vegetables on cancer prevention¹³ and the Portfolio Diet¹⁴, demonstrating that a healthy pattern of eating, based on Canada's Food Guide and emphasizing whole foods lower in fat and sodium and higher in dietary fibre, is an important factor in chronic disease prevention. Fortifying nutrient-poor foods will not provide these same health benefits.

Canada's current dietary surveillance system and nutrient database are insufficient to monitor or evaluate the impact – both positive and negative - of a discretionary fortification

- Discretionary fortification of foods with nutrients, notably calcium, folate and niacin, is not without risk to certain subpopulation groups - children and adolescents in particular¹⁵. According to the National Institutes of Health Consensus and State-of-the Science Statement on Multivitamin/Mineral Supplements and Chronic Disease Prevention¹⁶, there is concern about the cumulative effects of fortification and supplementation which may exceed the Upper Tolerable Intake Level of the DRIs for some people. This is of particular concern for those individuals consuming a healthy diet rich in fortified foods in combination with MVM supplements.

¹⁰ Moorman, C. Market-level effects of information: competitive responses and consumer dynamics. J. Marketing Research 1998. 35:82-98.

¹¹ Young TK, Reading J, Elias B and O'Neil JD. Type 2 diabetes mellitus in Canada's First Nations: Status of an epidemic in progress. E-CMAJ 2000; 16(5).

<http://www.cmaj.ca/cgi/content/abstract/163/5/561>

¹² Maruthur NM, Wang NY, Appel LJ. Lifestyle interventions reduce coronary heart disease risk: results from the PREMIER trial. Circulation 2009; 119(15): 2026-31.

¹³ World Cancer Research Fund and American Institute for Cancer Research. Food Nutrition, Physical Activity, and the Prevention of Cancer: A Global Perspective, 2007.

¹⁴ Jenkins DJ, Josse AR, Wong JM, Nquyen TH, Kendall CW. The portfolio diet for cardiovascular risk reduction. Curr Atheroscler Re 2007; Dec 9: 501-7.

¹⁵ Sacco, J. Assessing the potential population health impact of proposed changes to food fortification in Canada. Presentation made at the Symposium on Research Results from the CCHS Cycle 2.2. Nutrition Focus. May, 2009.

<http://events.onlinebroadcasting.com/statcan/053009/index2.php?page=launch>

¹⁶ National Institutes of Health. NIH State-of-the-Science Conference Statement. Multivitamin/Mineral Supplements and Chronic Disease Prevention. May 2006. [Cited 2009 17 July] <http://consensus.nih.gov/2006/MVMFINAL080106.pdf>

- A recent study by Shakur et al¹⁷ revealed that there is a significant gap between the actual folate content of fortified foods and those reported in the Canadian Nutrient File [CNF] and on food labels. On average, the actual levels were about 50% higher, although the magnitude of this overage varied considerably by food category; ready-to-eat cereals contained, on average, the highest amount of folate relative to the CNF values – 188% ±57. From a risk management standpoint, it is important to ensure that discretionary fortification of foods with folic acid [and other nutrients] will do no harm. Older adults are especially vulnerable to high folic acid intakes which can delay diagnosis of vitamin B12 deficiency, and in combination with poor B12 status may be associated with impaired cognitive function.¹⁸
- Discretionary fortification of foods will result in a changed food supply and in foods that are no longer of the expected nutrition profile. In Canada, as in the US, there is a lack of accurate data on fortified foods, which will only become more problematic with increased discretionary fortification. The Institutes of Medicine have cautioned that it is imperative that the contribution of existing fortification practices and dietary supplements to current intakes be understood before regulations are introduced that would dramatically alter these practices.¹⁹
- Access to a more comprehensive database of both processed and fresh foods than is currently widely available is needed. The database must be readily accessible to health professionals in a form that responds to their information needs; in settings where they support the public with respect to health promotion and disease prevention and management; as well as for research, evaluation, monitoring and surveillance.
- There is no reference to post-market evaluation measures within the discretionary policy proposal to monitor both positive and negative impacts of the policy. If discretionary fortification is adopted in Canada, better surveillance data, collected at timely intervals, are needed on Canadian eating patterns, including intake of processed and manufactured foods. Data must also include vulnerable populations such as children, adolescents, pregnant and breastfeeding women, geographically remote populations, Aboriginal reserves, the elderly, recent immigrants and the homeless.
- While Health Canada has conducted statistical modeling that indicates risks of excessive intakes are unlikely, this data looked only at food exposure because there were no available data on vitamin and mineral supplement intakes. The data base used was a composite from the provincial surveys which covered an extended period of time, and in several provinces would have been collected

¹⁷ Shakur YA, Rogenstein C, Harman-Craven B, Tarasuk V and O'Connor DL. How much folate is in Canadian fortified products 10 years after mandated fortification? *Can J Public Health* 2009; 100(4):281-84.

