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Disease Risk Reduction and Therapeutic Claims: Opportunities for Canada's Agri-Food Sector

Increased media coverage, rising health care costs, and growing consumer awareness of the importance of a nutritious diet have driven rapid growth in market opportunities for foods with value-added health benefits. Today, some consumers are not only changing their diets to maintain their everyday health, but also actively seeking foods and beverages to reduce the risk of diseases (Datamonitor, 2009). As a result, interest in the use of disease risk reduction and therapeutic claims has grown within the Canadian agri-food sector. Disease risk reduction and therapeutic claims are specific types of health claims, along with general health claims and function claims (including nutrient function claims), that can appear on food product labels in Canada. All health claims must be truthful and not misleading, and substantiated by science; disease risk reduction and therapeutic claims must have pre-market approval from Health Canada before being used on product labels or in advertising.

In 2010, Health Canada approved two new health claims for foods. The first substantiates the relationship between the consumption of plant sterol-enriched foods and blood cholesterol lowering. The second links the consumption of oat products containing beta-glucan oat fibre to a reduction of blood cholesterol. These new therapeutic claims, in addition to the existing five disease risk reduction claims previously approved in December 2002, represent market opportunities for foods with value-added health benefits.

Cardiovascular Disease and Consumer Trends

In Canada, nine out of ten adults have at least one risk factor for heart disease and stroke (Heart and Stroke Foundation, 2011), while about 50% of the general adult population is considered to be moderately to highly hypercholesterolemic (Health Canada, 2010a). Overall, cardiovascular diseases remain the second leading cause of death for both adult women and men in Canada (Statistics Canada, 2007). Organizations such as the Heart and Stroke Foundation of Canada are raising awareness of the dangers associated with poor cardiovascular health and encouraging consumers to modify their eating habits and incorporate more heart-healthy foods and beverages into their diet.

Manufacturers are interested in using educational material and health claims to clearly communicate the health benefits of their products as many consumers do not already understand the link between certain foods and cardiovascular health (Datamonitor, 2009). The success of a claim appears to depend on the familiarity of the food component. In the U.S., where a claim associating plant sterols with a reduced risk of coronary heart disease has been authorized since 2000, less than a third of consumers are able to identify the relationship between plant sterols and cardiovascular health (Datamonitor, 2009). However, fibre is more commonly understood to be beneficial for reducing the risk of heart disease (Datamonitor, 2009); approximately three quarters of Canadians understand that some types of dietary fibre can help to reduce blood cholesterol (Canadian Council of Food and Nutrition, 2008).

At the same time, consumer interest in food remains tied to other factors beyond their health, including taste, quality, convenience, and value for the dollar. While foods with value-added health benefits can command a premium, the added price must be justified to win over the consumer from other options (Datamonitor, 2009). Ultimately, food and beverage products carrying health claims must balance all of these factors to be successful in today's marketplace.

Canada

Plant Sterols and Blood Cholesterol Lowering

Plant sterols, or phytosterols, are naturally occurring compounds in some plants. Plant sterols mimic cholesterol in the small intestine, interfering with the absorption of low-density lipoprotein (LDL) cholesterol. While plant sterols occur naturally in vegetable oils, nuts, legumes, as well as some seeds, fruits and vegetables, the average daily North American diet contains only 0.2 to 0.4 g of plant sterols (IFST, 2005). Health Canada states that a daily consumption of 2 g of plant sterols can help lower total blood cholesterol as well as LDL-cholesterol levels, while having no detrimental effect on beneficial high-density lipoprotein (HDL) cholesterol levels. The result is an overall improvement in the blood lipid profile. Health Canada has approved the addition of plant sterols to the following food categories: spreads, mayonnaise, margarine, calorie-reduced margarine, salad dressing, yogurt and yogurt drinks, and vegetable and fruit juices (Health Canada, 2010a). Prior to marketing one of these products with added plant sterols, manufacturers are asked to notify the Food Directorate of Health Canada and receive a letter of no objection. Manufacturers who wish to market products not appearing on this list would be required to file a novel food submission to Health Canada in accordance with Division 28 of the *Food and Drug Regulations*.

