

CARMEN

CARMEN Pilot Canadian Case Study

Final Report

Stakeholder Convergence On Nutrition Labelling: Building Consensus On A Complex Issue



Nutrition Fact	S
Amount	04.
Calories 80	% Daily Value
Fat 0.5 g	
Saturated 0 g	1 %
- Filans () a	0 %
Cholesterol 0 mg	
Sodium 0 mg	
Carbohydrate 18 a	0 %
Fibre 2 g	6 %
Sugars 2 g	8 %
Protein 3 g	
Vitamin A 2 % Vita	
Calcium 0 % Iron	10 %
o /o iron	2 0/
	2 %





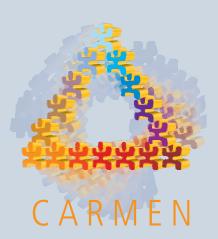
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— Public Health Agency of Canada
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Stakeholder Convergence On Nutrition Labelling: *Building Consensus On A Complex Issue*

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Executive Summary



On December 12, 2002, mandatory nutrition labelling was introduced in Canada. The scope of the regulations place Canada at the forefront of nutrition labelling, and the initiative is widely regarded as ground-breaking from a health policy perspective. Over the next 20 years, the accrued benefits to Canadians will be in the range of \$5 billion, an estimate based on reductions in direct and indirect costs associated with cancer, diabetes, coronary heart disease and strokes.¹

Under the new system, the labels of most pre-packaged foods sold in Canada must carry a *Nutrition Facts* table. Consumer interests and health needs, combined with recent advances in nutritional science, contributed to the innovative design and content of the *Nutrition Facts* table. The mandatory regulations include updated criteria for nutrient content claims to better address consumer health issues. For the first time in Canada, diet-related health claims are allowed that highlight the relationship of certain nutrients and foods with the reduction of heart disease, cancer, high blood pressure and osteoporosis.

To date, the systematic analysis and evaluation of policy making in the prevention and control of chronic diseases is a neglected area of research efforts. In the Pilot Canadian Case Study, policy processes leading to the approval of mandatory nutrition labelling regulations are explored. Specifically, we examine the formulation and decision-making stages of the policy cycle, and assess the key success factors in the development of nutrition labelling policies. In carrying out the study, we focus on the interactions among the various stakeholders in this policy arena, including representatives of federal government departments and/or agencies, non-governmental organizations, industry, scientists and consumers to explicate the intersectoral nature of policy making.

The 2002 regulations address three inter-related topics (i.e., nutrition labelling, nutrient content claims, and health claims). Importantly, the policy development process for these initiatives "followed separate collaborative routes of documentation, expert and stakeholder consultations and feedback." However, an unexpected result was the regulations pertaining to nutrition labelling, nutrient content claims, and health claims being merged into one comprehensive "policy package" in the publication of the *Canada Gazette*, Part II (January 1, 2003).

In conducting the research we carried out extensive document review and synthesis of the nutrition labelling policy formulation process, followed by semi-structured interviews with 24 key informants from government, industry, academia, health professional associations, non-governmental organizations and consumer-advocacy groups. Data collection began in July 2005 and was completed by early January 2006.

¹ Health Canada. Canada Gazette, Part II. Regulations Amending the Food and Drug Regulations (Nutrition Labelling, Nutrient Content Claims and Health Claims). 2003, January 1. Available from: http://canadagazette.gc.ca/partII/2003/20030101/pdf/g2-13701.pdf Accessed 16 Oct 2006.

World Health Organization. (2004). Policy development and noncommunicable disease prevention: The road from Kaunas. Copenhagen, Denmark: WHO Regional Office for Europe.

Memorandum To The Minister, Amendment to Food and Drug Regulations, Schedule No. 1172, Nutrition Labelling, (undated). Health Canada, p. 1.

Case study findings provide strong evidence that the nutrition labelling policy-making process was complex, often chaotic and unpredictable, hampered by a shortage of human and financial resources, and negatively affected by policy silos. In spite of formidable barriers and very tight timelines, a high degree of stakeholder convergence developed and this convergence facilitated the process of ground-breaking policy development. Stakeholder convergence on nutrition labelling was largely due to three main factors: (1) a common population health policy frame adopted by all participants in the consultative process; (2) the emergence of strong "champions" within the federal government's health policy sector; and (3) the implementation of an innovative policy development process overseen by an intersectoral Nutrition Labelling Advisory Committee.

The study conclusions position findings within a framework depicting policy-making capacity (PMC) at three levels: individual, organization and system. Evidence indicates that https://doi.org/10.21/ three levels: individual, organization and system. Evidence indicates that https://doi.org/10.21/ the organization and with https://doi.org/10.21/ the organizational level, included barriers in securing resources necessary to enforce the new mandatory regulations. The dichotomy between policy formulation and implementation suggests that, while there was convergence at the policy development stage, there may be challenges at the implementation stage (e.g., enforcement of the nutrition labelling regulations).

In presenting lessons learned, we confirm the findings of earlier policy studies namely that timing is key to successful policy making and that decision-makers must have the capacity to act quickly when a policy window opens. New lessons learned through the Pilot Canadian Case Study suggest that when organizational policy-making capacity is weak, partially as a result of resource shortages and/or restructuring, policy makers must implement strategic change management practices to overcome organizational barriers. Our recommendations include a follow-up study to examine the nutrition labelling implementation process, as well as short- and medium-term outcomes.

In summary, strong evidence depicting the nutrition labelling process as a highly successful policy innovation is reflected in the title of the Pilot Canadian Case Study: "Stakeholder Convergence On Nutrition Labelling: Building Consensus On A Complex Issue."

1. Background and Rationale



1.1 Background

On December 12, 2002 mandatory nutrition labelling was introduced in Canada. The new regulations under the *Food and Drugs Act* require that labels of most pre-packaged foods sold in Canada carry a *Nutrition Facts* table listing the number of calories and 13 key nutrients contained in a specified amount of food (refer to Figure 1). The core nutrients include the amount of fat, saturated and *trans* fat, cholesterol, sodium, carbohydrate, fibre, sugars, protein, Vitamins A and C, calcium and iron.

Figure 1: Sample Nutrition Facts table.

Nutrition Per 125 mL			
Amount		% Da	Ily Value
Calories 80)		
Fat 0.5 g			1 %
Saturated + Trans 0	_		0 %
Cholestero	I 0 mg		
Sodium 0 r	ng		0 %
Carbohydr	ate 18	g	6 %
Fibre 2 g			8 %
Sugars 2	g		
Protein 3 g			
Vitamin A	2 %	Vitamin C	10 %
Calcium	0 %	Iron	2 %

The nutrition labelling regulations include updated criteria for nutrient content claims to better address consumer health needs. In addition, for the first time in Canada, diet-related health claims are allowed that highlight the relationship of certain nutrients and/or foods with the reduction of heart disease, cancer, osteoporosis, and high blood pressure. Thus, companies are permitted to acknowledge a relationship between diet and disease on food labels, and in advertising, providing the food qualifies for the claim by meeting specified compositional criteria. Data reported in 2006 suggests that of 2 014 Canadians studied nationwide, 77 percent used food labels, described as the "most popular source of nutrition information", at least once, and 32 percent indicated that a nutrition or health claim had attracted their attention.⁴

Before 2002, the use of nutrition labels was voluntary in Canada and approximately 50 percent of pre-packaged foods displayed nutritional information. However, the information was inconsistent, often illegible to consumers, and the formatting was not standardized:

They could boast of low-fat content, without disclosing high sodium numbers. It was hard to know if the term "light" meant fat-reduced, light in texture, or light in colour.⁵

Canadian Council of Food and Nutrition. (2006, October). Tracking Nutrition Trends VI, Available at www.ccfn.ca/events/agm.asp.

⁵ Beck, L. (2005, November 9). Food companies must serve up nutrition facts. *The Globe And Mail*, p. A17.

The passage of the "Nutrition Labelling and Education Act" in the United States (US) in 1990 mandated an innovative and expanded nutrition label for virtually all foods. Canadians traveling in the US were introduced to the new nutrition labels on food packaging and they began to advocate for changes at home.

"We like to think that our health system is superior to that of the US, however, when it comes to preventive information we are a distant second. Like many others, I have a cholesterol problem and not wishing to take prescription drugs to lessen it, the type of information on packaging as in the United States would be most beneficial." Alliance for Food Label Reform, July 5, 1999

Under the new 2002 regulations, the Canadian food industry was given three years to display the *Nutrition Facts* table on packaging, and smaller businesses (i.e., those with sales under \$1 million annually) were given five years to comply. Exemptions apply to a variety of foods and beverages including fresh fruit and vegetables, raw meat and poultry (except ground), coffee beans, tea leaves, herbs and spices, alcoholic beverages, and items prepared from ingredients where the foods are sold (e.g., bakery goods). The exemptions were granted partially to ease the requirements on small businesses.

The nutrition labelling regulations are the result of a four-year public policy process which involved consumer research, expert advice, and extensive consultation with key sectors namely, consumers, health organizations and the food industry. In 2002, the Minister of Health described the highly collaborative process as a "huge undertaking" overseen by members of an external Advisory Committee.⁶

The 2002 regulations address three inter-related topics (i.e., nutrition labelling, nutrient content claims, and health claims). It is important to emphasize that the policy development process for these initiatives "followed separate collaborative routes of documentation, expert and stakeholder consultations and feedback." However, an unexpected result was the regulations pertaining to nutrition labelling, nutrient content claims, and health claims being merged into one comprehensive "policy package" in the publication of the *Canada Gazette*, Part II (January 1, 2003).

⁶ Nutrition Labelling. (2003, January 2). Ministerial, p. 3.

Memorandum To The Minister, Amendment to Food and Drug Regulations, Schedule No. 1172, Nutrition Labelling, (undated). Health Canada, p. 1.

1.2 Rationale for the Study

In 2004, a World Health Organization report examining the global regulatory environment surrounding nutrition labels and health claims concluded that

Nutrition labelling can be an effective means of helping consumers to make healthful food choices, although existing evidence concerning the effect of health claims on diet and public health is insufficient. Regulations can play a crucial role in enhancing the potential for nutrition labelling and health claims to promote health (p. 57).8

However, the report cautions that the design and implementation of regulatory nutrition labelling frameworks must be part of an integrated approach to reduce the prevalence of dietrelated chronic diseases at both the individual and population level.

On the international stage, the scope of the 2002 regulations placed Canada at the forefront of nutrition labelling and the initiative is widely regarded as ground-breaking from a health policy perspective. Both policy makers and consumer advocates predict that there will be significant long-term reductions in nutrition-related chronic diseases, thus lower healthcare costs, as a result of the new regulations.

In 2000, the federal government calculated the value of the nutrition information initiative, accrued over a 20-year timeframe, to be in the range of \$5 billion for reductions in the direct and indirect costs associated with cancer, diabetes, coronary heart disease and stroke. Compared to the \$300 million costs to industry, Health Canada stated that mandatory nutrition labelling could achieve significant cost savings. Cost-effectiveness data, together with the scope of the regulations published in the *Canada Gazette*, Part II (January 1, 2003), are attracting the attention of the international community as decision-makers seek information on the innovative policy-making process.

Currently at a global-level, nutrition labelling and related topics pertaining to competitiveness, consumer information and regulation are "hot" policy issues. A 2006 consultative document published by the European Commission (Health and Consumer Protection Directorate-General) on labelling states:

In the EU, there are many rules affecting labelling, and there is much debate about the proper use of labels and the best parameters for labelling . . . there is a need to identify as far as possible a coherent overall approach to labelling.¹⁰

⁸ Hawkes, C. (2004). *Nutrition labels and health claims: The global regulatory environment*. Geneva, Switzerland: World Health Organization.

Health Canada. Canada Gazette, Part II. Regulations Amending the Food and Drug Regulations (Nutrition Labelling, Nutrient Content Claims and Health Claims), op. cit., p. 386.

¹⁰ European Commission. (2006). *Labelling: Competitiveness, consumer information and better regulation for the EU*. Health and Consumer Protection Directorate-General, p. 1.

The report calls for the development of a comprehensive approach to labelling that fulfills the following criteria:

- Provides consumers with requisite information to make food choices that, in addition to being healthy, are also safe and sustainable;
- Encourages a pro-competitive environment in which industry can utilize labelling to highlight the benefits of their products to consumers;
- Ensures that information is presented in a consistent, understandable and transparent manner;
- Reflects a common framework and rules in order to minimize trade barriers, where feasible.¹¹

The European Commission consultative document addresses nutrition labelling, emphasizing that it is currently optional: ". . . it becomes compulsory when a nutrition claim is made in the labelling, presentation or advertising of a foodstuff" (p. 7). While current directives outline a standardized format in which nutrition labelling must be presented, the authors emphasize that "there is a need to address more fundamental issues relating to nutrition labelling." Further, they conclude that "the current system . . . is not working . . . it needs changing; however there is no agreement on the best way forward." 12

Focusing specifically on nutrition labelling, the 2006 report identifies a series of key policy questions that must be addressed by the European Commission prior to moving forward. For example, should nutrition labelling be mandatory? How much information is required? Are there alternative formats for providing nutrition information? Where should the nutrition label be put? How important is the presentation of the information?

It is significant that the Canadian policy-making process that led to mandatory nutrition labelling examined the same questions currently being raised by the international community, as well as many more. This report explicates findings gleaned through the process of conducting the Pilot Canadian Case Study in 2005-06. The goal of the study was to answer three key research questions:

- 1. What were the processes by which policies pertaining to nutrition labelling, nutrient content claims, and health claims were formulated and approved?
- 2. What were the key conditions and factors influencing the formulation and approval of the policies pertaining to nutrition labelling, nutrient content claims, and health claims?
- 3. What were the salient lessons learned about the design and implementation of intersectoral approaches to policy formulation and approval?

The case study findings presented in the report provide relevant, timely and hopefully useful answers to the questions posed by the European Community, as well as by other international health and nutrition partners. Further, the research illuminates promising practices pertaining to the design and implementation of intersectoral approaches to policy formulation and approval. In the conclusion, firstly, capacities are examined with respect to the nutrition labelling policy-making process at three levels (individual, organization, system). Secondly, we summarize salient lessons learned and present recommendations focused on future areas of investigation and policy research.

¹¹ European Commission, op. cit., p. 2.

¹² European Commission, op. cit., p. 7.

2. Methodology



This section of the case study report provides an overview of the methodology with emphasis on the following topics: Justification of a Case Study Approach; Conceptual Framework; Data Collection; Data Analysis; Limitations; and Ethical Approval.

2.1 Justification of a Case Study Approach

According to Kishchuk¹³, a Canadian researcher who conducted six comprehensive case studies and a cross-case analysis of the *Regional Mobilization Of Population Health*, the case study is a strategy that focuses on understanding the dynamics present in single settings¹⁴ (Eisenhardt, as cited in Kishchuk, 2001) by performing these tasks:

- "Conducting a holistic analysis of action systems through understanding actions, events, and processes contextually and considering their interactions from multiple perspectives¹⁵ (Snow and Andserson, as cited in Kishchuk, 2001);
- Triangulating multiple data sources in order to capture the complex and multi-faceted nature of the situations being studied¹⁶ (Campbell, as cited in Kishchuk, 2001);
- Using an open and emergent case study design leading to the discovery of unanticipated and fortuitous findings."¹⁷ (Snow and Anderson, as cited in Kishchuk, 2001).

In the Pilot Canadian Case Study, a Technical Working Group (TWG) provided advice on the research design including the sampling process. The TWG also participated in the interpretation of findings and members provided input into the construction of the final case study report. Membership in the TWG included a policy coordinator; experts in qualitative methods, health and nutrition policy research and evaluation; as well as policy makers and policy analysts.

2.2 Conceptual Framework

Governments at all levels are involved continuously in the process of making choices among competing options. The end result, or public policy, is the course of action (or sometimes inaction) that a government chooses to follow. We know that this process of choosing goes through many different stages, and policy analysts have called these stages the policy cycle. The policy cycle has five stages: agenda-setting, policy formulation, decision-making, implementation, and evaluation. Some analysts suggest that the agenda-setting stage is the most important one in this cycle, since it sets the stage for later events. This is the point in the cycle when governments generally, or departments specifically, decide to take action on an issue. The way in which the issue is framed, or conceptualized, will affect the shape of the

¹³ Kishchuk, N. (2001). Case studies of the regional mobilization of population health. Ottawa, ON: Health Canada, Regional Offices, Population and Public Health Branch, p. 3.

¹⁴ Eisenhardt, K. (1989). Building theories from case study research. Academy of Management Journal, 14(4).

¹⁵ Snow, D. and Anderson, L. (1991). Researching the homeless: The characteristics, features, and virtues of the case study. In J. Feagin, A. Orum and G. Sjoberg (Eds.), A case for the case study, University of North Carolina Press.

¹⁶ Campbell, D. (1979). Degrees of freedom and the case study. In T. Cook and C. Reichardt (Eds.), *Qualitative and quantitative methods in evaluation research*. Beverly Hills, CA: Sage.

¹⁷Snow. D. and Anderson L., op. cit.

¹⁸ Howlett, M. and Ramesh, M. (1995). Studying public policy: Policy cycles and policy subsystems Toronto, ON: Oxford University Press, p. 11.

Methodology

policy that emerges. Early agreement among stakeholders on a common issue frame (e.g., nutrition as a health issue) has been shown to facilitate the policy development process.

At every step in this cycle, politicians and government decision-makers are making value judgments, and deciding among alternatives. Sometimes the process is a fairly straightforward one of building on past decisions (incremental policy). At other times, an extraordinary event or crisis will result in a shift in the agenda, to respond to the crisis. In the case of nutrition labelling policies, the federal government was building on its long-standing commitment to food safety, and to facilitating healthy eating choices by consumers.

In the real world of politics, policy making is not always as well organized as this stagiest approach¹⁹ would suggest. Factors such as changes in government, lack of resources, bureaucratic reorganization, or major events can result in a shift of governmental priorities and changes in the interests of the policy community. Nevertheless, the policy cycle is a useful descriptive tool, signaling that different processes may be at work at various stages in the policy development process. The condensed timelines, stages of the policy cycle and examples of actions relative to the Pilot Canadian Case Study appear in Table 1.