¹⁸ Morris MS, Jacques PE, Rosenberg IH, Selhub J. Folate and vitamin B-12 status in relation to anemia, macrocytosis, and cognitive impairment in older Americans in the age of folic acid fortification. *Am J Clin Nutr* 2007; 85(1): 193-200.

¹⁹ Institutes of Medicine. *Dietary Reference Intakes. Guiding Principles for Nutrition Labeling and Fortification.* The National Academies Press. 2003 Available from:

<http://www.nap.edu/books/0309091438/html/126.html>

before the bottled water and other new supplemented drinks and energy bars achieved maximum market penetration. The data on market penetration were from the US, supplied by the US industry. Canadians have very different patterns of food consumption overall and from region to region. The recent analysis by Sacco²⁰, using more current intake data on a much larger, more representative sample and modeling a fuller slate of nutrients, using different sets of assumptions, suggests that questions of safety have not been adequately addressed. Actual surveillance of nutritional intakes of Canadians is critical as a means to assess the impact of the policy, both positively and negatively, on health status.

THE NATURAL HEALTH PRODUCTS/FOOD INTERFACE

Background

A concern closely associated with discretionary fortification of foods with vitamins and minerals is that of the interface between Natural Health Products [NHPs] and food. Changing market dynamics has resulted in an increase in the availability and use of NHPs in food format²¹, such as juices or water with added vitamin/minerals, vitamin/mineral supplements in candy format and energy drinks, rather than more conventional formats such as capsules, pills or tablets. Not only is there the potential to confuse consumers with this form of marketing NHPs, but more concerning is the potential risk to consumers' health and safety.

In Canada, the addition of NHPs to food is regulated under the Food and Drugs Act [FDA] and associated regulations²². While products defined as food must comply with the FDA, a product that is both an NHP and a food is subject to the Natural Health Products Regulation [NHPR] and to the FDA as it applies to a drug, but is exempted from the FDA and its regulations as they apply to a food²³. This means that the "food" portion is not subject to the safety provisions of the Food and Drugs Act and Regulations pertaining to foods. For example, limits on contaminants determined on the basis of population exposure to the food such as heavy metals or mycotoxins in nuts, grains, apple juice; limits on residues of agricultural chemicals or on regulations on food additives including permitted colours, packaging materials or microbiological standards for foods; regulations governing the safety of bottled water do not apply. Additionally, NHPs in food format do not carry nutrition labelling so the consumer cannot compare calories, saturated fat, trans fat [any regulations on trans fat would not apply to NHPs] and sodium content.

Maximum levels of vitamins and minerals in NHPs are based on the Upper Tolerable Intake Level [UL], which should include exposure from both foods and supplements.

²⁰ Sacco, J. Assessing the potential population health impact of proposed changes to food fortification in Canada. Presentation made at the Symposium on Research Results from the CCHS Cycle 2.2. Nutrition Focus. May, 2009.

²¹ Health Canada. Natural Health Products in Food Format: Exploring Health and Safety Issues. Background Paper to the April 2009 Workshop.

²² Natural Health Products Directorate and the Food Directorate. Health Canada. Classification of Products at the Food-Natural Health Product Interface: Products in Food Formats. March 2009.

²³ Section 3 Natural Health Products Regulations.

However, if the level of the vitamin or mineral in the NHP is at the UL, then consumers will exceed the UL just by eating food. Even if the level is not at the UL and exposure from foods is not taken into account, population groups could be exposed to more than the UL if the margin between the Estimated Average Requirement [EAR] and UL is narrow.

The potential for nutrient-drug interactions is another critical health and safety factor to consider in permitting NHPs to be added to and marketed as conventional foods. Food can enhance, delay, or decrease drug absorption,²⁴ and high intakes of certain vitamins/minerals and herbal products²⁵ can potentiate or inhibit some drug reactions. For example, high intake levels of folate reduce the effectiveness of anti-folate drugs used in treating rheumatoid arthritis, psoriasis and cancer²⁶ and may actually promote cancer.^{27, 28} A careful medication and nutrient supplement history, taken by a physician or other health professional, would alert the care provider to the potential for drug-nutrient interactions and prompt appropriate counselling or advice to mitigate risk. When vitamin/minerals and/or herbal products are added to foods as NHPs, health professionals may not take these products into consideration in taking a history and consumers may also be unaware of the importance of sharing this information with their care providers.

In the United States, the Dietary Supplement Health and Education Act [DSHEA] prevents the marketing of dietary supplements as a conventional food; they may only be marketed in a conventional food form, such as a liquid or a bar, if they are labelled as a dietary supplement and not represented as a conventional food.²⁹

Dietitians of Canada's position

- While Health Canada is looking at risk mitigation strategies that include labelling, packaging, advertising and education³⁰, it is our view that NHPs should not be sold in a food format, marketed as a conventional food. None of the proposed risk mitigation strategies are sufficient to protect Canadians adequately from the risk of intakes of vitamins and minerals above the UL.

²⁴ Merck Manual Online Medical Library. Accessed 2009 04 August.

