

## Health Canada

# U.S. Generic Health Claims in Canada

Stakeholder Consultation "Summary Report"

July 7 - 8, 1999



#### Introduction

The Health Claims Consultation workshop was held July 7-8, 1999 in Aylmer, Quebec. This report is a summary of the feedback that stakeholders provided. The summary is drawn from a verbatim transcript which is available upon request.

#### **Background and Purpose**

The Food Directorate of Health Canada is in the process of implementing the policy on health claims for foods released in the Policy Paper. The implementation plan consists of three components:

- 1. Tailoring existing U.S. generic health claims for implementation in Canada.
- 2. Developing standards of evidence for new health claims for foods..
- 3. Developing a regulatory framework for new health claims for foods.

The consultation workshop held on July 7 - 8, 1999 (Appendix A) focused on the first component and had the following purpose:

To seek the views of Canadian stakeholders on implementation issues and strategies for tailoring existing U.S. generic health claims for use in Canada.

#### **Workshop Participation**

A cross-section of stakeholders interested in the health claim issue were invited to participate in the 2-day workshop (Appendix B). Stakeholder representation included views on behalf of consumers, industry, government, health professionals, disease- specific advocacy groups and other health or diet related special interest groups.

### **Areas of Stakeholder Input**

Stakeholders worked together to identify the issues and make recommendations for tailoring U.S. requirements for the Canadian context. Input was sought in the following areas:

1. General Requirements The overriding list of criteria that all generic health claims must meet for eligibility, validity and labelling requirements as well as those prohibiting claims. These criteria must be met before a claim is considered at the more specific diet/disease level. (e.g. calcium and osteoporosis)

**2. Specific Requirements** The list of mandatory and optional criteria for a health claim to be made for a specific diet/disease relationship.

**3.** Credibility Issues Factors which affect the credibility of a health claim.

## **General Requirements**

The general US requirements for making a health claim for a food product were assessed in 4 parts:

- 1. Eligibility
- 2. Validity
- 3. Labelling
- 4. Prohibited health claims

A fifth topic was also assessed from a general perspective

5. Format

The following is a summary of the output provided by participants for each of the 5 parts.

Note: All references to U.S. and FDA will be amended to reflect the relevant Canadian terms.

## 1.0 Eligibility Requirements (21 CFR 101.14 (b))

#### **U.S.** Requirements

1.1 "The substance must be associated with a disease or health-related condition for which the general U.S. population, or an identified U.S. population (e.g., the elderly) is at risk..."

#### Issue:

 The requirements may create an inappropriate shift to consumption of foods with health claims at the expense of other food choices

#### Recommendations:

- Monitor national consumption over time and address identified shifts (20 support)
- Ensure education to consumers is sufficiently sophisticated (not complex) so appropriate information is rec@lesupport)

#### Issue:

 The clause has a narrow focus on one issue to the potential detriment of another (e.g. some foods high in calcium may be beneficial to osteoporosis, at the same time as being high in cholesterol, which could increase risk of cardiovascular disease)

#### **Recommendations:**

- Use both qualifying and disqualifying criteria (15 support)
- Utilize a rigorous scientific approach to validate benefits and risks (11 support, 2 oppose)

- 1.2 "If the substance is to be consumed ... at decreased dietary levels, the substance must be a nutrient that is required to be in the Nutrition Facts Panel"
- No issues or recommendations

1.3 "If the substance is consumed at other than decreased dietary levels, the substance must ... contribute taste, aroma, or nutritive value, or ... other technical aspect ... when consumed at levels that are necessary to justify a claim; and..."

#### Issue:

• The intent of the clause is unclear and seemingly unrelated to health claims.

#### **Recommendation:**

• Eliminate the statement based on the subjective nature of the requirements (5 support)

1.4 ".... has been demonstrated to FDA's satisfaction, to be safe and lawful"

#### Issue:

Statement needs to be more evolutionary

#### Recommendation:

Delete "has been demonstrated" and change to "meets
Health Canada / CFIA's satisfaction ....." and include
monitoring enforcement and sanctions (11 support)

## 2.0 Validity Requirements (21 CFR 101.14 (c))

#### **U.S. Requirement**

2.1 " ... FDA will promulgate regulations authorizing a health claim only when it determines based on the totality of publicly available scientific evidence from well-designed studies conducted in a manner which is consistent with generally recognized scientific procedures and principles, that there is significant scientific agreement, among experts qualified by scientific training and experience to evaluate such claims, that the claim is supported by such evidence."