¹⁹ Note: A stagiest approach is one that is comprised of an ordered set of categories into which policy processes and/or actions can be classified and which identifies factors that could induce movement from one category to the next.

Table 1: Condensed Timelines, Stage of the Policy Cycle and Examples of Actions Relative to the Pilot Canadian Case Study

Component	Stage of Policy Cycle	Process Steps
1988	Agenda-setting	E.g., <i>The Guidelines on Nutrition Labelling</i> (Food Directorate Guideline No. 2, November 30, 1989) was released, concluding a process initiated in 1983.
1990	Agenda-setting	E.g., Nutrition Recommendations: A Call for Action (Health Canada, 1990) included specific recommendations re: food labelling.
1993	Agenda-setting	E.g., <i>The Future of Nutrition Labelling in Canada Discussion Paper</i> (Health and Welfare Canada, 1993) intended to promote discussion among a full range of stakeholders.
1996	Agenda-setting	E.g., National plan of action, <i>Nutrition for Health: An Agenda for Action</i> (Joint Steering Committee, 1996), called for improving food label information, etc.
1998	Agenda-setting	E.g., Policy paper on Nutraceuticals/Functional Foods and Health Claims on Foods (Health Canada, 1998) recommended that risk reduction claims be allowed for foods.
1993-1998	Policy formulation and Decision-making	E.g., Consultations on nutrient content claims (Consultation documents in 1993, 1996 and 1998 as well as ad hoc stakeholder meetings).
1998	Policy formulation	E.g., A nutrition labelling policy review was launched and a Nutrition Labelling Advisory Committee established.
2000	Policy formulation and Decision-making	E.g., Ministerial announcement of intent to proceed included mandatory labelling on pre-packaged foods.
2001	Decision-making	E.g., Pre-publication of the proposed amendments in the <i>Canada Gazette</i> , Part I (June 16, 2001).
2003	Decision-making	E.g., Publication of amendments to the <i>Food and Drug Regulations</i> re: nutrition labelling, nutrient content and health claims in the <i>Canada Gazette</i> , Part II (Jan. 1, 2003).
2002-2006	Implementation (Transition Period, only)	E.g., Three-year compliance period for companies with annual Canadian sales of over \$1 million and a five-year period for companies with sales under \$1 million. The Canadian Food Inspection Agency (CFIA) is responsible for compliance.

In this case study, we focus on the steps leading up to the decision to impose new regulations on nutrition labelling namely, the first three stages in the policy cycle. But we also recognize that issues related to later stages in the cycle may have had an impact on the policy development process. Our conceptual framework for analyzing the first three stages of federal nutrition policy development is set out in Appendix 1 (Framework for Analyzing Policy Formulation Processes). The formal and informal processes, nature and availability of evidence, combined with resource capacities of stakeholders all impact on policy formulation. Implicit in the framework is the recognition that a major goal of policy formulation is to achieve consensus (i.e., stakeholder convergence) on how best to address a policy idea.

2.3 Data Collection

Data collection drew extensively on multiple sources of information. Strategies included (a) document review and synthesis; and (b) key informant interviews. The unique strength of case study is its ability to deal with a full variety of evidence.²⁰ Multiple data-collection techniques acted as an internal validity/credibility check (triangulation) such that data obtained by one method could be checked against data obtained by another method.²¹ Data collection strategies are described in the following section.

■ Document Review and Synthesis

Data gathered through document review were linked to the four general research questions for the case study and the key concepts embedded in the "Framework for Analyzing Policy Formulation Processes" (Appendix 1). The document-review process was greatly facilitated by the exemplary file management system and record-keeping protocols employed by Health Canada. Various types of evidence were considered as outlined in Table 2.

Types of Evidence	Pilot Canadian Case Study Examples
Research	Peer-reviewed articles
Knowledge and information	"Grey literature" (government documents/reports); consultation reports; consumer research reports; Business Impact Test (BIT); Health Canada official files; Internet.
Ideas and interests	Opinion and view ("expert knowledge" of individuals, groups, networks); media reports
Politics	Information relevant to the agenda of government (e.g., Regulatory Impact Analysis Statement); Hansard (Parliamentary record)
Economics	Cost-effectiveness studies

Table 2: Types of Evidence

Source: Adapted from Types of Evidence and How They Are Used in Policy Making (Bowen and Zwi, 2005).22

Key Informant Interviews

A semi-structured interview guide (Appendix 2) was used to solicit information from key informants. The interviews took place in a face-to-face meeting or over the telephone, according to the expressed wishes of respondents. Trained researchers conducted the interviews, which were tape-recorded and transcribed by an experienced research secretary. Key informants were asked to review drafts from the audio-taped interviews for accuracy and, if necessary, revision or inclusion of additional data (member checking). Where key informants chose to make changes, the corrected transcript was used in all reporting of the data.

Each interview took approximately one-and-a-half hours to complete. If desired, respondents were provided with a copy of the interview questions in advance. All key informants signed an informed consent form indicating that they understood the nature of their participation in the study. Where required, the consent materials were reviewed by the Legal Departments in the key informants' workplaces. Respondents were guaranteed anonymity and assured that any report of the findings would be generic and not attributed to specific individuals.

²⁰ Yin, R.K. (1989). Case study research: Design and methods. Newbury Park, CA: Sage.

²¹ Miles, M.B. and Huberman, A.M. (1994). Qualitative data analysis: An expanded sourcebook. (2nd ed.) Thousand Oaks, CA: Sage.

²² Bowen, S. and Zwi, A.B. (2005). Pathways to "evidence-informed" policy and practice: A framework for action [Electronic version]. PLoS Medicine, 2(7), pp. 600-605.

■ Selection of Key Informants

Key informants are selected for their expertise in areas relevant to the case study. Marshall and Rossman²³ note that key informants will "respond best to inquiries about broad areas of content and to a high proportion of intelligent, provocative, open-ended questions that allow them to use their knowledge and imagination" (p. 83).

In the case study, key informants were identified using a "snowball sampling" technique.²⁴ The process began by asking members of the TWG, and others, two questions: "Who are the experts on policy formulation processes pertaining to nutrition labelling and/or nutrient content claims and/or health claims in Canada?" And, "Who are the most relevant and/or appropriate individuals to serve as key informants in a study on policy formulation processes pertaining to nutrition labelling, nutrient content claims and health claims?" Individuals who were consistently highly recommended took on special importance. According to Patton (1987), the sampling process will initially diverge as many valuable sources are mentioned, and then converge as a few key names get mentioned over and over again (p. 56).

A total of 21 key informant interviews were conducted between September 2005 and January 2006 involving 24 individuals (i.e., some interviews included more than one individual). Key informants were affiliated with the following sectors: Federal Government (Health Sector); Federal Government (Non-Health Sector); Provincial and regional governments (Health Sector); Non-governmental organizations; Health professional associations; Consumer advocacy groups; Food industry; Trade associations; and Academia. Of the 24 key informants interviewed, four individuals had either retired or changed employers since their active involvement in the nutrition labelling initiative.

2.4 Data Analysis

Researchers performed content analysis²⁵ of the data meaning that it was read several times and apparent themes and patterns were identified in a process of open coding. Open coding involves closely examining the data, breaking them down into discrete categories, comparing similarities and differences, and asking questions about the phenomena being investigated.²⁶ The research team used a systematic inductive identification of themes in the data to categorize the primary patterns of ideas and concepts that emerged. A qualitative data analysis software program (i.e., NVivo6) was helpful in sorting the data.

Responses to the interview questions, interview notes, and other data including those emerging from document review were coded based on the four key research questions, concepts embedded in the "Framework for Analyzing Policy Formulation Processes" (Appendix 1), and other themes that arose during the course of the research.

²³ Marshall, C. and Rossman, G.B. (1995). *Designing qualitative research*. (2nd ed.) Thousand Oaks, CA: Sage.

²⁴ Patton, M.Q. (1987). How to use qualitative methods in evaluation. (2nd ed.) Newbury Park, CA: Sage.

²⁵Berg, B.L. (1995). Qualitative research methods for the social sciences. Boston, MA: Allyn and Bacon.

²⁶ Strauss, A. and Corbin, J. (1989). *Qualitative research methods*. Newbury Park, CA: Sage

2.5 Limitations

In contrast to epidemiological research, there are no simple qualitative methodologies to generalize the results beyond the sets of units of analysis used in the study. In this case study the process of triangulation increased external validity. The adoption of a common conceptual framework (Appendix 1) was important as well. The use of code books and de-briefing sessions to resolve coding issues helped to increase consistency. In addition, we established an audit trail to document the process that we followed to arrive at the final conclusions.

One problem noted was the tendency for key informants to forget some of the details (e.g., dates; titles of documents, etc.) pertaining to the nutrition labelling process. Although individuals were generally well prepared for the in-depth interview, on occasion memory gaps were problematic. This is not surprising given that the majority of the key informants terminated their involvement in 2002. The extensive document review process was invaluable in "filling in" the missing evidence and/or "gaps" noted during the key informant interviews.

2.6 Ethical Approval

Ethical approval for the Pilot Canadian Case Study was received from the University of Ontario Institute of Technology Research Ethics Board (File No. 04-020) and the Research Ethics Board, Office of the Chief Scientist, Health Canada (File No. 2005-0007).

3. Findings



In Section 3, case study findings are discussed under two over-arching themes: (3.1) Contextual Factors and Ideas; and (3.2) An Interactive Model of Building Consensus on Policy Making. Each theme is broken down into sub-themes in order to explicate the pertinent findings. When reporting findings, italics are used only for information gleaned through key informant interviews. Regular font is used for reporting findings associated with document review and synthesis. To increase transferability of the findings, key observations and/or lessons learned have been positioned in a series of "policy innovation" text boxes appearing throughout Section 3.

3.1 Contextual Factors and Ideas

There is a growing recognition that genetic make-up, socio-demographic status, cultural beliefs, environmental conditions, location (proximity to societal resources), and general economic conditions can affect the health of individuals. As this knowledge has entered into policy discussions, decision-makers have devoted increasing resources, to addressing the broad socio-environmental determinants of health. Thus, an examination of contextual factors is important in determining (a) how policy problems are perceived; (b) the nature/strength of the evidence base; and (c) the range/mix of policy instruments best suited to addressing the changes in the policy environment.^{28, 29, 30}

Ideas, on the other hand, represent the variety of information that policy makers rely on when recognizing an issue and deciding how best to respond. In addition to considering contextual factors, values are an important source of information, particularly at the political level. Values represent the collective wisdom of society resulting from the constant interaction of what people see happening around them and what they think ideally should happen. Naturally, people have differing values about the realities and the possibilities for dealing with policy ideas.

Section 3.1 discusses the key contextual factors that shaped the nutrition labelling, nutrient content claims, and health claims policy processes between the mid-1990s and late 2002. The ideas and interests of key individuals, groups and networks are introduced and then further explicated in Section 3.2 (An Interactive Model of Building Consensus on Policy Making).

In Section 3.1, findings are presented under the following headings: The Institutional Setting for Canada's Nutrition Policy; Nutrition as an Emerging Priority; Emphasis on Health Promotion; Advancing Compatibility with the United States; Citizen Engagement; and Intersectoral Collaboration in Policy Making.

Note: This idea built on the earlier work of Sutton, R. (1999). The policy process: An overview. London, UK: Chameleon Press, pp. 1-32.

²⁸ Weller, G.R. (1980). The determinants of Canadian health policy. Journal of Health Politics, Policy and Law, 5(3), pp. 405-418.

²⁹ Angus, D. et al. (1995). Sustainable health care for Canada. Ottawa, ON: University of Ottawa.

³⁰ Evans, R.G. and Stoddart, G.L. (1994). Producing health, consuming health care. In R.G. Evans, M.L. Barer, M.L. and T.R. Marmor, T.R. (Eds.), *Why some people are healthy and others are not*. New York: Aldine De Gruyter, pp. 4-27.

3.1.1 The Institutional Setting for Canada's Nutrition Policy

An overview of the institutional setting for Canada's nutrition policy is presented in two parts namely, Part A, focusing on the Federal Department–Health Canada and Part B, focusing on the mandate of the Canadian Food Inspection Agency.

Part A: The Federal Department — Health Canada

Health Canada is the Federal department responsible for helping Canadians maintain and improve their health, while respecting individual choices and circumstances. To achieve this mission, Health Canada decision-makers:

- Rely on high-quality scientific research as the basis for its work;
- Conduct ongoing consultations with Canadians to determine how to best meet their long-term health care needs;
- · Communicate information about disease prevention to protect Canadians from avoidable risks;
- Encourage Canadians to take an active role in their health, such as increasing their level of physical activity and eating well.³¹

Further, policy makers at Health Canada maintain that prevention and health promotion can "hold health care costs down and improve quality of life in the long term." To this end, the Department fosters and supports partnerships with researchers nationally and globally, while working collaboratively with ten provinces and three territories to test ways in which the Canadian health care system can be improved and ensure its sustainability for the future.

The Health Products and Food Branch at Health Canada focuses on the regulation of food products, and works to provide consumers with the information that will enable them to make healthy food choices. Within the context of a broad health mandate, the federal government has demonstrated a strong financial commitment to assisting consumers to make healthy food choices. In 2000, for example, it committed approximately \$256 million over four years to the health protection program of Health Canada. These funds were allocated to environmental health initiatives, disease surveillance and control, health safety, the control of both chronic and infectious diseases, as well as research on drugs and food products. At the same time, the government also emphasized its new commitment to public consultation on health protection and food safety.

This commitment was an important part of the federal government's new public management strategy that was initiated in the late 1980s, designed to improve service delivery to Canadians while at the same time increasing public consultation on public policy initiatives. New public management is an essential part of the framework within which Health Canada has operated throughout the period of nutrition labelling policy development. Under new public management guidelines, the federal government seeks to maximize public involvement in the development of its programs. The Canadian initiative, modelled on earlier reforms in Britain and New Zealand, was designed to improve public service delivery to Canadians, while at the same time increasing public accountability. It includes a new emphasis on the involvement of individual citizens and consumer groups on the development and delivery of public services, including health-related information.

³¹ Health Canada. About Health Canada. Available at: http://www.hc-sc.gc.ca/ahc-asc/index_e.html Accessed 16 July 2007

Part B: The Canadian Food Inspection Agency

Health Canada's mandate to deliver nutrition information to Canadians and to protect food safety is complemented by the enforcement responsibilities of the Canadian Food Inspection Agency (CFIA). The CFIA, reporting directly to the Minister of Agriculture and Agri-Food Canada, was created in April 1997 to enforce food safety and nutritional quality standards. The Federal agency operates inspection programs, and is responsible for enforcing the nutritional quality standards developed by Health Canada. With respect to nutrition labelling, it is the responsibility of the CFIA to enforce the regulations on nutrition labelling, nutrient-content claims and health claims. To fulfil this mandate the CFIA trains inspectors, who are responsible for monitoring compliance with the regulations across the country, and works with industry to assist in the implementation process.

3.1.2 Nutrition as an Emerging Priority

Case study findings provided strong evidence that nutrition is increasingly seen as an emerging priority at the federal level. The eating patterns of many Canadians contribute to the high incidence of diet and nutrient-related chronic diseases, including cardiovascular disease, diabetes, osteoporosis, obesity, and cancer resulting in premature death and disability. In 2003, the economic burden of poor diet in Canada was estimated to be \$6.6 billion annually, including direct care costs of \$1.3 billion.³² Thus, the role of appropriate food choices and a healthy lifestyle is significant in reducing the incidence of these multi-factorial diseases.

"We know that diet and physical activity are second only to use of tobacco in impacting Canadians' risk of getting some serious chronic diseases." (CBC Radio Transcripts, The Current, January 3, 2003, Interview with Dr. Karen Dodds, Director General, Food Directorate, Health Canada)

Today, with stronger scientific evidence of the importance of dietary modification in reducing the risk of chronic diseases, and escalating consumer interest in the relationship of diet and lifestyle to health, nutrition policy has become a higher priority of the federal government.

As described earlier in the report, the study examines three separate policy processes leading to the publication of the regulations in the *Canada Gazette*, Part II (January 1, 2003). Nutrition labelling and nutrient content claims were first implemented in the late 1980's through a mix of non-regulatory and regulatory policy instruments:

Companies have been encouraged to provide nutrition labelling voluntarily. To build on results achieved through regulations, Health Canada supported non-regulatory instruments that were developed to reduce diet-related risks and encourage appropriate food consumption patterns (p. 383).³³

While the voluntary approach to nutrition labelling was partially successful, Health Canada policy makers concluded that "a patchwork of content and style persists" and that "regulations mandating nutrition labelling on all prepackaged foods can best address the gaps in the system and provide clarity in presentation of nutrition information to the consumer." (p. 383)

³² Health Canada, Economic Research Analysis Section, Policy Research Division, Strategic Policy Directorate, Population and Public Health Branch. (2003). *Custom tabulations*. Ottawa, ON: Health Canada.

³³ Health Canada. Canada Gazette, Part II. Regulations Amending the Food and Drug Regulations (Nutrition Labelling, Nutrient Content Claims and Health Claims), op. cit., p. 383.

Findings

In defining nutrient content claims, policy makers considered the use of voluntary guidelines, rather than mandated regulations. As the guidelines would only be effective in the context of a pre-market approval system for claims, the strategy was rejected on the basis of cost, ineffectiveness and the length of time required for approval. In the case of diet-related health claims, new regulations were required "as such claims have not been previously permitted for foods sold in Canada." According to policy makers, regulations were necessary to establish a uniform approach and instil consumer confidence in the claims (p. 384).