The following statements are available for foods meeting the qualifying criteria and that are intended for adults who want to lower their blood cholesterol:

Primary statement:

> *"[serving size from Nutrition Facts table in metric and common household measures] of [naming the product] provides X% of the daily amount of plant sterols shown to help reduce/lower cholesterol in adults."*

Additional statements that may be used adjacent to the primary statement:

- *"Plant sterols help reduce [or help lower] cholesterol."*
- *"High cholesterol is a risk factor for heart disease."*

For complete information on eligible sources, qualifying criteria, prescribed wording and scientific evidence supporting this claim, consult Health Canada's summary health claim assessment (2010a) (www.hc-sc.gc.ca/fn-an/label-etiquet/claims-reclam/assess-evalu/phytosterols-eng.php).

Marketplace Trends and Opportunities

Since the claim for plant sterols was approved in May 2010, new plant sterol-enriched foods have appeared in the Canadian market in such categories as margarine, yogurt, drinkable yogurts, and fruit juice. A total of eight new products have been captured by Mintel (2011). For the U.S. (which permits the claim on more categories than in Canada), Mintel (2011) has captured 170 launches of products with plant sterols since the claim was approved in 2000. Plant sterol-enriched products in the U.S. now include hot cereal products, drinking milk products, bread products, pastries, corn-based snacks, soy-based drinks, crackers, and snack bars (Mintel, 2011).

All product launches in Canada have been accompanied by significant educational and promotional material, whether on the product label, on the company website, or through advertising campaigns in radio, television, print and social media, to enhance consumer awareness of the benefits of plant sterols.

Label visibility has been a key strategy for attracting consumers to new plant sterol-enriched foods. All product launches carrying the new health claim have used front-of-package labelling to identify the product as enriched with plant sterols. Typically, one of the permitted clear, simple statements (such as "*Plant sterols help lower cholesterol*") is positioned prominently, while the specific amount of plant sterols included in individual servings (relative to the daily amount of plant sterols shown to help reduce cholesterol in adults) is included on the side or back of packaging.

Other approaches include the use of symbols, brand names or comparisons. Popular symbols include green leaves in the shape of hearts or red-coloured heart shapes. Other products use brand names that directly imply heart health. Stressing the level of plant sterols available from enriched products over those in non-enriched foods has also been used to highlight the value of new products. For instance, on its website, Danone tells consumers that "*you would have to eat 57 oranges, 250 carrots,*

100 peaches or 105 bananas a day to obtain 2 grams of plant sterols. Or, you could have an 80 mL Danacol yogurt drink twice a day for the same effect." Manufacturers should consult the Canadian Food Inspection Agency (CFIA) *Guide to Food Labelling and Advertising* including the policy respecting the use of heart symbols and heart health claims on food as well as the use of brand names that imply a health claim (Chapter 8, Annex 8-4).

Oat Products and Blood Cholesterol Lowering

The soluble fibre in oats includes a class of polysaccharides known as beta-D-glucans that contribute to lowering LDL-cholesterol, a risk factor in coronary heart disease. In contrast to plant sterols, consumers have been aware of the health benefits of fibre for decades and high fibre foods remain among the most popular functional foods in the North American market (The Nielsen Company, 2007). Despite this high level of awareness and notable presence in the marketplace, Canadian adults may not be meeting the daily recommended intake of fibre (38 g/day for men and 25 g/day for women aged 19–50) (Health Canada, 2009). Eligible sources of beta-glucan oat fibre approved by Health Canada for the new health claim are: oat bran, rolled oats (or oatmeal), and whole oat flour, either as the foods themselves or as ingredients in formulated foods (Health Canada 2010b).

The following statements may be made in the labelling and advertising of food products that meet the qualifying criteria:

Primary statement:

> *"[serving size from Nutrition Facts table in metric and common household measures] of (Brand name) [name of food] [with name of eligible fibre source] supplies/provides [X % of the daily amount] of the fibres shown to help reduce/lower cholesterol."*

Additional statements that may be placed adjacent to the primary statement:

- *"Oat fibre helps reduce/lower cholesterol."*
- *"High cholesterol is a risk factor for heart disease."*
- *"Oat fibre helps reduce/lower cholesterol, (which is) a risk factor for heart disease."*

The "daily amount" referred to in the primary statement is 3 g of beta-glucan oat fibre, based on the evidence available on the lowest observed effective daily dose for lowering cholesterol. For complete information on eligible sources, qualifying criteria, prescribed wording and scientific evidence supporting this claim, consult Health Canada's summary health claim assessment (2010b) (www.hc-sc.gc.ca/fn-an/label-etiquet/claims-reclam/assess-evalu/oat-avoine-eng.php).