#### Issue:

 Need to be clear on the definition of "significant scientific agreement".

#### **Recommendations:**

- Omit "including evidence" to read "scientific evidence from well designed studies..." (4 support)
- Insert "...judged by their peers to be" between "...among experts" and "...qualified by..." (5 support)
- ...scientific evidence from well-designed studies conducted in a manner which is consistent with generally recognized scientific procedures and principles that there is... (i.e., support existing wording) (12 support)

#### Issue:

• Uncertain as to the forum to determine scientific validity, who the scientific experts will be and the process to be used

#### **Recommendation:**

- Provide an infrastructure that brings the broader (inclusive) scientific community together and allows Canada to stay current on the science. This would be publicly available information and not viewed as a sole responsibility for Health Canada (22 support)
  - e.g. National Academy of Sciences and U.S. FDA Food Advisory Committee

#### Issue:

Mutual recognition of science

#### **Recommendations:**

- Bring the US and Canadian approaches together as is being used with DRI's (mutual recognition should be a "given" because of the similarity in dietary habits between the two countries) (9 support, 6 oppose)
- Implement a food and nutrient intake monitoring system to assess commonalities and differences between Canada and USA. Unique policy requires unique supporting data (20 support, 4 oppose)

#### Issue:

• The regulatory amendment process is cumbersome and lengthy (currently 50-120 weeks)

#### Recommendations:

• Overhaul and streamline the regulatory amendment process (2 support)

## 3.0 Labelling Requirement (21 CFR 101.14 (d))

#### **U.S. Requirements**

3.1 "The claim ... describing the value that ingestion (or reduced ingestion) of the substance, as part of a total dietary pattern, may have on a particular disease or health-related condition"

#### Issue:

The claim statement could become too long

#### **Recommendations:**

- Allow a choice of standardized short statements. With scientific backing; allow a prototype that can be modified appropriately (19 support, 1 oppose)
- Market-test standardized statements for "message effectiveness" (14 support)
- Use other means of education other than the label (e.g. split claim, package insert, web etc.) (15 support)
- Use a linking statement which takes the consumer back to the total diet concept and beyond (healthy lifestyle overall) (20 support)
- Balance the risks, benefits, costs and responsibility
   associated with using a health claim (i.e. be prepared to
   provide additional information to consumers on context of
   total diet) (6 support)
- Short snappy claim on the package, plus requirement to provide additional information. All advertising should be subject to the same rules. (5 support, 1 oppose)

#### Issue:

• There is possibility of having warnings on the label which provide clarity for the consumer (e.g. "This product is high in iron") or if the claim is voluntary, "sickness claims" (vs "health claims") could be made.

#### **Recommendation:**

• Provide provision in the regulations that allows the use of warnings on the label (4 support, 5 oppose)

#### Issue:

• Should the requirements for labelling extend to advertisement?

#### Recommendations:

- Advertising must be put on the table at the same time as health claims on labels (19 support)
- Develop a committee of experienced stakeholders / experts to review advertising issues (2 support)
- 3.2 "is complete, truthful and not misleading..."

#### Issue:

The definition of these terms may not be commonly understood

#### Recommendations:

 Use standardized wording for each claim, perhaps with a few options for companies to choose from

(11 support, 1 oppose)

- Ensure the claim accurately reflects the science upon which it is based and presented in a manner that is not misleading to the consumer (12 support)
- Make certain the provisions of 5.1 of the Food and Drugs Act are carried over into any new legislation (Food Inspection Act) and clearly define "misleading" in the Act
- Standardized statements will address "truthful" and "misleading" (10 support, 2 against)
- 3.3 "All information required to be included in the claim appears in one place without other intervening material except that the principal display panel ... may bear a reference statement ... with the entire claim appearing elsewhere on the other labelling..."
- 3.4 "The claim enables the public to comprehend the information provided and to understand the relative significance ... in the context of a total daily diet ..."

#### Issue:

 Space and practicality limitations on the package may make it difficult to always put the entire claim, in all of its detail, in one place.