In this study, key informants agreed that a direction-setting 1996 document, *Nutrition for Health: An Agenda for Action*³⁴ (abbreviated *Nutrition Action Plan*), provided a context for policy development at the federal level, particularly in the area of nutrition labelling, nutrient content claims and health claims. Key actions were identified namely, improving the usefulness of nutrition labelling, increasing its availability, and broadening public education on its use. Importantly, the report concluded that "dietary practices which assist in reducing the risk of developing chronic diseases would be strengthened if food were labelled to facilitate informed choice."³⁵

"Ongoing research demonstrates that Canadians care about nutrition. In fact, 76 percent of consumers recently told us that they consider nutrition to be important when they buy food." Health Canada Briefing, Terry Dean, Heart and Stroke Association, January 2, 2003)

Some key informants criticized the *Nutrition Action Plan* (1996) as being "too generic" and/or "lacking focus." They also expressed disappointment and/or frustration that some of the key actions outlined in the *Nutrition Action Plan* had not been implemented to date. However, key informants concurred that the policy document signified a commitment on the part of government to move forward on nutrition labelling. Further, the release of the document was timely. It coincided with the policy idea (i.e., nutrition labelling) appearing on the political "radar screen", partly as a result of advocacy and increasing consumer interest.³⁶

When reflecting on the significance of key direction-setting documents, including *The Future* of *Nutrition Labelling* in Canada (Health and Welfare Canada, 1993), several key informants perceived that the early interests of policy makers focused on nutrition labelling and nutrient content claims. In contrast, there was a perception among key informants that industry had a much higher stake in the health claims issue. For example,

³⁴ Joint Steering Committee. (1996). Nutrition for health: An agenda for action. Available from: http://www.hc-sc.gc.ca/fn-an/nutrition/pol/nutrition_pol/nutrition_health_agenda-nutrition_virage_sante_e.html Accessed 25 Aug 2006.

³⁵ Health Canada. *Canada Gazette*, Part II. Regulations Amending the Food and Drug Regulations (Nutrition Labelling, Nutrient Content Claims and Health Claims), op. cit., p. 367.

³⁶ Note: According to the Canada Gazette, Part II, op. cit., "Nutrition labelling guidelines were introduced in Canada in 1988, concluding a process that started in 1983. Application of the system, in whole or in part, was voluntary, with a few exceptions. The Guidelines on Nutrition Labelling (Food Directorate Guideline No. 2, November 30, 1989) governed format, nutrient content information (core list and optional nutrients), and a declaration of serving size (p. 366)."

... it was really the nutrition labelling and nutrient content claims parts that were priorities [of Health Canada]. The health claims part was the part they did for industry because they knew if they were going to impose nutrition labelling on them, it would be nice if industry had something positive for them as well that could be a part of the package

It is important to point out that this perception on the part of some stakeholders (reflected in the quote above) is not congruent with the case study findings that explicate how stakeholder convergence was achieved on a complex policy issue. The notion, espoused by some stakeholders, is further explored in Section 3.2.4 under the subtitle "A Three-legged Stool?"

In 2003, with the publication of the new regulations in the *Canada Gazette*, Part II (January 1, 2003), the Regulatory Impact Assessment Statement (RIAS) clearly articulated the objectives of nutrition labelling in Canada:

- 1. To provide a system for conveying information concerning the nutrition content of food in a standardized format which allows for comparison among foods and prevents consumers' confusion in respect of the nutrient value and composition of a food at point of purchase;
- To enable consumers to make appropriate food choices in relation to reducing the risk of developing chronic diseases and permitting dietary management of chronic diseases of public health significance;
- 3. To encourage the availability of foods with compositional characteristics that contribute to diets that reduce the risk of developing chronic diseases;
- 4. To advance compatibility with the US system and further work towards mutual acceptance by Canada and the US of their respective nutrition labelling requirements (p. 367).

Contemplating on the priority of nutrition at the federal level today, there was strong agreement among respondents that nutrition had shifted from a low-to-medium priority in the mid-1990s to a medium-to-high priority in 2006. One key informant cited the 2005 federal budget as evidence:

In the most recent budget, a substantial amount of money was dedicated to a chronic disease prevention strategy that involves healthy eating and obesity prevention . . . there are plans to have a national nutrition promotion mass-media campaign start any day now. The Food Guide is under review . . . an indication that nutrition has become a priority.

Others referred to the re-structuring within Health Canada that led to the creation of the Office of Nutrition Policy and Promotion. This development was cited as additional evidence that the government was placing a higher priority on nutrition today than it had a decade earlier:

... that is underscored by the establishment of the Office of Nutrition Policy ... a strong statement ... the fact that it has continued ... to exist even through the formation of the Public Health Agency of Canada ... one didn't just wipe out the other ... it could have been consumed ... nutrition has a higher profile now within the interests of government

Policy innovation happens when . . . new policy documents (e.g., *The Future of Nutrition Labelling in Canada* [Health and Welfare Canada, 1993]; *Nutrition for Health: An Agenda for Action* [1996] are launched that chart a future course and set out an appropriate agenda for action.

3.1.3 Emphasis on Health Promotion

Case study evidence suggests that the potential role of nutrition labelling in "assisting consumers to make informed food choices and change dietary practices to reduce the risk of developing chronic diseases" was a powerful policy lever. Canadians were becoming nutritionally savvy through the media and they were demanding more information to make healthy food choices (Overview Document, June 16, 2001). In response, consumer-based advocacy organizations and health professionals became increasingly vocal about the need for an improved nutrition label. Research had demonstrated that Canadians had difficulty understanding food labels as the terminology was overly complex, unclear and incomplete (National Institute of Nutrition, 1992). Some consumers were familiar with the US Nutrition Facts panel and they expressed interest for a similar nutrition labelling system in Canada.

"... consumers were requesting improvements ... it [nutrition labelling] was largely consumer-driven." (Radio Interview, February 19, 2002, Dr. Margaret Cheney, Health Canada)

From the outset, policy makers maintained that an improved nutrition label, combined with a broader educational framework, would reduce consumer confusion when reading labels and support informed food choices. An underlying premise was the consumer's right to know what he/she was eating. Thus, the information on the label had to be scientifically accurate and understandable. Health professionals emphasized that the new regulations would only be effective if they were supported by public education. A spokesperson for York Region recommended that

Health Canada take the lead in ensuring a public education strategy for the new label. We recommend a mass media campaign designed to increase public awareness among the population at large (Letter, York Region, September 13, 2001).

The Toronto Board of Health adopted a report urging the Minister of Health to (a) make nutrition labelling mandatory on all foods in Canada and (b) allocate resources to the development of a comprehensive consumer education plan to ensure that Canadians can understand and use nutrition labels to make healthier food choices (*The Interest Meter*, undated).

According to Health Canada policy makers, linking the nutrition labelling policy process to a broad-based educational strategy targeting health professionals, consumers and industry was a key success factor:

³⁷ Memorandum To The Minister, *Amendment to Food and Drug Regulations*, Schedule No. 1172, Nutrition Labelling, undated. Health Canada, p. 1.

³⁸ Tandemar Research. (1992). Consumer use and information of nutrition information on food package labels. Ottawa, ON: National Institute of Nutrition.

... education was recognized as being important from the beginning ... there were people working on education at the same time as the regulations were moving forward. And that I think is very important ... that you do have committed supports for education, communication as well as resources.

Some key informants stated that the nutrition labelling educational strategies implemented by the federal government to date had limited "reach" as well as limited impact. Further, the strategies had not gone far enough in addressing the nutritional needs of vulnerable populations. Findings pertaining to educational strategies are discussed in Section 3.2.1 (Process Innovation) under the sub-theme of Intersectoral Collaboration — Breaking New Ground.

Policy innovation happens when . . . a complex policy idea is reduced to a simple 'story' (e.g., *nutrition labelling helps consumers make informed choices for healthy eating*) that hits a common chord within the stakeholder community.

3.1.4 Advancing Compatibility with the United States

A key objective of the nutrition labelling policy process was to "advance compatibility with the US system and to further work towards mutual acceptance by Canada and the US of their respective nutrition labelling requirements." Policy makers discussed advancing compatibility within a technical framework under the North American Free Trade Agreement (NAFTA). To date, mutual equivalence on nutrition labelling has not been attained. In other words, the mandatory core elements of the Canadian and US nutrition label differ.

Early in the policy process, stakeholders wanted a "made in Canada" approach. Consensus shifted to a mandatory declaration of a core list of calories and nutrients similar to the US Nutrition Facts and presented in a similar format for legibility, consistency, ease of use and compatibility. Canadian and American approaches to nutrition labelling could not be entirely harmonized. For example, Canada requires bilingual nutrition labelling information. There were other differences between the two countries including the trans fat declaration and the criteria for "rounding" trans fat and saturated fat to "0".40

³⁹ Health Canada. Canada Gazette, Part II. Regulations Amending the Food and Drug Regulations (Nutrition Labelling, Nutrient Content Claims and Health Claims), op. cit., p. 386.

⁴⁰ Note: Canadian criteria for rounding trans fat to "0" is: a) food contains i) less than 0.2 g of *trans* fatty acid per reference amount and serving of stated size, or ii) per serving of stated size, if the food is a prepackaged meal; and b) meets the conditions set out in column 2 of item 19 for the subject "low in saturated fatty acids" In the US the criteria for *trans* fatty acids is less than 0.5 g per reference amount.

3.1.5 Citizen Engagement

The increasing commitment of the federal government to citizen engagement (i.e., collaboration, partnership and the active engagement of all citizens in public policy development) was instrumental in shaping the nutrition labelling policy formulation process. In 1998, David Dodge, Deputy Minister (DM) of Health distributed a speech written by the Clerk of the Privy Council entitled "A Voice for All: Engaging Canadians for Change." The correspondence, sent to all Health Canada employees, emphasized the "increasing importance of engaging citizens in key areas of our business lines." Referring specifically to the policy-making process, the DM stated that

. . . we need to ensure that citizens have a clearly defined role in the early stages of a process and that their expressed viewpoints will be openly acknowledged and seriously considered when decisions are made. (p. 2)

The DM concluded by reminding employees that government decision-makers — both elected officials and public servants — have a responsibility to effectively engage citizens, to listen, and to be accountable to citizens in explaining how their views have been considered in the decision-making process.

Policy innovation happens when . . . the culture and norms of an organization foster innovation and risk-taking behaviours (e.g., actively engaging citizens in the public policy process).

3.1.6 Intersectoral Collaboration in Policy Making

Since the mid-1990s, the population health approach has been a key orientation of Health Canada. As outlined in *Strategies for Population: Investing in the Health of Canadians*⁴² (1994), the goal of the approach is to maintain and improve the health of the population and to reduce inequities in health among population groups. An essential feature is directing interventions aimed at improving health towards broad, systemic determinants many of which lie outside the traditional healthcare system. Thus, developing, fostering and supporting collaborations between multiple sectors (e.g., government, business and voluntary sectors) are critical to the success of the approach.

In the areas of foods and nutrition, there are calls for better and more effective policies utilizing an integrated approach. A Canadian report entitled "Integrating Food Policy with Growing Health and Wellness Concerns" (Cash, 2004)⁴³ states that dietary choices are complex. Further, they are influenced by a kaleidoscope of policies in the areas of agriculture, transportation, education, unemployment, zoning, trade liberalization and revenue generation. Cash emphasizes the need for improved coordination of policy making across jurisdictions and the need to examine virtually all public policy through a health and nutrition lens.

⁴¹ Message to all Health Canada employees from David A. Dodge, Deputy Minister and Alan Nymary, Associate Deputy Minister. (1998, October 27). Health Canada, pp. 1-2.

⁴² Health Canada. (1994). Strategies for population health: Investing in the health of Canadians. Ottawa, ON: Health Canada.

⁴³ Cash, S.B. (2004). Integrating food policy with growing health and wellness concerns: An analytical literature review of the issues affecting government, industry, and civil society. Ottawa, ON: Agriculture and Agri-Food Canada.

Other Canadian researchers conclude that, at the federal level, the development of intersectoral partnerships with other government departments and agencies is limited (Kishchuk, 2001). As Rachlis (1999) notes, "the organization of government into separate departments compromises intersectoral action for health." More recently, Lavis et al. (2001) states that the lack of organizational capacity to transcend non-traditional policy boundaries to produce harmonized policy outputs across sectors (i.e., transcending "policy silos"), is an increasing barrier to addressing the complex issues identified through a population health approach.

In the Pilot Canadian Case Study, the finding that policy silos exist between federal departments and/or agencies is not unexpected. However, a conclusion that lower intersectoral policy-making capacities at the organizational level (i.e., among/between federal departments and agencies) can be overcome by higher policy-making capacities at either the individual and/or system levels may be a new finding. This issue will be addressed in Section 3.2.2 (Barriers to Building Consensus) under the sub-heading: Policy Silos.

3.2 An Interactive Model of Building Consensus on Policy Making

Condensed chronologies associated with nutrition labelling, nutrient content claims, and health claims policy processes were developed through the document review and synthesis process. The data were triangulated with those emerging from the key informant interviews, and together they inform the development of a model depicting the key components of the policy formulation process (Figure 2: An Interactive Model of Building Consensus on Policymaking). The model is introduced in Section 3.2 under four sub-themes: Process Innovation; Barriers to Building Consensus; "Champions"; and Stakeholder Convergence.

⁴⁴ Kishchuk, N., op. cit., p. 86.

⁴⁵ Rachlis, M. (1999). *Intersectoral action workshop: Background paper and evaluation report*. Edmonton, AB: Health Promotion and Programs Branch, Alberta/Northwest Territories Region, Health Canada, p. 22.

⁴⁶ Lavis, J. et al. (2001). Barriers to employment-related healthy public policy in Canada. Health Promotion International, 16(1), pp. 9-20.

Figure 2: "An Interactive Model of Building Consensus on Policy Making"



3.2.1 Process Innovation

In a Briefing Note developed in the early days of the policy process, a senior Health Canada policy maker proposed an innovative "corporate approach" to nutrition labelling. It was envisioned that "a partnership with stakeholders form the basis of the process to review current nutrition labelling and develop a system that will be useful and meaningful for consumers, health professionals and industry." Specific components of the approach were (a) pre-consultation with stakeholders, (b) development of prototypes, (c) consumer research, (d) stakeholder consultation, (e) implementation, and (f) education. Interestingly, evaluation of the policy was not considered at that time.

⁴⁷ Nutrition labelling of foods. (1996, November 21). Briefing, Agenda Item No. 5, HPB/Food Industry Liaison Committee, Health Canada, p. 2.

In Section 3.2.1 (Process Innovation), sub-themes are addressed under the following headings: Casting a Wide Net; Decision-Making Criteria; Developing the Evidence-Base; A "Stop-Start" Process; and Intersectoral Collaboration — Breaking New Ground.

"... nutrition labelling was a great process ... it was such a departure from what we had been doing ... it involved people right from the start ... Health Canada had been criticized for its public approach so it developed a new public consultation procedure ... (CARMEN Pilot Canadian Case Study Key Informant)

■ Casting a Wide Net

The processes by which nutrition labelling, nutrient content claims, and health claims policies were formulated signalled a new policy direction and an increasing recognition within the federal government that old approaches to policy making were not working as well as they could. Central to the approach was the emphasis placed on broad stakeholder consultation and citizen engagement, particularly with respect to the nutrition labelling initiative. A key informant reflected, ". . . it was at a time when the government and Treasury Board in particular had increased the mandate for consultation . . . they did far more consultation than they may have in previous items."

Another respondent, commenting on the policy process, suggested that its success signalled a new way of conducting business within the federal system. The key informant stated that the approach trialed during the nutrition labelling initiative has since "become the norm . . . recognition that, how we take things forward, how we develop, how we consult in areas of regulatory issues and food, food safety and nutrition could be improved upon."

Several Health Canada policy makers identified a pattern to the policy-making process that developed over time. A common feature was the ongoing commitment to broad stakeholder consultation:

... these were ongoing projects that followed a certain pattern ... we would put forth proposals and then there would be consultation and then there would be comments and these would be discussed and our positions determined. We would seek approval through the approval process that existed in the Food Directorate and if it was a high profile thing, all the way up and then we'd go on to the next stage . . . multi-stage consultations

Stakeholder consultation took multiple forms including the formation of expert working groups; the use of contracted facilitators at stakeholder meetings; consumer-based research utilizing web-based technologies; regular updates and/or communiqués to the stakeholder community; and media communications. Repeatedly, key informants referred to the positive outcomes associated with the use of contracted facilitators at stakeholder consultations: "Health Canada did use facilitators that were very helpful in moving it forward . . . this was a huge policy and you had to have consultation for sure."

Findings

According to a Health Canada policy maker, the citizen engagement component was designed to "increase public awareness about nutrition labelling; build understandings related to nutrition labelling; and provide feedback on the development of policy" (e-mail, July 22, 1999). The approach included specific strategies: media communications; an Internet component whereby consumers could voice their opinions on the Health Canada website; and a regional dissemination process to share information and resources across the country. Key informants described the citizen engagement process as innovative and exemplifying risk-taking behaviours on the part of Health Canada policy makers:

". . . the whole citizen engagement piece was very much part and parcel of what was going on at the time. That was part of the environment that was very critical for this file."

"Interested parties were invited to respond to the proposed regulations that were published in the *Canada Gazette*, Part I Approximately 4 400 comments were received, including more than 4 100 letters as a result of 7 write-in campaigns, and about 250 comments from individual stakeholders. The vast majority of comments expressed support for the proposed amendments." (*Canada Gazette*, Part II, January 1, 2003, p. 388)

Policy makers identified broad stakeholder consultation as an enabling factor primarily because it "allowed consumers, health groups, and industry to talk directly to each other to explain position[s]. . . "However, they emphasized that although the consultation efforts were far-reaching, they were also focused. This was a deliberate strategy to "keep the discussion away" from other controversial topics including, but not limited to, genetically modified (GM) foods. A key informant emphasized the importance of keeping the discussion centered on nutrition labelling, while constantly scanning the "radar screen" to avoid pitfalls. On occasion, it was necessary to strategically "untangle" the policy issues in order to move forward. The following quote illustrates the importance of issue framing in the policy process:

... there was huge fear that GM food labelling was going to overtake this file. Our DM [Deputy Minister] and ADM [Assistant Deputy Minister] were really worried that if we got ourselves entangled in a discussion of GM foods and its labelling . . . it would start to cloud the issue . . . It was very strategic on their part It was a wonderful coming together of what the system should do. They brought the insight that said, 'Let's keep these issues [nutrition labelling and GM foods] on separate tracks.'