Marketplace Trends and Opportunities

This new health claim represents a promising opportunity for manufacturers to draw attention to the health benefits of many existing products. Manufacturers may also benefit from a trend toward increased availability of oat products in the food service market, particularly among fast food eateries, due in large part to significant promotional attention being given to whole grains (The Hartman Group, 2011).

Breakfast cereals may be best positioned to capitalize on the claim associating oat fibre with lowering blood cholesterol levels, as consumers tend to ingest most of their daily fibre intake with the morning meal (Datamonitor, 2008). Since the claim was approved in November 2010, two hot breakfast cereal products have started to carry the claim in Canada (Mintel, 2011). Hot cereals are most popular among older consumers (NASFT, 2006), who are likewise more drawn to breakfast foods with health benefits as they are aware that the onset of a variety of illnesses may be altered through diet (Mintel, 2008).

The cereal bar market represents a second sector that is well placed to use the health claim. This sector is increasing far more rapidly than the traditional cereal market in most countries; from 2004 to 2009, the value of the Canadian cereal bar market grew 8.6% (Datamonitor, 2011). The increasing trend toward shortened breakfast times—in Canada, most breakfasts (84%) are prepared within five minutes or less (McCann-Hiltz, 2009)—is contributing to this growth. Use of the claim by qualifying cereal bars is likely as the sector continues to gravitate toward more health and wellness products.

Similar to plant sterol-enriched food products, manufacturers of oat products carrying the new oat fibre health claim are using eye-catching labels to draw attention to the health benefits of their products. The trend is to use the simple claim options (such as "*Oat fibre helps reduce cholesterol, a risk factor for heart disease*) for highly visible front-of package labelling. However, because oat-based cereals are popularly understood to be healthy choices with a wide range of health benefits, some manufacturers have chosen less prominent positioning, by including the health claim with other nutrition information on side or back packaging panels. Finally, Quaker has maintained its large red-coloured heart emblem as a front-of-package symbol of the heart health benefits of its products; many companies marketing similar oat-based cereals in the U.S are using similar symbols familiar to many consumers (Mintel, 2011). Manufacturers intending to use such symbols are advised to consult the CFIA *Guide to Food Labelling and Advertising*.

Use of Health Claims in New Product Launches

In addition to the two new therapeutic claims described above, five previously approved disease risk reduction claims are available to Canada's agri-food industry to promote food–health relationships:

- *a diet low in sodium and high in potassium, and the reduction of risk of hypertension;*
- *a diet low in saturated fat and trans fat, and the reduction of risk of heart disease;*
- *a diet rich in vegetables and fruit, and the reduction of risk of some types of cancer;*
- *a diet adequate in calcium and vitamin D, and the reduction of risk of osteoporosis; and*
- *maximal fermentable carbohydrates in gum, hard candy or breath-freshening products, and the reduction of risk of dental caries.*

The table below provides a glimpse at the volume of use of six health claims — the first four of these disease risk reduction claims and the two therapeutic claims — in various food categories since their approval (Mintel 2011).

New Product Launches in Canada with Disease Risk Reduction and Therapeutic Claims by Category

Product Category	**Sodium, Potassium and Hypertension** (2003–June 2011)	**Saturated Fat, Trans Fat and Heart Disease** (2003–June 2011)	**Vegetables and Fruit and Cancer** (2003–June 2011)	**Calcium, Vitamin D and Osteoporosis** (2003–June 2011)	**Plant Sterols and Blood Cholesterol Lowering** (May 2010–June 2011)	**Oat Products and Blood Cholesterol Lowering** (November 2010–June 2011)
Bakery	2	12				
Breakfast Cereals	6	19				2
Dairy*		17		2	6	
Fruits and Vegetables		1	2			
Prepared Meals		1				
Non-alcoholic Beverages	1		8	1	2	
Processed Fish, Meat & Egg Products		12				
Savoury Spreads		1				
Side Dishes		1				
Snacks	1	3				
Soup		3				
Total	**10**	**70**	**10**	**3**	**8**	**2**

* For the products included in this table, the "Dairy" category includes milk, flavoured milk, drinking yogurt, spoonable yogurt, soy-based drinks, and margarines and other spreads or blends.

References

Canadian Council of Food and Nutrition [CCFN]. (2008). *Tracking Nutrition Trends VII*. Mississauga: CCFN.

Datamonitor. (2008). *Fiber & Whole Food Consumption Trends: Profitable Innovation Opportunities.* Datamonitor 360 database.

Datamonitor. (2009). *Opportunities in Heart Health: Consumer Attitudes & Behaviours.* Datamonitor 360 database.