#### **Recommendation:**

 Use split claims in statements where more detail is required (supported in NIN study) (13 support)

#### Issue:

• The public may not understand the concept of "In the context of a total daily diet"

#### **Recommendations:**

• Implement an education campaign to supplement the health claim (17 support)

- Effectively convey the phrases "total daily diet" and "total lifestyle" (11 support)
- 3.5 "Nutrition labelling (as described in 21 CFR 101.9) shall be provided in the label or labelling of any food for which a health claim is made......"

#### Issue:

• Is it a "given" that foods with a health claim should be accompanied by a nutrition label?

#### **Recommendations:**

- When a health claim is made, a nutrition label should be required (9 support)
- For foods without labels, the information could appear on shelf talkers, posters, 1-800 numbers etc. (9 support, 6 oppose)

#### 4.0 Prohibited Health Claims

#### **U.S. Requirement**

4.1 "None of the disqualifying levels in 21 DFR 101.14(a)(5) (nutrient levels of total fat, saturated fat, cholesterol or sodium above which the food will be disqualified from making a claim) is exceeded in the food...."

#### Issue:

 There is a need for levels of qualifying and disqualifying nutrients as qualifying levels are not established in Canada for all nutrients

#### **Recommendations:**

- Implement a process to determine relevant nutrients and their levels in coordination with other nutrition initiatives such as micro nutrient fortification (use Canadian core nutrient list instead of U.S. core list) (14 support)
- May not need to have disqualifying levels if already covered on nutrition panel (1 oppose)
- Build in some "sensitivity" (flexibility) into disqualifying levels (e.g. allowing only 1 g above the level) (5 support, 1 oppose)
- Adopt internationally, scientifically credible standards where necessary (13 support)

#### Issue:

• The science is currently outdated in the area of fat. The type of fat is important, not necessarily quantity e.g. Omega-3.

#### Recommendations

• Review the science to ensure some healthy foods are not

- precluded from making claims e.g. olive oil (monosaturates). (14 support)
- Develop the process for determining "fair" levels for a disqualifying nutrient (e.g. total fat). (2 support)
- Use other media beyond the health claim on a product label to highlight positive aspects of a product.
- Dietary recommendations still exist to educate consumers regarding total diet. Don't need to use a health claim per se to highlight the positive aspects of a product (e.g. a nutrient content claim). (4 support)
- 4.2 "no substance is present at an inappropriate level ...", (i.e., above these disqualifying levels unless:
- 4.3 "The label does not represent or purport that the food is for infants and toddlers less than 2 years of age ... ",

#### Recommendation:

 Maintain exemption as an essential and useful regulatory tool (2 support)

#### Issue:

 There may be health claims that apply to young children and there may be adult claims that have an adverse effect on young children

#### Recommendation:

• Abolish the limitation

(1 oppose)

4.4 "unless the food contains 10% or more of the Reference Daily Intake or the Daily Reference Value for vitamin A, vitamin C, iron, calcium, protein, or fibre per reference amount customarily consumed prior to any nutrient addition."

#### Issue:

• A food rich in phytochemicals but nothing else would not be eligible for a claim

#### **Recommendation:**

 Conduct individual assessments for foods that have a legitimate claim e.g. tea, wine, Benecol margarine this assessment could lead to product specific claims (10 support)

#### Issue:

• There are differences between US and Canadian regulations and some are not the same, such as protein and fibre

#### **Recommendations:**

- Develop a "made in Canada" list (8 support)
- Put % DRI U.S. versus absolute value (1 support)

#### 5.0 Format

#### Issue:

• Limited space on the label

#### **Recommendations:**

- Provide relief / flexibility re; location of the claim, size of lettering etc. in the context of all labelling information required (1 oppose)
- Test label for readability

(6 support)

• Standardized list of options regarding wording of claims and split claims – symbol instead of text (18 support)

• Use symbols and logos – e.g. a Heart and Stroke Foundation heart logo to constitute a health claim

(5 support, 8 oppose)

#### Issue:

• To what degree is the label, an educational tool versus an information tool?