Communication processes were strengthened by the positive working relationships that existed between Health Canada and the broader stakeholder community. Using the existing policy network, positions and ideas were exchanged and thoughts clarified about possible policy directions. Triangulation of data indicated that the key components of the nutrition labelling process were compatible with "The Interactive Model" of policy making described in the literature (Nutbeam, 2003).⁴⁸ The underlying premise is that given the complexity of the policy idea, the search for knowledge must move beyond research to include a full variety of sources such as politics and interests. This finding is reflected in "An Interactive Model of Building Consensus in Policy Making" (Figure 2) and emphasizes the importance of considering multiple forms of evidence in the policy formulation process.

Policy innovation happens when . . . there is agreement at the organizational level that the old ways of doing business are no longer working as well as they should and that it is necessary for policy makers to trial new approaches.

■ Decision-Making Criteria

Health Canada used a criterion-based, decision-making process that involved consensus-building together with regular, relevant and sufficient communication with stakeholders. Individuals from a wide variety of backgrounds were recruited for consultation throughout the lengthy process. These included academics and key representatives of trade associations (e.g., Food and Consumer Products Manufacturers of Canada); advocacy organizations (e.g., Centre for Science in the Public Interest); industry (e.g., Canadian Snack Food Association); consumer organizations; professional associations; health groups; topic experts; and other federal government departments (e.g., Agriculture and Agri-Food Canada). Of special importance was the Federal/Provincial/Territorial Group on Nutrition, described by a key informant as a "sounding board."

Health Canada policy makers worked closely with an external Advisory Committee (AC) throughout the nutrition labelling policy formulation process. The nine members of the AC brought "diverse expertise from many areas and covered national, provincial and local perspectives." The AC included individuals with strong linkages to organizations and/or groups representing health, consumer and producer interests. Case study findings confirmed that individual members of the AC ". . . were not specifically representing an association, organization" Rather, they were viewed as experts in areas relevant to the nutrition labelling initiative with connections to the key stakeholder community.

The mandate of the AC was to review existing related work; agree on an appropriate analytical framework; identify data gaps and consult/survey special interest groups for their views. After findings from stakeholder consultations and consumer research were reviewed, the AC provided recommendations to Health Canada to aid their decision-making. However, Health Canada had final authority on decisions and recommendations.

⁴⁸ Nutbeam, D. (2003). How does evidence influence public health policy? Tackling health inequalities in England. *Health Promot J Australia* 14, pp. 154-158.

⁴⁹ Members, Nutrition Labelling Advisory Committee. (1998, March) Health Canada, p. 1.

Findings

The decision-making criteria outlined in the Terms of Reference for the AC was identified by key informants as a key success factor. It consisted of the following steps: (a) State the decision to be made; (b) Develop criteria; (c) Identify the options; (d) Assess options against criteria; and (d) Select most appropriate option. Key informants, familiar with the role of the AC, suggested that the Guiding Principles, also included in the Terms of Reference, were helpful in moving the policy process forward (refer to Table 3).

Table 3: Nutrition Labelling Guiding Principles

1.	Make nutrition labelling useful to consumers (clear, relevant, simple, accurate, practical, readable, informative, not misleading, consistent and legible)
2.	Increase the availability of nutrition labelling
3.	Link nutrition to public health priorities and national dietary guidelines
4.	Respect Canada's bilingual labelling policy
5.	Be sensitive to trade issues affecting nutrition labelling policy
6.	Be sensitive to implementation issues
7.	Provide for a sustained and continuing education program as a collaborative effort among stakeholders
8.	Provide for regular review and evaluation of nutrition labelling policy.

Source: Nutrition Labelling: Vision, Guiding Principles, Purpose and Objectives, Health Canada, July 1998.

■ Developing the Evidence-Base

According to Bowen and Zwi⁵⁰ (2005, p. 601), evidence-informed policy making refers to the "use of different types of information in a variety of forms and from a variety of sources, reflective of, and responsive to the policy and practice context." Case study findings indicated that key actors within the stakeholder community "sourced" the evidence, considered the evidence in decision-making, and adapted the evidence, as necessary, prior to formulating the nutrition labelling regulations. A series of examples follow describing how the evidence-base was developed.

Between 2000 and 2001, a Business Impact Test (BIT) was carried out for Health Canada to ascertain costs associated with the proposed nutrition labelling regulations. From the 170 food industry members and associations contacted, 47 completed questionnaires were returned. Close to 50 percent of respondents indicated that prices of their products would rise slightly and approximately 30 percent indicated that there would not be an impact to consumers.⁵¹ The results of the BIT, although it did not comprise a statistically significant sample, were used in the development of the Regulatory Impact Analysis Statement (RIAS) along with information from an earlier study conducted for Agriculture and Agri-Food Canada that examined costs associated with the proposed regulations.⁵²

⁵⁰ Bowen, S. and Zwi, A.B., op. cit., p. 601.

⁵¹ Health Canada announces new mandatory nutrition labelling to help Canadians make informed choices for healthy eating. (2003, January 2). *Health Canada News Release*, p. 4.

⁵² Note: Industry costs to implement the proposed nutritional labelling requirements are summarized in the *Canada Gazette*, Part II, based on implementation periods of one, two and three years: "Using a 6% discount rate, the net present value of cost to industry would be approximately \$476 million for a one year implementation period versus \$357 million for a two year and \$263 million for a three year implementation period." (p. 386). These estimates are further sub-divided into types of costs.

In 1999, the National Institute of Nutrition⁵³ (NIN) conducted a consumer research study in partnership with Health Canada, Agriculture and Agri-Food Canada, industry and NGOs to determine views on the current labelling system, level of understanding of terms and educational needs (Report by NIN, June 1999). Case study findings provided strong evidence that the consumer research, in particular, was very helpful. For example,

... it helped to identify the types [of labels], the language that we used on the labels ... so that research on the whole was very informative. We also did qualitative research with consumers in terms of messaging and with health professionals . . . in terms of developing educational materials

Other respondents indicated that the NIN research provided useful baseline indicators that would assist Health Canada to address evidence gaps pertaining to the effectiveness of the mandatory regulations in increasing consumers' knowledge, attitudes and behaviours.

A Health Canada policy maker described the nutrition labelling decision-making process and the emphasis placed on analyzing the scientific evidence. She inferred that producing tangible scientific evidence was critical because it offered policy makers concrete data to act on:

... initially we were really looking at the science around trying to understand which nutrients were of public health significance... understanding what were the chronic diseases and how much attention we should give to each of the nutrients... there was a lot of attention given to what does the science say about the nutrient and how does that fit within the context of being a nutrient of public health significance.

A guiding principle in the development of nutrient content claims stated that they should be <u>science-based</u>, informative and useful to the consumer in selecting healthy diets. A nutrient content claim is a claim that describes the amount of a nutrient in a food (e.g., low sodium; high in fibre). According to the NIN, nutrient content claims are the "pivotal element" influencing consumer product choice when health is a concern.

The importance of weighing the scientific evidence in the development of health claims was highlighted in a Health Canada Briefing held on January 2, 2003. A media reporter questioned a Health Canada spokesperson as to why the US had a more extensive list of health claims than those proposed by Health Canada. In her answer, the Health Canada spokesperson emphasized the significance of the scientific evidence:

We evaluated the ones [health claims] that the United States have and concluded that the four that are in these regulations are those where we feel science is very sound and supporting a strong relationship between the diet and the health states mentioned ⁵⁴

⁵³ Note: The National Institute of Nutrition (NIN) merged with the Canadian Food Information Council (CFIC) to form the Canadian Council of Food and Nutrition (CCFN) in 2004. The CCFN provides communication on critical food and nutrition issues in Canada wile advocating for evidence-based nutrition policy.

⁵⁴New nutrition food labelling regulations. (2003, January 2). *Health Canada Briefing Transcription*, p. 15.

Findings

A second example illustrating the importance of scientific evidence and peer review was the process to determine whether a percent Daily Value (% DV) should be used for cholesterol. Many stakeholders, primarily health professionals, requested various deletions from the proposed core list for the *Nutrition Facts* table, including cholesterol. Meanwhile, significant numbers of industry respondents advocated for the declaration of the % DV for cholesterol in order to harmonize with the US. At the same time, other stakeholders voiced their support for the proposal not to allow the declaration of cholesterol as a % DV.

The final policy decision with respect to the declaration of cholesterol as a % DV is summarized in the Text Box. The decision-making process relevant to cholesterol highlights a shared ideology at the system level. Further, the evidence points to an epistemic community defined by mutual exchange, joint creation of knowledge and considerable common ground pertaining to the creation of new knowledge.

"... with regard to dietary cholesterol, it has been decided that cholesterol would continue to be included in the core list in the *Nutrition Facts* table. It has also been decided to provide for the <u>optional</u> declaration of the % DV for cholesterol in the *Nutrition Facts* table based on a Daily Value for cholesterol of 300 mg." (*Canada Gazette*, Part II, January 1, 2003, p. 392-393)

Policy innovation happens when . . . policy actors agree with the types of evidence "sourced" and the manner in which they are used in policy making.

■ A "Stop-Start" Process

The literature describes the policy formulation process as a "fluid, dynamic process in which problems, policy and political streams couple and uncouple in an effort to link problems to solutions" (Kingdom, as cited in Milstead, 2004, p. 252). Key informants, both internal and external to government, described a "stop-start" process influenced by a variety of factors including the timing of electoral cycles, government re-organization and Ministerial changes. One respondent stated:

... it appeared to be a stop-start policy ... there would be a huge lag time ... before the next component was brought forward ... no one knew what was going on in those particular gap moments ... that generated a lot of frustration for most of the stakeholders that I was in contact with

⁵⁵ Note: Canada Gazette, Part II (January 1, 2003) provides additional background information: "Education programs in Canada aimed at reducing risk of heart disease have not focused on dietary cholesterol per se, but rather on reducing saturated fat. A reduction in intake of saturated fat, found in meat and dairy products, will be accompanied by a reduction in cholesterol intake. Permitting the declaration of a % DV for cholesterol on an optional basis is consistent with the lack of emphasis on cholesterol in Canadian nutrition education programs (p. 393)."

⁵⁶ Milstead, J.A. (2004). Health policy and politics: A nurse's guide. (2nd ed.). Sudbury, MA: Jones and Bartlett Publishers, p. 252.

Others attributed the delays to the policy processes at Health Canada, particularly the involvement of the Legal Department in approving the proposed regulations. A key informant, not employed by government, provided his perspective: ". . . getting the lawyers involved and writing the final Gazette proposal they run into huge delays because they are bumped by other projects or items that are given a higher priority ranking within Health Canada."

For some stakeholders, particularly those involved with the implementation of educational initiatives, delays in announcing the regulations were challenging. For example, evaluators assigned to a nutrition education initiative, "Healthy Eating is in Store for You" (HESY), articulated how policy delays impacted on the work of the HESY Advisory Committee (AC): "If regulation and information could be disseminated in a more timely fashion, it would help" The AC explained that "because the project was intended to complement what Health Canada was doing", delays on the part of government were problematic (Lindhorst, 2004, p. 92).⁵⁷

A Health Canada policy maker described the "peaks and the valleys" of the policy process, explaining that lengthy delays made it difficult to maintain the motivation, interest and momentum of the broader stakeholder community.

Policy innovation happens when . . . actors understand that policy making is a political, sometimes unpredictable process, often occurring in the absence of a clear beginning and/or end point.

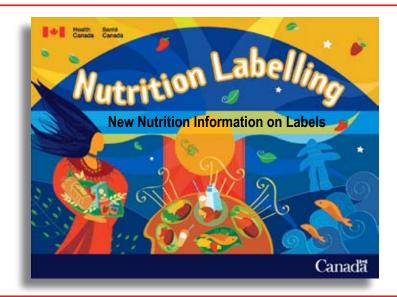
■ Intersectoral Collaborations: Breaking New Ground

Health Canada undertook a series of ground-breaking intersectoral projects to help move the policy process forward. Two initiatives highlighted below involved partnerships between government, industry, academia, NGOs, health professional associations, and consumers. In addition to providing significant in-kind contributions to the projects, some stakeholder groups also contributed financial resources. It was significant that a branch of the federal government not directly involved in the nutrition labelling initiative (i.e., Population and Public Health Branch) provided funding for the HESY project through the Canadian Diabetes Strategy, Grants and Contributions component.

A third collaboration, described by key informants as a positive and unanticipated outcome of the policy-making process, involved industry stakeholders, the Food and Consumer Products Manufacturers of Canada (FCPMC) and package designers (Davis). The collaboration resulted in the production of useful tool entitled *Mandatory Nutrition Labelling: A Guide for Food and Beverage Packaging in Canada* (Appendix 3).

⁵⁷ Lindhorst, K. (2004). *Healthy Eating is in Store for you: Evaluation final report.* Toronto, ON: Canadian Diabetes Association and Dietitians of Canada, p. 92.

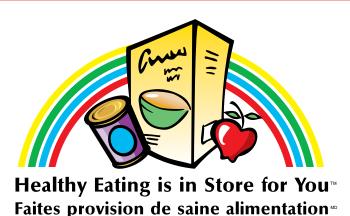
Collaboration between Health Canada, Industry, NGOs, health professional associations, literacy groups and the Canadian Public Health Association



As part of the nutrition labelling educational strategy, Health Canada launched a *Nutrition Labelling Toolkit for Educators* to support health professionals in consumer education. The Tool Kit was sent to 8 300 dieticians, diabetes educators, provincial nutritionists, and other nutrition partners across Canada. Key informants suggested that Health Canada *"missed an important leveraging opportunity"* by limiting the dissemination of the Toolkit to a "mail-out" campaign. There was strong agreement that the implementation of training programs and/or workshops designed to assist educators in the application of the new knowledge would be both timely and useful. Unfortunately, resource limitations at Health Canada at this stage in the policy-making process curtailed further nutrition labelling education programs targeting health professionals.

For educators working with First Nations and Inuit populations, a version of the Tool Kit was developed with a culturally appropriate focus. The collaboration on the design of the *First Nations and Inuit Tool Kit* was ground-breaking because it involved working with non-traditional partners namely, "off-reserve" First Nations' communities. A key informant explained that ". . . we did want to try to reach off-reserve groups . . . it was working with organizations that even for the First Nations and Inuit Branch employees weren't traditional partners" She indicated that the key partners in the production of the Tool Kit included representatives from First Nations and Inuit Health Branch, the Nutrition Evaluation Division, the Food Directorate, the CFIA, and the Communications, Marketing and Consultation Directorate.

Collaboration between the Canadian Diabetes Association and Dietitians of Canada: "Healthy Eating is in Store for You" (HESY project)









To assist consumers interpret the nutritional information on labels, Dietitians of Canada (DC), in collaboration with the Canadian Diabetes Association (CDA), launched an educational program funded by Health Canada (Population and Public Health Branch) through the Canadian Diabetes Strategy. The Healthy Eating is in Store for You (HESY) initiative was designed to coincide with the announcement of mandatory nutrition labelling regulations on January 2, 2003. The goals of the program were to (1) develop and/or enhance consumers' ability to interpret nutrition labelling information; and (2) have consumers apply this knowledge to the selection of healthy food choices.

Tools created through the HESY initiative include a web-based virtual grocery store; fact sheets; frequently asked questions; and an interactive online inventory of resource materials. A project evaluation indicated that the HESY initiative "created a successful environment for consumers to learn about nutrition labelling on packaged foods in Canada and for intermediaries to use the resources created" (Lindhorst, 2004, p. 3).58 Case study findings suggested that the lessons learned through the HESY project could serve as the foundation of a pan-Canadian public education campaign to increase consumers' knowledge and awareness of the new nutrition labels.

⁵⁸ Lindhorst, K., op. cit., p. 3.

An Area of Concern and a Call for Action

Key informants raised an area of concern related to the escalating use of nutrition labelling logos and/or programs designed by both NGOs and industry (e.g., the Heart and Stroke Foundation's "Health Check", Kraft Canada Inc.'s "Sensible Solutions"). There is a perception among some members of the stakeholder community that the "custom-designed" logos are competing with the regulated *Nutrition Facts* table and causing confusion in the marketplace. An individual stated.

... a big area I see as problematic now is how various groups are developing their own little labels to put on . . . supposedly helping consumers make good choices . . . without any monitoring or regulations . . . these are unregulated . . . totally up to industry to develop them and apply them. I would say industry sees that as their education program. I see it competing with using the food label in the way that it was intended for consumers to make healthy food choices . . . it's confusing for consumers

A second key informant concurred that the food industry's increasing use of "custom-designed" logos added to marketplace confusion and, in some cases, "outright deception about nutrition." This individual joined other key informants in calling for immediate federal government attention and corrective action.

In light of these findings, case study researchers recommend examining this issue (i.e., customized nutrition symbols and/or logos) in future studies measuring relevance, effectiveness and impact of nutrition labelling regulations.

Collaboration between Industry Stakeholders, Food and Consumer Products Manufacturers of Canada (FCPMC) and Package Designers (Davis)

Industry stakeholders, in partnership with the FCPMC and one of industry's leading package design experts, produced a bilingual resource: *Mandatory Nutrition Labelling: A Guide for Food and Beverage Packaging in Canada* (Appendix 3). The guide features (a) a decision-tree for the *Nutrition Facts* table format determination, (b) a list of key elements for mandatory nutrition labelling regulations, (c) *Nutrition Facts* table format graphics, (d) calculation of Available Display Surface, (e) a list of optional elements for package copy, (f) exemptions to the regulations, and (g) government contact points for additional information.

Policy innovation happens when . . . faced with insufficient resources, policy makers have the capacities to leverage staff and in-kind donations from the broad stakeholder community until resources can be secured.

3.2.2 Barriers to Building Consensus

This section of the report describes the barriers to building consensus under two general headings: Tensions in the Policy-making Process, and Policy Silos. Each topic is addressed under a series of sub-themes in order to explicate the case study findings.

Tensions in the Policy-making Process

Initially, tensions and/or conflicts are presented under a series of sub-themes including: Costs to Industry and Timelines for Implementation; Design of the *Nutrition Facts* table; Exemptions to *Nutrition Labelling Regulations*; and Information on the *Nutrition Facts* table.