Datamonitor. (2011). *Cereal Bars Market in Canada to 2014 (Confectionery).* Datamonitor 360 database.

Hartman Group, The (2011). *Tasted: Oats*. HartmanSalt. www.hartmansalt.com/tasted/tasted-oats/214

Health Canada. (2009). *Do Canadian Adults Meet Their Nutrient Requirements Through Food Intake Alone?* Canadian Community Health Survey, Cycle 2.2 Nutrition (CCHS 2.2). www.hc-sc.gc.ca/fn-an/surveill/nutrition/commun/art-nutr-adult-eng.php

Health Canada. (2010a). *Plant Sterols and Blood Cholesterol Lowering: Summary of Health Canada's Assessment of a Health Claim about Plant Sterols in Foods and Blood Cholesterol Lowering.* www.hc-sc.gc.ca/fn-an/label-etiquet/claims-reclam/assess-evalu/phytosterols-eng.php

Health Canada. (2010b). *Oat Products and Blood Cholesterol Lowering: Summary of Assessment of a Health Claim about Oat Products and Blood Cholesterol Lowering.* www.hc-sc.gc.ca/fn-an/label-etiquet/claims-reclam/assess-evalu/oat-avoine-eng.php

Heart and Stroke Foundation. (2011). *Denial is putting Canadians at high risk of cutting their lives short.* 2011 Heart and Stroke Foundation Report on Canadians' Health. www.heartandstroke.com/atf/cf/%7B99452d8b-e7f1-4bd6-a57d-b136ce6c95bf%7D/lr-FINAL-Reportcard%20HSF_2011-english.pdf

Institute of Food Science and Technology [IFST], 2005. Information Statement. London: IFST. www.ifst.org/document.aspx?id=133

McCann-Hiltz, D. (2009). Breakfast Trends in Canada. Consumer Corner, Issue 2. Government of Alberta. www1.agric.gov.ab.ca/$department/deptdocs.nsf/all/sis12787

Mintel. (2008). Breakfast Foods: The Consumer – U.S.

Mintel. (2011). Global New Products Database.

National Association for the Specialty Food Trade, Inc [NASFT]. (2006). Breakfast Cereal Faces Lifestyle Challenges. Specialty Food Magazine. www.specialtyfood.com/news-trends/featured-articles/market-trends/breakfast-cereal-faces-lifestyle-challenges/

Nielsen Company, The. (2007). Organics and Functional Foods: A Global Nielsen Consumer Report. http://pt.nielsen.com/documents/tr_0710_OrganicsFood.pdf

Statistics Canada. (2007). Leading Causes of Death in Canada. Catalogue no. 84-215-XWE. www.statcan.gc.ca/pub/84-215-x/84-215-x2010001-eng.htm

Select Resources

Agriculture and Agri-Food Canada

- *Canada's Regulatory System for Foods with Health Benefits—At a Glance*
  www.agr.gc.ca/food-regulatory-issues
- *Research Gaps and Priorities Related to Health Claim Validation*
  www.agr.gc.ca/food-regulatory-issues (select "Reports and Reviews")
- *Best Practices in Promoting Food Health Benefits*
  www.agr.gc.ca/food-regulatory-issues (select "Reports and Reviews")
- *Promising Health Claim Opportunities for Canada's Agri-Food Sector*
  www.agr.gc.ca/food-regulatory-issues (select "Reports and Reviews")

Canadian Food Inspection Agency

- *Guide to Food Labelling and Advertising*
  www.inspection.gc.ca/english/fssa/labeti/guide/toce.shtml

Health Canada

- *Guidance Document for Preparing a Submission for Food Health Claims* (March 2009)
  www.hc-sc.gc.ca/fn-an/legislation/guide-ld/health-claims_guidance-orientation_allegations-sante-eng.php
- *Food Directorate Guidance Documents*
  www.hc-sc.gc.ca/fn-an/legislation/guide-ld/index-eng.php
- *Summary of Assessment of a Health Claim about Plant Sterols in Foods and Blood Cholesterol Lowering*
  www.hc-sc.gc.ca/fn-an/label-etiquet/claims-reclam/assess-evalu/phytosterols-eng.php
- *Summary of Assessment of a Health Claim about Oat Products and Blood Cholesterol Lowering*
  www.hc-sc.gc.ca/fn-an/label-etiquet/claims-reclam/assess-evalu/oat-avoine-eng.php

Contact us to learn more about regulations for health claims, novel foods and ingredients.

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