#### **Recommendations:**

• Promote the educational aspect in the information package

(2 support)

• Encourage consumers to seek additional information that may be elsewhere – this should be highlighted on the package (9 support)

• Use humour in the statement as an educational tool

(2 support, 7 oppose)

## **Specific Requirements**

Participants assessed the specific food requirements and health claim wording requirements for the following nutrient-disease pairings:

A	Calcium	Osteoporosis
В	Dietary Fat	Cancer
С	Sodium	Hypertension
D	Dietary saturated fat and cholesterol	Coronary Heart Disease
Е	Fibre containing grain products, fruits, vegetables	Cancer
F	Fruits, vegetables and grain products that contain fibre (soluble)	Coronary Heart Disease
G	Fruit and vegetables	Cancer
Н	Dietary sugar alcohols	Dental Caries
I	Soluble fibre from certain foods	Coronary Heart Disease
J	Folate	Neural Tube Defects

For each pair, the participants provided comments on the following:

- 1. Food requirements
- What criteria must a food satisfy to enable the use of a specific health claim?
- 2. Claim wording requirements
- For a particular claim statement, what elements should be included and not included?
- 3. Proposed model claim statements
- Participants were asked to provide feedback on proposed claims that were provided for some of the nutrient / disease pairings

## The following were derived by summarizing similar comments from the verbatim report.

A. Calcium & Osteopo	rosis	(21 CFR 101.72)	
Food Requirements:		For a food to use the claim "high in calcium", the level of calcium must be henough to be credible and needs to be clearly defined in the nutrient content claims initiative. The science must also support the requirement that the "phosphorous" content can not <u>exceed</u> the calcium content.	
Claim Wording Requirements:		See appendix C.	
Proposed Model Claim		Two statements received support:	
Statements:		• "Enough calcium in a healthy diet is important for everyone and may reduce the risk of osteoporosis". (4 support)	
		• "Enough calcium in a healthy diet helps maintain good bone health". (6 support)	
basis) is related to cancer risk  C. Sodium & Hyperten	ζ.	research is inconclusive that simple total fat reduction (on a product by product (21 support)  (21 CFR 101.74)	
or coulding riyporton		<u> </u>	
Food Requirements:		The "low sodium" requirement should have links to disqualifying nutrients. The food should not contain other cardiovascular disease or diabetes promoting ingredients such as total saturated fat and/or cholesterol.	
		The current "low sodium" reference amount of 140 mg leaves an extremely limited number of products eligible to use the claim.	
Claim Wording Requirements:	۵	See appendix C.	
Proposed Model Claim Statements:		The favoured statement read: "A low sodium diet may reduce the risk of high blood pressure". (7 support)	

## D. Dietary Saturated Fat, Cholesterol & Coronary Heart Disease (21 CFR 101.75)

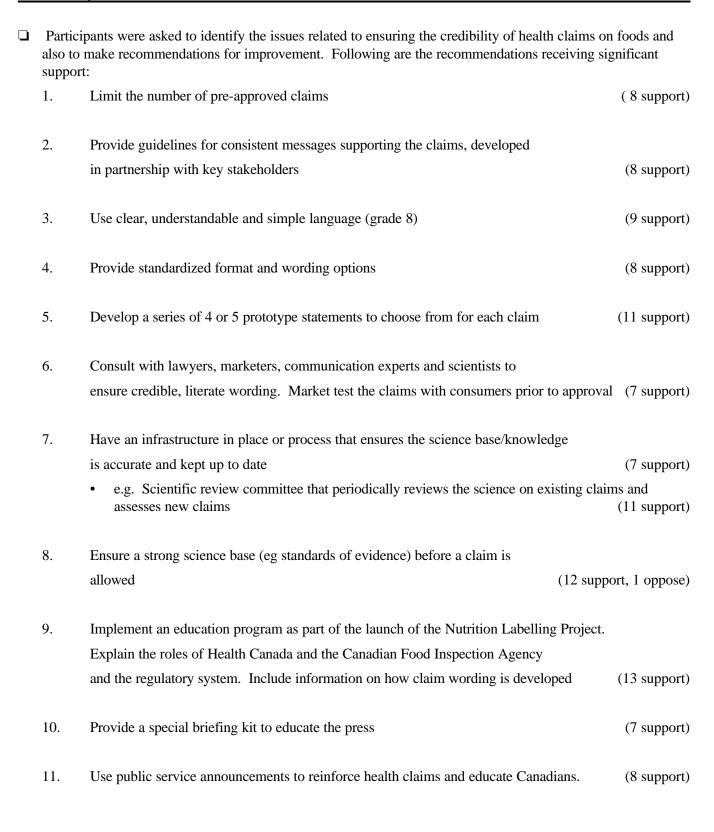
Food Requirements:		The need for low cholesterol as an eligibility requirement was seen as less important than saturated and trans fat. The food requirements should also assess type of fat more than total fat e.g. trans, mono-unsaturated, poly unsaturated, omega 3/6 etc.
Claim Wording Requirements:	ū	See appendix C.
Proposed Model Claim Statements:  E. Fibre-containing Gra	Most support was given to the phrase  "While many factors affect heart disease, the type and lower amount of fat in this 'product' (insert product name) is consistent with a healthy diet".  (6 support)  roducts, Fruits and Vegetables and Cancer (21 CFR 101.76)	
L. Tibre-containing Ord		Todacis, Frants and Vegetables and Gander (27 OF N. 101.10)
Food Requirements:		There were suggestions that certain foods be specifically mentioned and/or included as part of the foods eligible to make a claim under this section. These include legumes, processed and meal type products. The effects of different kinds of fibre on cancer prevention also necessitates an update of the background information.
Claim Wording Requirements:		See appendix C.
Proposed Model Claim Statements:		There was no strong indication of support for either of the proposed model statements.
F. Fruits, Vegetables an and Coronary Heart		rain Products that contain Fibre, particularly Soluble Fibre ase <i>(21 CFR 101.77)</i>
Food Requirements:		The food should have 2 g or less of saturated fat and 0 .6 g of the soluble fibre/reference amount. The question of whether it is necessary to have 2 g or more of total dietary fibre was also put forward. Is low cholesterol a necessary requirement?
Claim Wording Requirements:		See appendix C.
Statement:		Neither proposed statement received significant support, however, were identified as "heading in the right direction". With some modifications the following statement received some support: "diets low in saturated fat and rich in fibre containing fruits, vegetables and grain products may reduce the risk of heart disease". (2 support)