■ Costs to Industry and Timelines for Implementation

Early in the process, industry officials claimed that nutrition labelling would cause a disruption of trade; a reduction in consumer choice; and increased costs pertaining to administration, nutrient analysis and the disposal of obsolete packaging. A member of the Flavour Manufacturers Association of Canada (FMAC) wrote

... we were concerned with the severe economic consequences both in added costs and in disruption to trade that would occur if the regulations required nutrition panels on non-retail packages for food, food ingredients and additives that are used by food processors and other manufacturers. (Letter, to Health Canada from FMAC, February 2002)

A letter from the Canadian Snack Food Association pointed out that there would be costs to industry to change the nutrition label and that this would put them at a trade disadvantage with the US. The Food Processors of Canada agreed that costs to industry were a major concern. A spokesperson stated,

The new nutrition labelling will physically take up more space and we will need to modify our packaging in order to comply with that. This will include the cost of designing and making new printing plates for our containers and associated costs of abandoning existing ones. (Regulations: Round One, Market, April 24, 2003)

To estimate the costs to industry associated with compliance, Agriculture and Agri-Food Canada funded a study in 2000. Costs included administration, product analysis, packaging re-design, and the disposal of out-dated labels and packaging inventory. The costs were calculated based on three implementation scenarios namely, one, two and three years. Findings suggested that the costs to industry would be \$476 million (one-year implementation); \$357 million (two-year implementation); and \$263 million (three-year implementation).

⁵⁹ Health Canada announces new mandatory nutrition labelling to help Canadians make informed choices for healthy eating. (2003, January 2). Health Canada News Release, p. 3.

The proposed timelines for compliance, published in the *Canada Gazette*, Part I, stated that businesses would be given two years to comply with the regulations and small businesses would be given three years. Food industry officials strongly voiced their concerns that the timelines were too short. In response, Health Canada changed the proposal to read:

... the transitional period has been extended to three years, and for small manufacturers with total annual sales of less than one million dollars during the 12 months preceding the coming into force of the new Regulations, to five years.⁶⁰

■ Design of Nutrition Label

The proposed design of the *Nutrition Facts* table posed challenges for many in the industrial sector. There were issues with size, format and surface area of the container, as well as with Health Canada's perceived inflexibility concerning certain aspects of the label design. After publication of the draft regulations in *Canada Gazette*, Part I, representatives of the Confectionery Manufacturers Association of Canada stated that space for labels was a problem (letter to Health Canada, August, 2002). Many of their products tended to be small. In addition, packages were often designed as gifts and they worried that the standard size label might detract from the appeal of their products.

Other industry groups, including the FCPMC, consistently commented on the lack of flexibility of the label. They recommended a flexible use of options within the *Nutrition Facts* format hierarchy based on package size (Letter from FCPMC to Health Canada, September 5, 2001). A key informant recalled some of the serious design challenges resulting from the proposed regulations (*Canada Gazette*, Part I):

... they had actually prescribed a specific size for the Nutrition Facts table ... and we would have to separate English and French on every package ... so, what we did was we actually went through the very elementary but time consuming process of cutting and pasting the different Nutrition Facts panels and putting it on a whole slew of our products. And the entire industry did this. We asked Health Canada to come in, as well as the design studios . . . they [Health Canada representatives] were just admittedly dumbfounded

She explained that the presentation of a *Nutrition Facts* panel in both English and French on a "double package, would have wiped out the entire package . . . there was no room for anything else!" The key informant claimed that involving Health Canada policy makers in ongoing negotiations with package designers was a critical success factor in developing workable options for industry.⁶¹ An explication of policy-makers' responses to the concerns raised by industry stakeholders can be found in the *Canada Gazette*, Part II, beginning on page 369.

⁶⁰ Health Canada. Canada Gazette, Part II, January 1, 2003, op. cit., p. 401.

⁶¹ Note: The detailed response of Health Canada policy makers to concerns raised by industry stakeholders re: the design on the nutrition label can be found in the *Canada Gazette*, Part II (January 1, 2003), beginning on page 369.

■ Exemptions to Nutrition Labelling Regulations

Some stakeholder groups "expressed regret that new labelling laws would not apply to all food products" (CSPI, *La Presse*, January 3, 2003). The CSPI, in a fax to Health Canada (November 23, 2001) said that Health Canada could better protect consumers by requiring nutrition labels on prepackaged foods, meat, poultry, seafood and in-store baked goods, in addition to those foods included in the proposed nutrition labelling regulations.

"Many respondents recommended that more categories of foods than originally proposed [in *Canada Gazette*, Part I] be required to carry nutrition information. In particular, over 4 000 comments from write-in campaigns from the public and health sector recommended that prepackaged fresh meat, poultry and seafood, and in-store baked goods be required to bear nutrition labelling." (*Canada Gazette*, Part II, January 1, 2003, p. 389)

The Canadian Poultry and Egg Processors Council also expressed concerns pertaining to the proposed exemptions: "We would encourage Health Canada to implement mandatory nutrition labelling in the poultry meat products sector at the same time as the USDA." (Canadian Poultry and Egg Producers Council, Letter to Health Canada, December 4, 2000). Later on, a spokesperson stated that some manufacturers should not be exempted because "the exemptions may result in unintended and unexpected competitive impacts" (Letter from Canadian Poultry and Egg Processors Council to Health Canada, December 4, 2000).

■ Information Presented on the Nutrition Facts Label

While the mandatory declaration of cholesterol was included in the proposed *Nutrition Facts* table (*Canada Gazette*, Part I), the inclusion of a percent Daily Value (% DV) was reexamined in light of the strong opposition by the egg producer and marketing sectors. The Canadian Egg Marketing Association (CEMA) stated that allowing the declaration of a % DV for cholesterol would be confusing and misleading to consumers. The CEMA enlisted the support of the Heart and Stroke Foundation who characterized the inclusion of a % DV for cholesterol as unfounded "Americanization" of the Canadian nutrition label. After reviewing the evidence, Health Canada determined that there was insufficient evidence to include the % DV declaration of cholesterol in the proposed core list. Refer to the section of the Pilot Canadian Case Study report entitled Process Innovation (Developing the Evidence-Base) for the final policy decision as outlined in *Canada Gazette*, Part II (January 1, 2003, p. 392). The decision to allow for the optional declaration of the % DV for cholesterol in the *Nutrition Facts* table furthered the compatibility of the Canadian nutrition label with that of the US.

Findings

The sugar industry strongly objected to the inclusion of sugars in the mandatory core list, claiming lack of scientific justification. However, individual consumers and consumers' organizations were requesting that sugars be included in the Nutrition Facts table. A 2002 report⁶² recommended that not more than 25 percent of daily energy be provided in the form of added sugars based on studies showing that diets high in added sugars were low in micronutrients. Policy makers concluded that

... there are many foods, particularly in the "Other Foods" category of Canada's *Food Guide to Healthy Eating*, which contain primarily added sugars. Including sugars in the *Nutrition Facts* table will allow consumers to identify sources of sugar in their diet and to make informed food choices (p. 393).⁶³

Policy Silos

The final topic to be addressed under the sub-theme "Barriers to Building Consensus" reintroduces the notion of "policy silos" as briefly described in Section 3.1.6 (Intersectoral Collaboration in Policy Making). The ways in which government is organized, together with processes mandated through the various arms of government, significantly impact on the capacities of decision-makers to respond to policy issues.

The formulation of nutrition labelling regulations was complex, time-consuming work requiring the coordination of policy across several federal departments and agencies. Health Canada took the lead role with other sectors, including Agriculture and Agri-Food Canada and the Canadian Food Inspection Agency (CFIA), playing a secondary role. Key informants agreed that the nutrition labelling initiative "was Health Canada's show" with some suggesting that there were "limited partnership opportunities" for other federal government departments and/or agencies, including the CFIA. There were exceptions, however, and respondents provided specific examples where the CFIA worked collaboratively with Health Canada: "In the nutrient content claims consultations and [in] the regulatory phase, the CFIA was jointly involved [with Health Canada]."

In some instances progress was hampered by differing organizational mandates and priorities. Policy makers working in non-health sectors at the federal level stated that while Health Canada ranked nutrition labelling as a high priority in the late 1990s, "for the CFIA it was low priority because of the potential need for resources to enforce [the regulations]." Health Canada decision-makers acknowledged that in the early stages of policy formulation, a shortage of resources posed considerable challenges:

... there was no money to do anything. I had just come out of this process around the 'Agenda for Action' and was committed to the process... I convinced my boss not to block it, let's take it to the next level."

⁶² Institute of Medicine (Food and Nutrition Board). (2002). Report of the Panel on Macronutrients of the Standing Committee on the Scientific Evaluation of Dietary Reference Intakes. Washington, DC.

⁶³ Health Canada. Canada Gazette, Part II, January 1, 2003, op. cit., p. 393.

External stakeholders also identified the lack of resources and competing priorities of government as barriers to moving forward. The capacity of decision-makers to quickly mobilize resources from other levels of government (e.g., negotiating staff secondments) was helpful in mitigating some of the human resource shortages:

The resources to do it were probably not sufficient It was the resource part that probably slowed them down . . . they were working on other priorities at the same time . . . they just needed more resources to get them done guickly.

■ Dichotomy between Policy Making and Implementation⁶⁴

At the organizational level, policy gaps surfaced between Health Canada and the Canadian Food Inspection Agency (CFIA). Under the jurisdiction of the Minister of Agriculture and Agri-Food Canada, the CFIA is responsible for the enforcement of the food requirements of the *Food and Drugs Act*. Additionally, the Agency is in charge of the administration, including policy development, related to Section 5 (1) of the *Food and Drugs Act*, which prohibits misrepresentation and fraud.

Several informants alluded to "long standing barriers" between Health Canada and the CFIA. Findings indicated that these tensions were exacerbated as the work on the nutrition labelling file progressed. One individual described the historical relationship between the CFIA and Health Canada, emphasizing that the nutrition labelling policy process was in Health Canada's domain:

... the CFIA worked with Health Canada The CFIA chairs the Technical Working Group on Food Labelling and the Codex Committee on Food Labelling. These are the CFIA's responsibilities, since it administers the Food and Drugs Act with regard to fraud and misrepresentation in labelling and advertising. As well, the CFIA administers the Consumer Packaging and Labelling Act The CFIA had this history of being involved in labelling . . . when Health Canada decided to make it a priority, I wouldn't say the CFIA was involved in that decision . . . the policy thing about nutrition labelling was Health Canada's show."

The document review process highlighted the compliance and enforcement issues at the heart of the policy debate between the CFIA and Health Canada. Although the CFIA officially voiced support for Health Canada's proposals, the Minister of Agriculture and Agri-Foods pointed out that the CFIA required increased funding to enforce the regulations. The CFIA calculated that it would require "incremental resources for enforcement and compliance activities, which would be applied to all food manufactures, both federally registered and non-registered, retailers and importers." The cost estimates prepared by the CFIA included:

- Transitional costs for staff training, trader education, development of programs and policy guidance, etc.;
- Ongoing costs to cover increases in existing programs/activities, such as inspection and complaint investigation, pre-market label review, etc.

⁶⁴ Note: The idea pertaining to a "dichotomy between policy making and implementation" was partly informed by the following article: Sutton, R. (1999). *The Policy Process: An Overview*. London, UK: Chameleon Press, p. 22.

⁶⁵ Memorandum To The Minister, Amendment to *Food and Drug Regulations*, Schedule No. 1172, *Nutrition Labelling*. (undated). Health Canada, p. 5.

It is significant to this discussion that when the *Nutrition Action Plan* was released by the Joint Steering Committee in 1996, new financial resources for nutrition labelling were not identified at the federal level. For example, a Briefing Note stated: "At this time there is no specific funding for this initiative. Discussions will be held with stakeholders in this regard." 66

Reflecting on the policy silo between Health Canada and the CFIA, case study evidence suggested that it represented a dichotomy between policy formulation and the other interrelated steps of the policy cycle namely, implementation and evaluation. Findings indicated that it was important for policy makers not to artificially separate these steps and to approach the planning process in a more holistic manner. Further, it was necessary to consider the complexities of implementation, as well as the resource requirements, at the same time as work was progressing on policy formulation.

Case study findings pertaining to policy silos also highlighted the importance of "managing change" at the organizational level. In the words of Brinkerhoff (1996),

New policies often reconfigure roles, structures and incentives thus changing the array of costs and benefits to implementers, direct beneficiaries and other stakeholders Experience has shown that an inwardly focused, 'business as usual' approach will fall short of achieving intended results.⁶⁷

According to Bowen and Zwi (1995)⁶⁸, the failure to manage the change process at either the individual or organizational level can cause "inertia", hence contributing to negative policy outcomes.

Policy makers estimated the potential economic benefits to be derived from the nutrition labelling regulations early on in the process. In contrast, they neglected to acknowledge the projected costs associated with compliance and enforcement until much later. However, the document review process indicated that by the late 1990s there was increased collaboration between Health Canada and the CFIA, particularly with respect to the creating and evaluating data for use in nutrition labelling (e-mail correspondence, July 8, 1999).

One key informant, reflecting on the tensions that surfaced between Health Canada and the CFIA, suggested that the earlier involvement of senior management from the CFIA would have been helpful in "managing change" at the organizational level. The key informant explained,

Where there is a strongly entrenched difference in culture (example, health versus agriculture), there should be more involvement of the non-health group at an earlier stage Involving more people from the CFIA might have given us a stronger perspective of the concerns.

⁶⁶ Nutrition labelling of foods. (1996, November 21). Briefing, Agenda Item No. 5, HPB/Food Industry Liaison Committee, Health Canada, p. 2.

⁶⁷ Brinkerhoff, D.W. (1996). Process perspectives on policy change: Highlighting implementation. World Development 24,(9).

⁶⁸ Bowen S. and Zwi, A.B., op. cit., p. 602.

On the topic of insufficient funding at the organizational level, a key informant called for "a more equal or fair approach to making sure that all those departments that were involved . . . had a say in the decision-making, where the funding would go and how the resources would be allocated." Others voiced similar sentiments calling for more work "upfront" focusing on both relationship-building and two-way communication processes, could have mitigated some of the barriers at the organizational level:

. . . there just wasn't enough communication or relationships that had been established prior to this policy development process . . . everybody thinks of their own needs and doesn't really think about the implications for somebody else.

A second example of policy silos between two federal government departments — Health Canada and Environment Canada — became apparent when a key informant associated with the food industry recalled an issue related to the proposed timelines for implementation. In the example cited, the short transition period would have resulted in copious amounts of unused food packaging being wasted. This was problematic as the industry had "committed to Environment Canada to help save the environment by reducing waste and packaging write-offs" The individual described industry's dilemma resulting from conflicting government policies: "And yet we were getting another government body tell us, no, this other set of regulations [proposed transition period] would force you to break your commitment to Environment." The key informant concluded that as a result of industry representatives bringing this policy silo to the attention of government, Health Canada indicated a willingness to discuss a longer transition period.

Policy innovation happens when . . . government opens up strong lines of communication within and across departments and agencies, continues the dialogue, and keeps everyone abreast of the direction they are going (CARMEN Pilot Canadian Case Study Key Informant)

3.2.3 Champions

The policy literature emphasizes the importance of identifying individuals who will lead change (Bridger, cited in Ambrose, 1989). These people give direction and momentum to the policy-making process. Crosby (1996) suggested that, in some cases, it is difficult to identify a single individual or agency to lead the change. In such circumstances leadership may be embodied in special committees, work groups, etc. Case study findings provide strong evidence of the critical role played by "change agents" within the federal government. Further, at the system level, policy advocates affiliated with a variety of stakeholder groups helped to keep the nutrition labelling policy-making process moving forward.

On the political stage, findings indicate that the advocacy effort of a Member of Parliament (i.e., Tom Wappel) was a facilitator, particularly at the "policy idea" stage. For example, as early as 1989, Mr. Wappel introduced several private members' bills advocating mandatory nutrition labelling. In the opinion of one key informant,

⁶⁹ Ambrose, A. (1989). Key concepts of the transitional approach to managing change. In Klein, L. (Ed.), Working With Organizations, Papers to Celebrate the 80th Birthday of Harold Bridger. Loxwood: Kestrel Print.

⁷⁰ Crosby, B. (1996). "Policy implementation: The organizational challenge". World Development 24, (9).

Mr. Wappel's efforts demonstrated early on that there was a strong basis of public and political support for mandatory nutrition labelling, in principle . . . furthermore, years later, a Parliamentary Secretary to the Minister of Health (in the 38th Parliament) acknowledged, in the House of Commons, Mr. Wappel's important role in championing the nutrition labelling rules that are now an integral part of our federal health protection law.

■ Role of "Change Agents"

"Change agents" were identified within a variety of structures including, but not limited to Health Canada, the Nutrition Labelling Advisory Committee, and Expert Working Groups. Importantly, "change agents" were also identified at the senior political level. In the study policy success was related to the knowledge, skills, and personalities of the "change agents": "I think it had a lot to do with the people leading the file as well...they were very passionate and visionary. . . ."

At the organizational level, "change agents" tended to be persons in authority with a particular interest in the issue. As a result, they were able to influence those around them to work on nutrition labelling and develop policy in that area. This was facilitated by the strong linkages between Health Canada and the policy community whereby knowledge and experience could be shared and acted upon.

When discussing the important contribution of policy advocates at the system level, the visibility of the Centre for Science in the Public Interest (CSPI) was repeatedly mentioned by key informants. Specific examples included ongoing editorials in the organization's newsletter; a leadership role in "write-in" campaigns; and media advocacy. Additionally, the contribution of the Consumers' Association of Canada (CAC) was highlighted through the research. However, it was pointed out that in the absence of a strong policy network, the contribution of the CAC would have been limited: "It would have been impossible for the CAC to be ahead of the game on an issue like this unless they were devoting most of their resources to it." One key informant suggested that the CAC could have assumed a more visible media advocacy role on nutrition labelling noting, "in contrast, they [the CAC] did appear to be very active on the issue of genetically modified foods labelling during this period [1997-2003]."

Findings attested to the proven track-record of Health Canada policy makers in doing the "behind-the-scenes" work that was so critical. A key informant described the contribution of one "change agent" in this way: "She spent a fair bit of time on the phone between meetings with people, like the industry, to figure out where they were at . . ." Additionally, personality attributes were also considered important: "Her wonderful bubbly personality brought us over the rough spots . . . she was always so enthusiastic."