<http://www.merck.com/mmpe/sec01/ch001/ch001d.html>

²⁵ Boon H and Smith M. Safety of Natural Health Products: Clinical Reports of Adverse Reactions and Interactions with Medications" Pharmacy Practice; 16(6):41-47, 2000.

²⁶ Smith AD, Kim YI, Refsum H. Is folic acid good for everyone? Am J Clin Nutr 2008; 87(3):517-33. Accessed 2009 05 Aug. <http://www.ajcn.org/cgi/reprint/87/3/517>

²⁷ Mason JB, Dickstein A, Jacques PE, Haggarty P, Sethub J, Dallal G et al. A temporal association between folic acid fortification an increase in colorectal cancer rates my be illuminating important biological principles. A hypothesis. Cancer Epididemiol Biomarkers Prev 2007; 16(7): 1325-29.

²⁸ Troen AM, Mitchell B, Sorensen B, Wener MH, Johnston A, Wood B, et al. Unmetabolized folic acid in plasma is associated with reduced natural killer cell cytotoxicity among postmenopausal women. J Nutr 2006; 136(1): 189-94. Accessed 2009 05 Aug.

<http://jn.nutrition.org/cgi/content/full/136/1/189>

²⁹ United States General Accounting Office. Report to Congressional Committees. Food Safety - Improvements Needed in Overseeing the Safety of Dietary Supplements and "Functional Foods". July 2000. <http://www.gao.gov/new.items/rc00156.pdf>

³⁰ Health Canada. Natural Health Products in Food Format Workshop: Risk Mitigation Strategies. April 23, 2009.

The toxicities of high doses of nutrients such as vitamins A, B-6, D, niacin, iron and selenium are well established, with most reported toxicity incidence occurring from supplementation³¹. Additionally, safety limits for many botanicals and other NHPs have not been established. When NHPs are sold as a conventional food, consumers have the expectation that they can be consumed ad libitum, without concern for adverse effects. Even where warning labels have been applied, they are ineffective. For example, energy drinks that fall under NHP regulation include the precaution "*not suitable for children and during pregnancy and breastfeeding.*" Yet energy drinks are reported to be available in vending machines in community recreation facilities and are commonly chosen by children under 18 – this risk population is being inappropriately targeted for these products.

- If the decision is made to continue to allow NHPs to be added to foods, such products should be excluded from NHP Regulations; instead they should be regulated as foods and subject to the same risk and safety assessments as foods. Such an approach would still require other risk mitigation strategies to address the safety concerns outlined in this brief.

Summary of Dietitians of Canada's position

- Dietitians of Canada is supportive of initiatives that will have a positive impact on the nutritional health of Canadians; we are not convinced the policy proposed for discretionary fortification will achieve that goal. Fortification of foods with vitamins and minerals should be applied to address defined public health need. Greater emphasis should be placed on improving the quality of diet by promoting the use of less processed foods and diversifying and increasing consumption of fruits, vegetables and whole grains, along with lower fat animal and dairy products in accordance to Canada's Food Guide.
- NHPs should not be sold in a food format, marketed as a conventional food. If this practice is to be continued, NHPs should be excluded from NHP Regulations; instead they should be regulated as foods and subject to the same risk and safety assessments as foods. With this strategy, additional risk mitigation strategies are required to protect the health and safety of Canadians.

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³¹ American Dietetic Association. Position of the American Dietetic Association: Food fortification and dietary supplements. 2001; 100: 1115-125.

APPENDIX

Foods eligible to be fortified under discretionary fortification after excluding staple and standardized foods*

<ul style="list-style-type: none"> ▪ Soft drinks ▪ All cakes, Danishes, doughnuts, pastries, croissants, cookies, muffins, squares/bars ▪ Hot chocolate /chocolate mixes ▪ Non-dairy creamer ▪ Frozen yogurt ▪ Yogurt ▪ Popsicles (ice cream or fruit-flavoured) ▪ Chocolate hazelnut spreads ▪ Pancakes/Waffles ▪ Eggnog ▪ Milkshakes / and other dairy drinks 	<ul style="list-style-type: none"> ▪ Mixed vegetable juices ▪ Potato chips ▪ Popcorn, plain and pretzels ▪ Instant coffee ▪ Salty and high-fat snacks ▪ Soup ▪ Candies, gums ▪ Gravy ▪ Salad dressing ▪ Thirst quenchers ▪ Candied/ dry fruits ▪ Bread crumb mixes ▪ Peanut butter ▪ Tofu ▪ Hummus 	<ul style="list-style-type: none"> ▪ French fries / hash browns ▪ Sauces (all kinds) ▪ Gelatine desserts ▪ Dessert toppings ▪ Puddings ▪ Chocolate bars ▪ Croutons ▪ Distilled water ▪ Canned pasta ▪ Frozen dinners ▪ Pizza ▪ Tortillas ▪ Fruit/veg mix drinks ▪ Crackers /crisp breads ▪ Fruit drinks /iced tea ▪ Commercial pies ▪ Pie crust/phylllo dough
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