## G. Fruits and Vegetables and Cancer (21 CFR 101.78)

Food Requirements:		The requirement that the food be a fruit or vegetable should also include juices. Concern expressed about excluded foods (e.g. apple juice).
		It was questioned as to whether the science adequately supported the specific requirements. For example, there is uncertainty about the relationship between fat and cancer; is cancer risk specifically linked to vitamin A or C? What about the links between cancer and other components such as phytochemicals and other antioxidants such as flavonoids?
Claim Wording Requirements:		See appendix C.
Proposed Model Claim Statements:		The most support was indicated for the following amended statement:  "Diets rich in fruits and vegetables (containing fibre, vitamins A, C and other antioxidants) may reduce the risk of some cancers". (5 support)
H. Dietary Sugar Alcohol	an	d Dental Caries (21 CFR 101.80)
Food Requirements:		The food need not be "sugar free" but rather free from fermentable carbohydrates. The current US requirements state that some "fermentable carbohydrate" is permitted if it does not lower plaque PH beyond 5.7, however, measuring PH at the tooth surface is difficult and not currently available in Canada. Use list of acceptable sugar alcohols instead.
Claim Wording Requirements:		See appendix C.
Proposed Model Claim Statement:		"Does not promote tooth decay" was felt to be adequate. (1 support)
I. Soluble Fibre from Ce	rtai	n Food and Risk of Coronary Heart Disease (21 CFR 101.81)
Food Requirements:		The current US food requirements were seen as acceptable with some opposition to the combined requirement of low cholesterol, low fat and low saturated fat. It was also suggested that trans fat be considered. The viscosity of the finished product must be maintained as hydrolysis may reduce cholesterol lowering effectiveness. The recommended amounts (of soluble fibre) should be considered in the scientific review. Methodology for determining soluble fibre should be defined and levels set.

Claim Wording Requirements:		See appendix C.
Proposed Model Claim Statement:	٥	The number of requirements in the claim lead to a long claim. A suggestion for a split claim was seen as appropriate. The first part of the claim could read:
		• "Soluble fibre from oats may reduce the risk of heart disease".
		The remaining claim requirements would be detailed elsewhere. (1 support)
Food Requirements:		The current US requirements allow a food to use this claim if the food is not fortified. However, it was suggested that this be changed to allow "foods for special dietary use (fortified foods) that meet a minimum daily requirement of folate". It was recognized that foods currently cannot provide sufficient folate to warrant a claim.
Claim Wording Requirements:		See appendix C.
Proposed Model Claim  There were no model statement available for participant review.  Statement		

#### **Credibility Issues**



## Following are the recommendations that received significant negative support:

1.	Trade mark or credit line to pr	omote claim - Ma	ay be problematic	(liability concerns).	(6 oppose)
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2. Develop a Health Canada logo - stamp of approval of claim. (5 oppose)