The keen interest at the senior political level was a key success factor in the nutrition labelling initiative. Health Canada policy makers emphasized the importance of building support at the level of the Deputy Minister (DM) and Assistant Deputy Minister (ADM): ". . . any change to regulations that you get through needs to have DM and Ministerial support, so it's absolutely essential."

Note: In 1997, the CSPI published a key advocacy document entitled "Nutrition Labelling: A Call for Reform." Available at: http://www.cspinet.org/reports/canlabel.html Accessed 26 July 2007

In summary, case study findings indicate that events were aligned in such a way that "champions" within the federal government were working concurrently with a powerful political authority, interested in the same agenda. Importantly, these findings underscore the political nature of the policy formulation process.

Policy innovation happens when . . . influential "champions" at the organizational level and "policy advocates" at the system level keep the policy idea moving forward with the primary objective of seeking stakeholder convergence on the proposed plan of action.

3.2.4 Stakeholder Convergence

This section of the report discusses how stakeholder convergence was achieved, beginning with a hypothesis raised by several key informants through out the interviewing process. To illuminate the convergence process, the researchers used an analytic tool described in the policy literature⁷² to map the shape of the nutrition labelling community at two points of time relative to the Pilot Canadian Case Study. The subtle shifts noted in the Policy Community Diagrams between 1996 and 2002 (Appendix 4, Figures 1 and 2) were helpful in increasing researchers' understandings of stakeholder convergence relative to the nutrition labelling, nutrient content claims and health claims policy process.

"A Three-Legged Stool?"

When describing how stakeholder convergence was achieved, one key informant used the analogy of a "three-legged stool":

There was tremendous pressure from industry not to move forward on [mandatory] nutrition labelling but nutrient content and health claims and the government tied those together . . . health claims and nutrient content claims, it will be done on the basis of, it will be tied to adequate nutrition information on food labels . . . that's how it became a three-legged stool.

According to case study findings, this is an overly simplistic explanation of how stakeholder convergence on nutrition labelling was realized. Further to the "three legged stool" analogy presented above, evidence suggested that it was actually the <u>potential</u> of health claims that brought industry fully "on board." A key informant explained: "it [health claims] was such a small piece . . . we're still working with Health Canada, opening up health claims a little more." The individual suggested that the scientific evidence is now in place for the federal government to expand the list of permitted health claims.

Another key informant reflected on the "three-legged stool" analogy and concluded that the idea minimized a key success factor namely, "the resolute high-level political commitment to mandatory nutrition labelling." The informant went on to suggest that the potential of health claims, in the absence of a broad base of political support, would not have been sufficient to win the cooperation of the food industry.

⁷² Pross, P.A. (1992). *Group politics and public policy*. (2nd ed.) Toronto, ON: Oxford University Press.

Stakeholder Convergence: A Plausible Explanation Based on Evidence

Firstly, the early development and consolidation of a nutrition labelling network among proponents that included both internal actors (i.e., within the federal government) and external actors (i.e., within industry, academia, NGOs, health professional associations and consumer organizations). A key finding supports the notion that there was strong agreement among stakeholders on a common health frame early in the consultative process.

A second explanation of stakeholder convergence relates to the implementation of an innovative and highly consultative policy process. Policy makers' reliance on multiple forms of evidence and clearly articulated decision-making criteria, all contributed to the success of the interactive model (Figure 2, p. 21). Further, the ability to leverage scarce resources and the effective utilization of new web-based information and communication technologies to build citizen engagement were key success factors.

Thirdly, there is strong case study evidence attesting to the critical role of "champions" within the organization and at the political level. Their work was enhanced by the contribution of policy advocates at the system level. Together, "champions", senior politicians and policy advocates kept the nutrition labelling process moving towards a successful outcome (i.e., stakeholder convergence).

In summary, as the process winded down in 2002, decision-makers were able to build a solid rationale for combining three inter-related policy ideas into one comprehensive policy package. Timing was also in Health Canada's favour as there was significant political interest in nutrition labelling, including the stated support of senior elected officials.

Policy innovation happens when . . . the policy-making process is highly tuned and sufficiently flexible to recognize "happenstance" (i.e., it can take advantage of unplanned opportunities and unintended results).

4. Conclusions



The nutrition labelling policy formulation process is considered ground-breaking by many within the health policy sector. At the time the regulations were announced in late 2002, the federal Minister of Health claimed that the scope of the mandatory regulations, together with the manner in which the information was displayed, placed Canada at the forefront of nutrition labelling internationally. The Minister stated:

Nutritional information is essential to helping Canadians make informed choices for healthy living. The *Nutrition Facts* label will allow Canadians to compare products more easily, assess the nutritional value of more foods and better manage special diets.⁷³

A representative of an influential advocacy organization concurred with the Minister, describing the regulations as "the gold standard" for nutrition labelling around the world. An industry spokesperson said: "We support the regulatory changes as a way to better inform Canadians It is all about helping Canadian consumers make informed food choices . . . "The An NGO representative concluded, ". . . health initiatives such as this can pay big dividends . . . it has been estimated that a comprehensive investment in prevention could reduce healthcare utilization by 10 percent over the course of 10 years". The

In presenting conclusions, we posit findings within a framework: "An Interactive Model of Building Consensus on Policy Making" (Figure 2). The framework is helpful in examining policy-making capacities at three levels namely, the individual, organizational, and system. Further, the components of the framework, and the manner in which they interact, highlight the key success factors leading to stakeholder convergence, and ultimately in policy adoption.

⁷³ Health Canada announces new mandatory nutrition labelling to help Canadians make informed choices for healthy eating". (2003, January 2). *Health Canada News Release*, p. 4.

⁷⁴New nutrition food labelling regulations. (2003, January 2). Health Canada Briefing (transcription), p. 10.

⁷⁵New nutrition food labelling regulations, op. cit., p. 8.

⁷⁶ New nutrition food labelling regulations, op. cit., p. 5.

4.1 Policy-making Capacity at the Individual Level

As depicted in Table 4, the "individual" in the case study refers to members of the Nutrition Labelling Advisory Committee, expert groups and "champions" within the federal government's health policy sector. At the individual level, policy-making capacities are described in terms of values and beliefs, leadership, knowledge and skills, partnership and networking abilities, in combination with other attributes.

In the study aggregated policy-making capacities at the individual level were <u>high</u> with gaps identified in the mobilization of internal resources. Additional gaps were noted in the area of organizational support with evidence suggesting that, in some situations, the clarity and/ or transparency of policy guidelines and directives within Health Canada could have been improved (refer to Table 4 for examples).

Table 4: Policy-making Capacity at the Individual Level: HIGH (E.g., members of Advisory Committees, Expert Groups)

Category	Policy-making Capacity	Capacities Documented (examples only)
Values and Beliefs	High	Congruence with basic principles of health promotion/population health; citizen engagement; etc.
Leadership	High	Clear vision; innovative; risk-takers; actively seek new ideas; favourable to change
Knowledge and Skills	High	Competent in analyzing information; adapting knowledge to task; critical thinking skills; procedural knowledge
Resources	Medium	Capacity to mobilize financial resources within Health Canada limited, especially in the early stages; Successful in leveraging in-kind resources through secondments, etc.
Organizational Support	Medium	Guidelines and policy directives within Health Canada not always clear and/or transparent
Partnerships	High	As documented (Policy Networks, Appendix 4)
Networking	High	As documented (Process Innovation, Section 3.2.1)

Source: Adapted from Capacities Required for Policy Adoption and Adaptation (Bowen and Zwi, 2005).77

⁷⁷Bowen, S. and Zwi, A.B., op. cit., p. 603.

4.2 Policy-making Capacity at the Organizational Level

As depicted in Table 5, the "organization" in the case study refers to the federal government (i.e., branches, departments and agencies). At the organizational level, policy-making capacities are described in terms of structures and processes, the ability to leverage and allocate resources, partnerships with other government branches and agencies, leadership, in combination with other attributes.

In the study aggregated policy-making capacities at the organizational level were <u>medium</u> with gaps identified in the mobilization of resources, particularly in the early stages of the process. Additional gaps were noted in the capacity of government to actively involve other key departments and agencies in all stages of the policy-making process (refer to Table 5 for examples).

Table 5: Policy-making Capacity at the Organizational Level: MEDIUM (E.g., across the federal government)

Category	Policy-making Capacity	Capacities Documented (examples only)
Policy Processes and Procedures	Medium	Innovative and ground-breaking process; links to "champions" a key success factor; highly-centralized decision-making within Health Canada identified as a barrier; systems/processes to support work not readily apparent in early stages; "stop-start" nature of the process problematic.
Partnerships	Medium	Success demonstrated in some areas (e.g., Agriculture and Agri-Food Canada support of consumer research; role of the F/P/T Group on Nutrition). Some federal departments and/or agencies, with potentially a role to play, assumed a much lower profile
Resource Allocation	Low to Medium	Limited early success in leveraging in-kind resources and/or technical expertise; Securing the CFIA resources for both compliance and implementation was a barrier in early stages (see Policy Silos, Section 3.2.2)
Leadership	Medium	Policy silos partially limited support for policy innovation and change management processes across the organization (see Policy Silos, Section 3.2.2)
Knowledge and Skills	High	Highly skilled and competent workforce (policymakers, researchers, etc); work of "change agents" recognized within the federal system

Source: Adapted from Capacities Required for Policy Adoption and Adaptation (Bowen and Zwi, 2005).78

⁷⁸ Bowen, S. and Zwi, A.B., op. cit., p. 603.

4.3 Policy-making Capacity at the System Level

As depicted in Table 6, the "system" in the case study refers to the entire policy network including industry, academia, NGOs, health professionals and consumers. Key indicators of policy-making capacities at a system level are processes, political will, contribution of policy advocates, as well as others. Building capacity at the system level requires cost-effectiveness evidence as well the "buy-in" of powerful advocacy groups and opinion leaders.

In the study, aggregated policy-making capacities at the system level were <u>high</u> with demonstrated support at the political level to move forward on nutrition labelling. Evidence of cost-effectiveness, gleaned through research, contributed to reducing barriers at the system level, as did the support of "policy advocates" within the broader stakeholder community (refer to Table 6 for examples).

Table 6: Policy-making Capacity at the System Level: HIGH (E.g., industry, academia, health professional organizations, NGOs, consumers)

Category	Policy-making Capacity	Capacities Documented (examples only)
Politics	High	Strong commitment at the political level; "Nutrition Action Plan" was a catalyst in moving nutrition labelling forward; policy networks created a mutual exchange of information that facilitated the process
Economics	High	Evidence of cost-effectiveness gleaned through research; stakeholders contributed resources to the process
Ideology	High	Shared values within stakeholder community pertaining to how knowledge is created and the issue framed
Values	High	Support of "policy advocates", powerful lobbyists and groups (e.g., CSPI, CAC, etc.); government valued both the issue and the proposed action

Source: Adapted from Capacities Required for Policy Adoption and Adaptation (Bowen and Zwi, 2005).79

In summary, aggregated findings from the Pilot Canadian Case Study summarized in Tables 4, 5 and 6 strongly support the following conclusion:

<u>High</u> policy-making capacity (PMC) at both the individual and system levels, combined with <u>medium</u> PMC at the organizational level, resulted in stakeholder convergence on nutrition labelling and ultimately, in policy adoption.

⁷⁹ Bowen, S. and Zwi, A.B., op. cit., p. 603.

5. Lessons Learned and Recommendations



This section of the report presents lessons learned for policy making and recommendations for consideration of government decision-makers; elected officials; policy makers; policy analysts; and representatives of health professional associations, NGOs, advocacy groups, and others with an interest in the policy-making process.

5.1 Confirmation of Earlier Policy Study Findings

The following lessons gleaned through the Pilot Canadian Case Study confirm findings associated with earlier policy studies:

- In addition to having expert knowledge about the issue, stakeholders require well developed interpersonal skills and access to resources to play an effective role in the policy-making process;
- 2. Early agreement among all members of the policy community on the issue frame greatly facilitates the policy-making process;
- Multiple forms of evidence and information sources are necessary for policy formulation. In this study, scientific evidence was supplemented with cost-effectiveness data, industry-supported studies and consumer research;
- 4. Policy formulation processes are often chaotic and unpredictable. Policy drivers must be flexible and skilled at adapting to changing circumstances;
- 5. Timing is key to successful policy making. Policy makers must have the capacity to act quickly when a policy window opens.

5.2 New Lessons Learned

Salient lessons learned through the Pilot Canadian Case Study include the following:

- 1. When organizational policy-making capacity is weak, partially as a result of resource shortages and/or restructuring, policy makers must implement strategic change management practices to overcome barriers;
- 2. Public demand for both broad stakeholder consultation and meaningful citizen engagement utilizing new information and communication technologies contributes to policy innovation;
- 3. Stakeholders' perceptions of the policy formulation process can differ significantly from those of policy makers. For example, in this study stakeholders described policy formulation as a "stop-start" process, characterized by unexplained and lengthy delays. Decision-makers, on the other hand, stated that the policy formulation process, particularly the complex work associated with moving from the proposed amendments (*Canada Gazette*, Part I, June 16, 2001) to the publication of mandatory nutrition labelling regulations (*Canada Gazette*, Part II, January 1, 2003), occurred at unprecedented speed;
- 4. Further to the finding described in No. 3 above, decentralized decision-making, clear and/ or transparent policy directives, and effective communication processes are helpful in (a) addressing knowledge gaps in the policy community; (b) establishing realistic expectations and timelines; and (c) facilitating active stakeholder participation;
- 5. Authentic partnerships between government, industry and the broad stakeholder community strengthen the policy-making process while improving outcomes;

- Policy silos at the organizational level have the potential to sabotage intersectoral policymaking. Barriers can be reduced through effective change management practices and innovative cross-cutting advisory and communication processes;
- Policy implementation barriers can be mitigated through the buy-in and demonstrated support of powerful stakeholders during the formulation and decision-making stages of the policy cycle.

5.3 Recommendations for Future Research

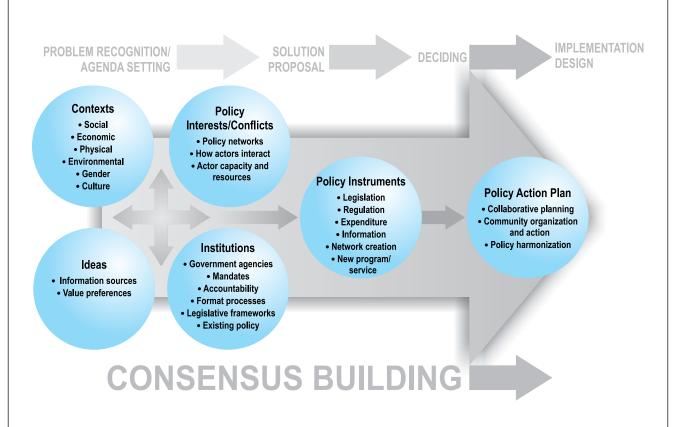
The following recommendations pertain to future areas of health policy research and investigation:

- Research on the implementation of mandatory nutrition labelling regulations in Canada should address evidence gaps pertaining to relevance, progress, efficiency, effectiveness and impact. The availability of baseline data would be helpful in this regard, particularly with respect to evaluating consumer knowledge, attitudes and behaviours.
- Research to examine the efficacy of nutrition labelling logos and/or programs sponsored by both industry and the NGO community is recommended to ascertain whether they are working synergistically with the mandatory nutrition labelling regulations and educational initiatives developed by the federal government.
- 3. Research should examine a variety of models and approaches to the policy-making process. For example, a future study could focus on the 2005-06 process and outcomes of a multi-stakeholder Task Force (led by Health Canada and the Heart and Stroke Foundation of Canada) charged with developing recommendations and strategies for reducing *trans fat* in Canadian foods to the lowest level possible.
- 4. In order to fully explicate the key success factors and barriers to policy formulation and adoption, it would be useful to conduct a study examining a policy-making process that did not achieve stakeholder convergence.
- 5. Future research should utilize the Pilot Canadian Case Study methodology to examine a complex policy idea (e.g., food security; the prevention and control of child obesity) necessitating an integrated, multi-level, and intersectoral approach to policy formulation, adoption, implementation and evaluation.
- 6. Given the paucity of data on policy-making capacity, research to explicate key indicators at the individual, organization and system level, would make a significant contribution to the knowledge base.

APPENDIX 1:

Analytic Framework – Policy Formulation Stage





APPENDIX 2:

CARMEN Pilot Canadian Case Study – Key Informant Interview Guide



Title of Pilot Canadian Case Study

Policy Formulation Pertaining to Nutrition Labelling, Nutrient Content Claims, and Health Claims in Canada

Key Research Questions

Key policy questions requiring careful investigation during Phase 1 of the Pilot Canadian Case Study include, but are not restricted, to:

- 1. What were the processes by which policies pertaining to nutrition labelling, nutrient content claims and health claims were formulated and approved?
- 2. What were the key conditions and factors influencing the formulation and approval of policies pertaining to nutrition labelling, nutrient content claims and health claims?
- 3. What were the salient lessons learned in the design and implementation of intersectoral approaches to policy formulation and approval?
- 4. What additional questions arose pertaining to the implementation of nutrition labelling, nutrient content claims, and health claims policies?

Key Concept	Focus	Interview Questions
1. INSTITUTIONS 2. CONTEXT		
Interviewer: I'd like to begin with a few general questions about your organization (government department, company, organization, etc.) and its role in nutrition policy development.	Mandate of NGO, government department, etc. Identification of lead agencies	What was the mandate of your organization (government department, company, organization etc.) in policy development pertaining to Nutrition Labelling, Nutrient Content Claims and Health Claims? What was your role in the policy formulation and approval process?
Interviewer: Next, I'd like to understand a little more about the policy environment at the time that the Nutrition Labelling, Nutrient Content Claims and Health Claims regulations were under development.	Past policy environment	How did the federal government rank nutrition policy as a priority for action at the time that Nutrition Labelling, Nutrient Content Claims and Health Claims were under development (e.g., low, medium or high priority)? At that time, what were the formal structures and processes through which nutrition policies were formulated and approved?
Interviewer: Transitioning from the past to the present, the next question asks about the current nutrition policy environment.	Formal decision-making structures and processes Current policy environment	Today, how does the federal government rank nutrition policy as a priority for action (e.g., low, medium, or high priority)? Explain.