## Appendix A

## Stakeholder Consultation Workshop on U.S. Generic Health Claims Agenda

## July 7, 1999

08:00	Registration and Coffee	
08:30	Opening Remarks and Purpose of the Session	Ian Shugart
08:45	Review of Agenda and Process	
	Introductions and Expectations	
09:30	Presentation - Project Overview	Melodie Wynne
09:45	Open Forum	
10:15	Health Break	
10:30	Focus on Evaluation of U.S. General Requirements	
	for Generic Health Claims	
12:00	Lunch	
13:00	Plenary Presentations	
13:30	Identification of Recommendations to Improve General Requirements	
14:45	Health Break	
15:30	Plenary Presentations	
16:30	Evaluation and Close	

### July 8, 1999

08:30	Introduction of Day 2 topics and Respond to Day 1 Evaluation
08:45	Working Group Session - Focus on "Food requirements"
12:00	Lunch
13:00	Working Session Continues
14:00	Health Break
14:15	Plenary Market Place
14:45	Working Group Session - Credibility Issues
15:30	Plenary Market Place
16:15	Messages Retained - Next Steps
16:25	Evaluation and Closure

#### Appendix B

## List of attendees at the Stakeholder Consultation Workshop on U.S. Generic Health Claims

Rick Adachi Osteoporosis Society of Canada

Catherine Airth Health Canada

Harvey Anderson Program in Food Safety University of Toronto Richard Black Confectionery MFRS Association of Canada

Lubna Bokhari Agriculture & Agri-Food Canada

Tracy Boudreau Health Canada

Pierrette Buklis Canadian Sugar Institute

Mary Bush Health Canada Maureen Carew Health Canada

Sherry Casey Canadian Council of Grocery Distributors

Peter Chan Health Canada
Eunice Chao Health Canada
Margaret Cheney Health Canada

Karen Cooper Federal/Provincial/Territorial Group on Nutrition

Renée Crompton Health Canada Halina Cyr Health Canada

Alison Davis Canadian Cancer Society
Colin Dawes Canadian Dental Association

Francis Descôteaux Health Canada

Carol Dombrow Heart and Stroke Foundation of Ontario Kelley Fitzpatrick Saskatchewan Nutraceuticals Network

Kevin Flanagan Food Institute of Canada

Rachel Goodwin Health Canada

Joyce Gordon Osteoporosis Society of Canada

Jenny Hillard Consumers Association of Canada

Pat Hunt Osteoporosis Society of Canada

Gordon Harrison Canadian National Millers Association

Isabelle Jacob Agriculture & Agri-Food Canada

Bill Jeffrey Center for Science in the Public Interest

**David Jenkins** Canadian Cancer Society

John Jenkins Breakfast Cereal Manufacturers of Canada

Anne Kennedy Canadian Egg Marketing Agency

Mary L'Abbé Health Canada

Bernard Leblanc Canadian Food Inspection Agency

Nora Lee Health Canada

Doug MacQuarrie Heart & Stroke Foundation Richard McCoy Canadian Dental Association

Arlette Marcotte Ordre professionnel des diététistes du Québec

Kim Meegan Canadian Federation of Agriculture

Sandy Morrison Brewers Association of Canada

Pierre Nadeau National Dairy Council

Carolyn O'Brien Food & Consumer Products Manufacturers of Canada

Danielle O'Rourke Tea Association of Canada

Jocelyne Phillion Association of Canadian Biscuit Manufacturers **Brian Raines** Canadian Institute of Food Science & Technology

Rod Ralph Agriculture & Agri-food Canada

Paula Roach Health Canada Fraser Scott Health Canada

Carol Seto Canadian Diabetes Association

Dietitians of Canada Marsha Sharp

Health Canada Josie Sirna

Canadian Meat Council **Bryan Smith** 

National Institute of Nutrition Alison Stephen Elizabeth Sterken Infant Feeding Action Coalition Lynn Stewart Agriculture & Agri-Food Canada **Brian Stowe** Canadian Pharmacists Association Canadian Food Information Council

Marie-Claude Thibault Canadian Produce Marketing Association

Anne Wilkie Canadian Health Food Association

Melodie Wynne Health Canada Christina Zehaluk Health Canada

Phyllis Tanaka