Key Concept	Focus	Interview Questions
3. IDEAS		
Interviewer: I'd like to hear your ideas about the policy development process leading to Nutrition Labelling, Nutrient Content Claims and Health Claims. You may not be in a position to answer every question. That is why we're piecing the story together with input from multiple sources.	Role of ideas in problem definition and agenda setting (problem recognition) What ideas were brought forward and by whom?	Who brought the Nutrition Labelling, Nutrient Content Claims and Health Claims issue to the attention of government? How was the issue framed? By whom? What are your thoughts on why the issue was framed that way? How would you have liked to have seen the issue framed? Why? Were there competing perspectives on how the issue was framed? If so, describe. Which perspective did government prefer? Explain. Why did government decide to add the issue to its policy agenda when it did?
4. POLICY INSTRUMENTS 5. POLICY INTERESTS / CONFLICTS		
Interviewer: Now I would like to talk about policy instrumentsor the various strategies (solutions) considered and ultimately chosen to address the issue of Nutrition Labelling, Nutrient Content Claims and Health Claims.	Policy instruments available to government to address the issue as defined Policy options considered Policy option chosen and the rationale	What range/mix of policy instruments were identified to address the issue? By whom? What policy instruments were favoured by government (e.g., information, legislation, regulation, taxation)? What factors or conditions influenced the choice of policy instruments? Reflecting on these factors and conditions, which were most significant in influencing the formulation and approval of Nutrition Labelling, Nutrient Content Claims and Health Claims? Was the decision-making process pertaining to the choice of policy instruments controversial? Explain. Did particular individuals and/or groups appear to dominate the policy development process? Explain. Were there any unintended consequences resulting from the choice of policy instruments?

Key Concept	Focus	Interview Questions
Key Concept 6. POLICY ACTION PLAN Interviewer: I'd like to hear your thoughts on partnerships or linkages and their role in the formulation and approval of the Nutrition Labelling, Nutrient Content Claims and Health Claims.	Focus Intersectoral collaboration Facilitators and Barriers	Uhat structures and processes were used to facilitate the development of an action plan to formulate and approve Nutrition Labelling, Nutrient Content Claims and Health Claims regulations? What partnerships and linkages existed, or were developed, to facilitate the development of an action plan? Were there key sectors or organizations not involved in the development of an action plan? Explain. What were the specific contributions of each of the partners?
		What were the main barriers to intersectoral collaboration in the policy formulation and approval process? How were they overcome? What were the enabling factors? How could they have been enhanced? What were the most significant outcomes associated with your government department/organization/company working collaboratively with other sectors in the formulation and approval of Nutrition Labelling, Nutrient Content Claims and Health Claims regulations?
7. APPLICATION OF FINDINGS	Integrated approaches to the prevention and control of chronic diseases	Reflecting on the prevention and control of chronic diseases (e.g., cardiovascular disease, diabetes and some forms of cancer), what are the most important lessons learned that could be applied to other "policy-gap" areas?
Conclusion to Interview Interviewer: Thank you for your thoughtful responses and your important contribution to this study. Within the next two weeks, you will receive via e-mail a transcript of the interview, as described in the Letter of Information.		Is there anything else that you would like to say about the policy development process pertaining to Nutrition Labelling, Nutrient Content Claims and Heath Claims? Is there a key individual that you think I should interview as a result of his/her role in this policy development process?

APPENDIX 3:







Mandatory Nutrition Labelling

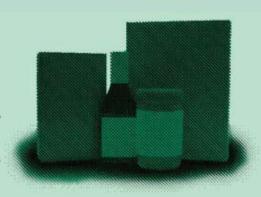
a guide for food and beverage packaging in Canada

Introduction

Health Canada's Mandatory Nutrition Labelling (MNL) regulations for food and beverage products sold in Canada came into effect December 12, 2002 and include a three-year compliance period for food and beverage companies that have annual sales in Canada of over \$1,000,000 and a five-year period for companies with sales under \$1,000,000.

This guide also briefly defines Nutrient Content Claims and the new Health Claims that were approved as a part of these regulations.

For complete details related to Mandatory Nutrition Labelling in Canada, please refer to Canada Gazette Part II "Regulations Amending the Food and Drug Regulations (Nutrition Labelling, Nutrient Content Claims and Health Claims)." This document can be requested from Health Canada in Ottawa or found on the Government of Canada Web-site at http://canadagazette.gc.ca/partII/2003/20030101/pdf/g2-13701.pdf starting on page 154 of the pdf file.



Key Elements

- MNL applies to all prepackaged food and beverage products sold in Canada.
- Health Canada has established format specifications for Nutrition Facts Tables (see inside for some possible formats, font sizes, colours, etc).
- The Nutrition Facts Table must contain the following information:
- Serving size
- Calories
- 13 mandatory nutrients (see adjacent Table).
- Nutrition Facts must always use the same prescribed terminology (e.g. Amount of Fat must be referred to as "Fat", "Total Fat" or "Fat, Total").
- Calculation of Nutrition Facts must be based on stated serving size. Serving sizes by product category can be found in the Canadian Food Inspection Agency Guide to Food Labelling and Advertising.
- Nutrition Facts must be stated in English and French; bilingual or unilingual formats are permitted.
- A Nutrition Facts Table must be located on the outer label of the unit of sale. If a package contains separately packaged ingredients or foods (e.g. multi-packs), the Nutrition Facts Table must be located on the outer container of the unit of sale.
- When two or more prepackaged products are combined together such that no common outer container or label is used (e.g. tandem packs or shrink wraps) a Nutrition Facts Table must be printed on each individual package.

Nutrition Facts Valeur nutritive

Per 125 mL (87 g) / par 125 mL (87 g) Amount % Daily Value % valeur quotidienne Teneur Calories / Calories 80 Fat / Lipides 0.5 g 1 % Saturated / saturés 0 g 0 % + Trans / trans 0 g Cholesterol / Cholestérol 0 mg Sodium / Sodium 0 mg 0 % Carbohydrate / Glucides 18 g Fibre / Fibres 2 g 8 % Sugars / Sucres 2 g Protein / Protéines 3 g Vitamin A / Vitamine A 2 % Vitamin C / Vitamine C 10 % Calcium / Calcium 0 % Iron / Fer 2 % Which Format Applies?

The following 6 steps will help to simplify the process and assist in determining the most suitable Table to be used.

Assess who the target market is

Assess whether the product is marketed for the general public or is specifically intended for Children under 2 years of age (Example A). This guide does not elaborate on multiple options for Children under 2; refer to the regulations for further detail (Gazette II, pages 272 to 296 and figures 20.1 (E) to 34.1(B)).

Choose one of 4 Non-Standard Tables if applicable conditions exist or the Standard Table (Example E) Additional Information† Aggregate (Example B) Dual (Example C) Simplified (Example D) Required when making non-core nutrient Choose if package contains May be chosen if package contains Choose if food contains "0" amount content claims, when nutrient is added, or if multiple, assorted packages foods that require adding additional (as defined) of seven or more of of food. ingredients to prepare. calories and core nutrients. one nutrient triggers the declaration of others

3 Calculate Available Display Surface (ADS) (See page 2)

▲ Choose Tables that correspond to ADS

THEN CONSIDER ESTIMATED‡ DIMENSIONS mm x mm ESTIMATED‡ TABLE SIZE cm ADS ≥ cm² **NUTRITION FACTS TABLE** 401 Standard 1 1 47 x 64 x 2 60.2 323 Standard 1.2 41 x 59 x 2 48.4 244 Standard 1.3 31 x 59 x 2 36.6 Standard 14 33.5 223 31 x 54 x 2 29 x 53 x 2 Standard 1.5 205 30.7 Standard 1.6 29 x 50 x 2 193 29.0 35 x 76 x 2 Narrow Standard 2.1 355 53 2 308 Narrow Standard 2.2 33 x 70 x 2 46.2 258 Narrow Standard 2.3 28 x 69 x 2 38 6 Narrow Standard 2.4 24 x 64 x 2 205 30.7 Bilingual Standard 3.1 52 x 80 416 277 Bilingual Standard 3.2 45 x 73 32.9 219 195 Bilingual Standard 3.3 40 x 73 29.2 154 Bilingual Standard 3.4 35 x 66 23.1 Bilingual Standard 3.5 34 x 63 21.4 143 138 Bilingual Standard 3.6 35 x 59 20.7 Bilingual Standard 3.7 33 x 52 17.2 114 221 Bilingual Horizontal 4.1 107 x 31 33.2 184 Bilingual Horizontal 4.2 95 x 29 27.6 158 Bilingual Horizontal 4.3 95 x 25 23.8 146 Bilingual Horizontal 4.4 95 x 23 21.9 143 Bilingual Horizontal 4.5 113 x 19 21.5 193 Linear 16.1 Varies 153 Linear 16.2 Varies Alternative Methods of Presentation (Example G) Provide manufacturer's postal address or <100 toll-free phone number (Example H) and font selected.

Build Tables according to requirements (summary below)

ő		POINT SIZE for						
	TYPE STYLE*	HEADING	COPY	LEADING	THIN RULES			
	Normal Width	13	8	12	0.5			
	Normal Width	13	7	11	0.5			
	Condensed	13	7	11	0.5			
	Condensed	10	7	10	0.25			
	Condensed	10	6	10	0.5			
	Condensed	10	6	9	0.25			
	Normal Width	12	8	12	0.5			
	Normal Width	11	7	11	0.5			
	Condensed	10	7	11	0.5			
	Condensed	10	6	10	0.5			
	Normal Width	13	8	12	0.5			
	Normal Width	13	7	11	0.5			
	Condensed	13	7	11	0.5			
	Condensed	10	6	10	0.5			
	Condensed	10	6	9	0.25			
	Condensed	10	6	8	0.25			
	Condensed	9	6	7	0.25			
	Condensed	13	7	11	0.5			
	Condensed	10	6	10	0.5			
	Condensed	10	6	9	0.25			
	Condensed	10	6	8	0.25			
	Condensed	10	6	8	0.25			
	Normal Width	10	7	8	n/a			
	Normal Width	10	6	7	n/a			

For each
Non-Standard
Table, multiple
options exist
to allow the
Nutrition Facts
Table to be
adjusted in size.

‡Will vary based on serving, additional nutrients, length of each line

Meet the ADS conditions

If the Nutrition Facts Table chosen is >15% of ADS or cannot be accommodated on a single continuous surface, a smaller version may be used. The Standard, Narrow Standard and Bilingual Standard formats are interchangeable. Formats arranged below the solid bar may only be used if all other options have been excluded; these formats must meet the specifications for Table construction, but there are no conditions for % of ADS used.

ADS CONDITIONS

n/a	Standard 1.1	X	Narrow Standard 2.1	X	Bilingual Standard 3.1		If Standard, Narrow Standard or Bilingual
	Standard 1.2	X	Narrow Standard 2.2	X	Bilingual Standard 3.2		Standard formats cannot be accommodated on a single continuous surface or in any
l							orientation without risking
Use largest table ≤ 15%	Standard 1.3	X	Narrow Standard 2.3	X	Bilingual Standard 3.3		damage to the product if turned over, must use: Bilingual Horizontal 4.1
of ADS	Standard 1.4	X	Narrow Standard 2.4	X	Bilingual Standard 3.4		Bilingual Horizontal 4.2
l	Standard 1.5						
	Standard 1.6						
Use only if none of the formats	Linear 16.1	X	Alternative Methods of Presentation	×	Bilingual Standard 3.5	> <	Bilingual Horizontal 4.3
above can be accommodated:	Linear 16.2		(Example G)	4	Bilingual Standard 3.6	> <	Bilingual Horizontal 4.4
				4	Bilingual Standard 3.7	> <	Bilingual Horizontal 4.5
<100cm ²	Provide manufac	turer's	postal address or toll-free	e phone	e number (Example H)		

^{*}Any single non-decorative sans serif type is permitted. Recommended: Helvetica (registered trademark of Hedelberger Druckmaschinen AG, Licensed to Linotype).

^{**}Tables are named and numbered according to regulations in Canada Gazette Part II. †Example on back panel of this guide.

Example A:

Foods for Children under 2

- Nutrition Facts must not include % Daily Value for fat, sum of saturated + trans fat, sodium, carbohydrate or fibre.
- Nutrition Facts may omit amounts of saturated + trans fat and cholesterol.
- Nutrition Facts must not include Calories from fat or from saturated + trans fat.
- There are 15 format options for this group including: unilingual, dual, aggregate and simplified.

Nutrition Facts Valeur nutritive

Per 1 jar (128 mL) pour 1 pot (128 mL)

Amo	unt / Teneur
Calories / Calories	110
Fat / Lipides	0 g
Sodium / Sodium	10 mg
Carbohydrate / Gluci	i des 27 g
Fibre / Fibres	4 g
Sugars / Sucres	18 g
Protein / Protéines	0 g
% Daily Value / % valeur	quotidienne
Vitamin A / Vitamine A	6 %
Vitamin C / Vitamine C	45 %
Calcium / Calcium	2 %

Bilingual Standard 22.1 (B)

2 %

Example B:

Aggregate

- Used when a package contains separately packaged foods that are tvpically consumed at separate eating occasions.
- Nutrition Facts are given for different units or serving sizes that reflect different uses.

Nutrition Facts / Valeur nutritive

Per 1 pouch	Regular Ordinaire		Apple & Ci Pomme et		Maple & Br Érable et ca	
pour 1 sachet	(35 g)		(35 g)		(35 g)	
	Amount Teneur	% DV* % VQ*	Amount Teneur	% DV* % VQ*	Amount Teneur	% DV* % VQ*
Calories / Calories	110		140		130	
Fat / Lipides	2 g	3 %	2 g	3 %	1 g	2 %
Saturated / saturés + Trans / trans	0 g 0 g	0 %	0 g 0 g	0 %	0 g 0 g	0 %
Cholesterol / Cholestérol	0 mg		0 mg		0 mg	
Sodium / Sodium	220 mg	9 %	310 mg	13 %	200 mg	0 %
Carbohydrate / Glucides	19 g	6 %	26 g	9 %	27 g	9 %
Fibre / Fibres	3 g	12 %	3 g	12 %	3 g	12 %
Sugars / Sucres	1 g		8 g		9 g	
Protein / Protéines	4 g		4 g		3 g	
Vitamin A / Vitamine A		0 %		0 %		0 %
Vitamin C / Vitamine C		0 %		0 %		0 %
Calcium / Calcium		2 %		0 %		0 %
Iron / Fer		6 %		0 %		0 %
* DV = Daily Value / VQ = valeur quotidien	ne					

Bilingual Aggregate 11.1 (B)

Example C:

Dual

May be used when:

- A food is to be prepared according to package directions;
- A food is commonly combined with other ingredients or cooked before consumed; or
- Nutrition Facts are given for different units or serving sizes that reflect different uses.

Nutrition Facts / Valeur nutritive

Per 1/4 package (22 g) / pour 1/4 d'emballage (22 g) About 1/2 cup prepared / environ 1/2 tasse préparé

Amount Teneur	Dry Mix Poudre	Prepared† Préparé†
Calories / Calories	80	140
% Daily Va	lue / % valeur	quotidienne
Fat / Lipides 2 g*	3 %	3 %
Saturated / saturés 1 g + Trans / trans 1 g	10 %	10 %
Cholesterol / Cholestérol 30 mg		
Sodium / Sodium 80 mg	3 %	6 %
Carbohydrate / Glucides 20 g	7 %	9 %
Fibre / Fibres 1 g	4 %	4 %
Sugars / Sucres 14 g		
Protein / Protéines 4 g		
Vitamin A / Vitamine A	0 %	0 %
Vitamin C / Vitamine C	0 %	0 %
Calcium / Calcium	0 %	15 %
Iron / Fer	2 %	2 %
* Amount in dry mix / Teneur de la poudre		

* Amount in dry mix / Teneur de la poudre † 1/2 cup skim milk adds 40 Calories, 65 mg sodium, 6 g carbohydrate (6 g sugars) and 4 g protein. 1 1/2 tasse de lait écrémé ajoute 40 Calories, 65 mg sodium, 6 g glucides (6 g sucres) et 4 g protéines.

Bilingual Dual 9.1 (B)

Example D:

Simplified

- A Simplified Format may be used if the food contains "0" amount (as defined) of 7 or more of calories and core nutrients.
- A Simplified Linear Format is also available.

Nutrition Facts Valeur nutritive

Per 1 stick (2.7 g) pour 1 bâtonnet (2,7 g)

Iron / Fer

	pour : pateriniet (2): 9)				
	Amount Teneur	% Daily Valu % valeur quotidienn			
	Calories / Calories 5				
	Fat / Lipides 0 g	1	0 %		
	Carbohydrate /	Glucides 2 g	1 %		
	Protein / Protéir	nes 0 g			

Not a significant source of saturated fat, vitamin A. vitamin C. calcium or iron. Source négligeable de lipides saturés, lipides trans, cholestérol, sodium, fibres, sucres, vitamine A. vitamine C. calcium et fer

Bilingual Simplified Standard 6.1 (B)

VQ = valeur quotidienne

Example E:

Standard

Per 125 mL (87 g)				
Amount		% D	aily Value	
Calories 80				
Fat 0.5 g			1 %	
Saturated + Trans 0	-		0 %	
Cholesterol 0 mg				
Sodium 0 m	0 %			
Carbohydrate 18 g			6 %	
Fibre 2 g			0 %	
Sugars 2 g				
Protein 3 g				
Vitamin A	2 %	Vitamin C	10 %	
Calcium	0 %	Iron	2 %	
		Standa	rd 1.1 (E)	

Nutrition Facts

Nutrition Facts

Per 125 mL (87 g)							
Amount	% DV*						
Calories 80							
Fat 0.5 g	1 %						
Saturated 0 g + Trans 0 g	0 %						
Cholesterol 0 mg							
Sodium 0 mg	0 %						
Carbohydrate 18 g							
Fibre 2 g	8 %						
Sugars 2 g							
Protein 3 g							
Vitamin A	2 %						
Vitamin C	10 %						
Calcium	0 %						
Iron	2 %						
* DV = Daily Value							

Narrow Standard 2.1 (E)

Nutrition Facts

Valeur nutritive Per 125 mL (87 g) / par 125 mL (87 g) Amount % Daily Value % valeur quotidienne Calories / Calories 80

Fat / Lipides 0.5 g 1 % Saturated / saturés 0 g 0 % + Trans / trans 0 g Cholesterol / Cholestérol 0 mg Sodium / Sodium 0 mg 0 % Carbohydrate / Glucides 18 g 6 % Fibre / Fibres 2 g 8 % Sugars / Sucres 2 g Protein / Protéines 3 g Vitamin A / Vitamine A 2 % Vitamin C / Vitamine C 10 % Calcium / Calcium 0 %

Iron / Fer

Example G:

Alternative Methods of Presentation

- The information must be ≥ 6 points on a tag attached to the package, on the inner side of a label or on a package insert.
- If the information is on the inner side of a label or on a package insert: the outer side of the label of the package must indicate in a type size \geq 8 points, where the information is located.

Example H:

Small Packages < 100cm²

• Reference to another source of information must be identified in a type size \geq 8 points and include a postal address or a toll-free phone number and indicate how the consumer may obtain the nutrition information which would otherwise be shown in the Nutrition Facts Table.

Example F:

Bilingual Horizontal

Amount / Teneur % DV / % VQ * Amount / Teneur **Nutrition Facts** Fat / Lipides 13 g 20 % Carbohydrate / Glucides 23 g 8 % Valeur nutritive Fibre / Fibres 0 g Saturated / saturés 5 g 42 % + Trans / trans 3.5 g Per 1 bar (40 g) Sugars / Sucres 20 g pour 1 tablette (40 g) Cholesterol / Cholestérol 10 mg Protein / Protéines 3 g Calories 220 Sodium / Sodium 70 mg 3 % Vitamin A / Vitamine A 2 % Vitamin C / Vitamine C DV = Daily Value

Calcium / Calcium

Bilingual Horizontal 4.1(B)

% DV / % VQ *

0 %

4 %

Note: Tables are sized at 100% of regulation requirements, actual sizes could vary based on copy content for specific products and font selected.

Example I:

Linear

Nutrition Facts per 1 cup (264 g): Calories 260

2 %

Bilingual Standard 3.1 (B)

Fat 13 g (20 %), Saturated Fat 3 g + Trans Fat 2 g (25 %), Cholesterol 30 mg, Sodium 660 mg (28%), Carbohydrate 31 g (10%), Fibre 0 g (0%), Sugars 5 g, Protein 5 g, Vit. A(4%), Vit. C(2%), Calcium (15%), Iron (4%). % = % Daily Value

Linear 16.1(E)

Valeur nutritive par 1 tasse (264 g): Calories 260

Lipides 13 g (20 %), Lipides saturé 3 g + Lipides Trans 2 g (25 %), Cholestérol 30 mg, Sodium 660 mg (28 %), Glucides 31 g (10 %), Fibres 0 g (0 %), Sucres 5 g, Protéines 5 g, Vit. A (4 %), Vit. C (2 %), Calcium (15 %), Fer (4 %). % = % valeur quotidienne

Linear 16.1(F)

Calculation of Available Display Surface (ADS)

Measurements should be determined by an informed individual and must be taken from the engineering or printer's dielines for the specific package being considered.

Available Display Surface is defined as the **total surface area of a package** and **includes** the:

- bottom of ornamental containers or the total surface area of both sides of a tag attached to the ornamental container; whichever is greater;
- total surface area of both sides of a tag attached to a package to which a label cannot be physically applied;
- bottom of the package as long as the contents will not leak or be damaged if the package is turned over.

and **excludes** the:

- area of the package where printing is not legible or easily viewed;
- area of the package where it is not technically feasible to either print or apply a label;
- part of any package that is destroyed upon opening, except if the package contents are intended to be consumed at a single eating occasion;
- area occupied by the Universal Product Code (UPC) symbol.

A Nutrition Facts Table is the only mandatory information allowed to be printed on a container bottom; the bottom may be excluded from ADS calculation unless the bottom can be used for printing.

Key Format Specifications

- 1. Table size is **NOT** specified; point sizes for copy, leading and rule weight (line thickness) are specified in Schedule L of Canada Gazette Part II (pg. 238-356).
- 2. Order of declared nutrients is fixed.
- 3. Characters and rules in a Nutrition Facts
 Table must be displayed in 100% solid
 black (or visual equivalent in available/
 desired colour) on a white background
 or on a uniform neutral background
 with a maximum 5% tint of colour.
- 4. Characters must be displayed in a single standard sans serif font that is not decorative. Characters must not touch each other or the rules.
- 5. English and French copy must be presented.
- 6. Upper and lower-case letters must be used.
- 7. Highlighting of characters or words, or reverse print, is not permitted.

Figure 1.1(E) Normal width font 8 point type except as indicate Thin rules - 0.5 point Rules centred between text Heading: 13 point bold type Nutrition Facts Serving of stated size: 10 point leading Per 125 ml (87 a Subheadings: 6 point bold type with 12 point leading - 2 point rule % Daily Value _ 1 point rule Calories 80 Text enclosed by a box with a 0.5 point rule within 3 points of ter Fat 0.5 g 1 % Saturated 0 g Value centred against multi-line information on left 9 point leading -+ Trans 0 g Cholesterol 0 mg Calories and non-indented Sodium 0 mg 0 % Numbers in hold type % sign in medium type, 12 point leading Carbohydrate 18 g Medium type 0 % Fibre 2 g Sugars 2 g ← Protein 3 a Vitamin A 2 % Vitamin C 10 % Medium type with 14 point leading-Medium type with 12 point leading-Calcium 0 % Iron 5 point spacing

Exemptions to Mandatory Nutrition Labelling

Refer to Canada Gazette Part II (pages 161 & 162 for more detail)

- 1. Foods containing insignificant amounts of calories and 13 mandatory nutrients defined as a declaration of zero.
- 2. Beverages with an alcohol content of more than 0.5%.
- 3. Fresh fruit and vegetables or any combination thereof.
- 4. Raw, single ingredient meat, poultry, and their by-products except for ground meat and ground poultry.
- 5. Raw, single ingredient marine and freshwater animal products.
- 6. Foods processed or prepared at retail, if ingredients other than water are added.
- 7. Foods sold only at roadside stands, craft shows, flea/farmers markets, and sugar bushes by the person who processed and prepared the product.
- 8. Individual serving of food that is sold for immediate consumption.
- 9. Foods packaged at retail and labelled by means of stickers where the Available Display Surface of the package is less than 200 cm².
- 10. Prepackaged "one bite" confections that are sold individually.
- 11. Prepackaged individual portions of food, solely intended to be served by a restaurant or other commercial enterprise with meals or snacks (e.g. condiments and sweeteners).
- 12. Fluid milk, including goat's milk and cream sold in refillable glass bottles.

"Optional" Elements/Opportunities for Package Copy

Nutrient Content Claims

- Are optional.
- Are a pivotal influence in consumer choice of foods and beverages.
- Assist the consumer in choosing a healthy diet consistent with Health Canada's Guidelines to Healthy Eating.
- Are simple, easily understood information on a single nutrient in a food.
- Describe the level of a nutrient in a food (e.g. "high fibre," "low fat," "source of calcium").
- Food or beverage must meet strict criteria established by Health Canada and as outlined in Canada Gazette Part II: http://canadagazette.gc.ca/partII/2003/20030101/pdf/g2-13701.pdf (pages 200-225).
- Over 50 different Nutrient Content Claims are available to be used.

Health Claims

- Are optional and are allowed for the first time in Canadian history.
- Are a pivotal influence in consumer choice of foods and beverages.
- Assist the consumer in choosing a healthy diet consistent with Canada's Guidelines to Healthy Eating.
- Are statements that describe the characteristics of a diet associated with the reduction of the risk of developing a diet-related disease or condition.
- Food or beverage must meet strict criteria established by Health Canada. The exact wording and criteria for health claims may be referred to in Canada Gazette Part II:

 http://canadagazette.gc.ca/partII/2003/20030101/pdf/q2-13701.pdf (pages 225-231).
- Permitted claims pertain to:
 - 1. A healthy diet with adequate calcium and vitamin D, and physical activity, may reduce the risk of osteoporosis.
 - 2. A diet low in saturated fat and trans fat may reduce the risk of heart disease.
 - 3. A diet high in potassium and low in sodium may reduce the risk of hypertension.
 - 4. A diet rich in a variety of fruits and vegetables may reduce the risk of some types of cancer.

The new regulations also provide for a claim with respect to dental caries for confectionery with minimal mounts of fermentable carbohydrates.

When OPTIONAL Nutrients Become MANDATORY:

• When a Nutrient Content Claim or Health Claim is made, the referenced nutrient that is the subject of the claim must be declared in the Nutrition Facts Table. When additional information is declared, the Table dimensions will vary.

For more information....

For manufacturers who want information to interpret the new regulations, contact Health Canada:

email: nutrition_labelling@hc-sc.gc.ca etiquetage_nutritionnel@hc-sc.gc.ca tel: 613-941-9252

For more specific questions regarding compliance or label reviews, contact the Canadian Food Inspection Agency:

email: nutrition@inspection.gc.ca tel: 800-273-3213

Nutrition Facts

Serving Size 125 mL (35 g) Servings Per Container 13

Amount Per Serving

Calories 90 Calories from fat 9
Calories from Saturated + Trans 0

	aily Value*				
Total Fat 1	9		2 %		
	Saturated 0 g + Trans 0 g				
Omega-6 I	Omega-6 Polyunsaturated 0.5				
Omega-3 I	Omega-3 Polyunsaturated 0 g				
Monunsati	Monunsaturated 0.2 g				
Cholesterol 0 mg 0					
Sodium 300	12 %				
Potassium 410 mg			12 %		
Total Carbo	hydrat	e 27 g	9 %		
Dietary Fib	Dietary Fibre 12 g				
Soluble Fibre 0 g					
Insoluble Fibre 11 g					
Sugars 6 g					
Sugar Alcohols 0 g					
Starch 9 g					
Protein 4 g					
Vitamin A	2 %	Vitamin C	10 %		
Calcium 0 %		Iron	2 %		
Vitamin D	0 %	Vitamin E	6 %		
Vitamin K	10 %	Thiamine	55 %		
Riboflavin	4 %	Niacin	25 %		
Vitamin B ₆	10 %	Folate	10 %		

* Percent Daily Values are based on a 2,000 Calorie diet. Your daily values may be higher or lower depending on your Calorie needs:

10 %

Chromium 10 % Molybdenum 10 %

Pantothenate 8 % Phosphorus 30 %

25 % Selenium

0 % Magnesium 50 %

20 % Manganese 10 %

30 %

Vitamin B₁₂ 0 % Biotin

lodide

Copper

Chloride

Zinc

 Calories:
 2,000
 2,500

 Total Fat
 Less than
 65 g
 80 g

 Saturated + Trans Less than
 20 g
 25 g

 Cholesterol
 Less than
 300 mg
 300 mg

 Sodium
 Less than
 2,400 mg
 2,400 mg

 Potassium
 3,500 mg
 3,500 mg
 3,500 mg

 Total Carbohydrate
 300 g
 375 g

 Dietary Fibre
 25 g
 30 g

 Calories per gram:
 Fat 9
 Carbohydrate 4
 Protein 4

Additional Information 18.1 (E) (shown with all additional nutrients)

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Anthem Group,
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This guide sets out the interpretation of FCPMC and its design partners of the January 1, 2003 *Canada Gazette* Part II publication of the nutrition labelling regulations. This guide is a starting reference point only – readers are advised to consult their legal counsel when making decisions regarding the applicability of and compliance with the regulations. FCPMC and its design partners assume no liability for reliance on or use of the information provided. Revised printing Mar. 03

APPENDIX 4:

Nutrition Labelling Policy Community 1996; 2002



Introduction

The concept of policy communities was developed by Paul Pross (1992) as a descriptive tool to indicate the relative positions of all stakeholders (e.g., government agencies, NGOs, advocacy groups, the media, and interested individuals) *vis-à-vis* their relationship to the actual decision-makers. In other words, it allows the researcher or policy analyst to visualize the relative positions of key stakeholders, and their influence in a specific policy development process. Information gleaned through the data analysis determines where researchers and/ or policy analysts position each stakeholder group within the policy community diagram. By examining the "shape" of a specific policy community at different points, it is possible to track shifts in stakeholders' positions over time. Importantly, the descriptive tool is <u>not</u> intended to provide researchers with information pertaining to the substance/content of the policy.

Additional Information

In Figures 1 and 2, we compare the "shape" of the nutrition policy labelling community at two points: 1996 (coincides with the release of the *Nutrition Action Plan*) and late 2002 (shortly before the regulations were introduced). The subtle shifts in the positioning of most stakeholder groups between Figures 1 and 2 (i.e., movement towards the centre of the diagram) gives readers a visual image of the stakeholder convergence that was achieved with Health Canada decision-makers on this policy issue.

Movement towards the centre of the diagram suggests that between 1996 and 2002, key stakeholder groups played an important and influential role *vis-à-vis* their interactions with Health Canada decision-makers in the nutrition labelling, nutrient content claims and health claims policy process. In situations where there is not a noticeable shift, data suggests that the relative position of the key stakeholder group was not significantly altered through its interactions with Health Canada decision-makers in this specific policy arena.

Figure 1: The Nutrition Labelling Policy Community, 1996

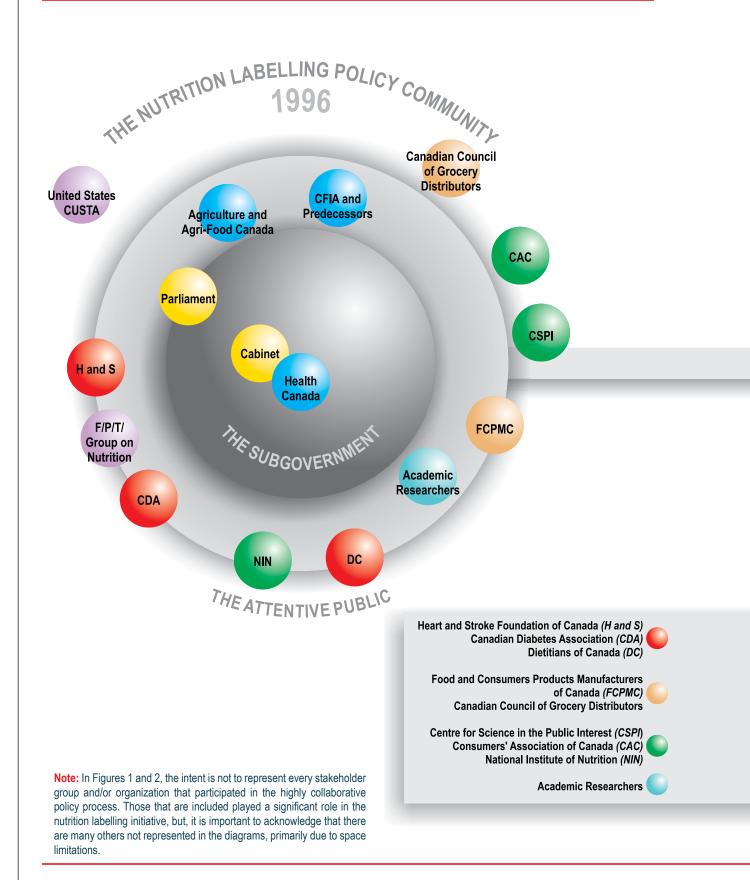
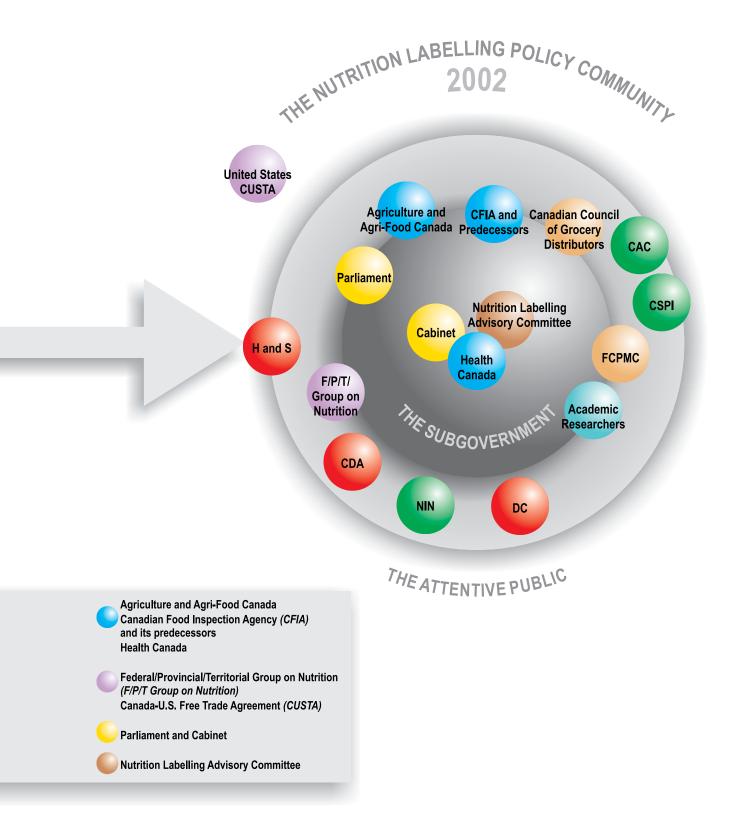


Figure 2: The Nutrition Labelling Policy Community, 2002



Reference: Pross, P.A. (1992). Group Politics and Public Policy. (2nd ed.) Toronto, ON: Oxford University Press.





Nutrition Facts Per 125 mL (87 g) Amount % Daily Value Calories 80 Test 0.5 g 1 % Saturated 0 g + Trans 0 g 0 % Cholesterol 0 mg Sodium 0 mg 0 % Carbohydrate 18 g 6 % Fibre 2 g 8 % Sugars 2 g Protein 3 g Vitamin A 2 % Vitamin C 10 % Calcium 0 % Iron 2 %