FOOD REGULATORY SYSTEMS:

Canada's performance in the global marketplace

A Case Study Approach

Executive Summary

The increased importance of disease prevention through diet, particularly as rising health care costs and aging populations continue to top the social agenda, boosts the demand for innovative food and beverage products with health benefits.

The government says it wants – and in fact encourages – Canada's food processors and manufacturers to innovate to meet this demand and be able to compete and prosper in a global economy.

However, Canada's rules and regulations governing food innovation actually hinder innovation. They are outdated, poorly functioning and, by the Government of Canada's own admission, "*increasingly limited and inflexible*", and "*falling behind international best practices*[1]."

In many instances Canada is decades behind in terms of building enabling regulatory frameworks to allow industry to innovate and communicate the benefits of food innovation to consumers.

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While the Government of Canada has been proposing food regulatory modernization for many years and has been consulting on how best to move forward, Canada's food industry and producers are seriously concerned about the slow pace of change, the lack of choice for consumers, the serious costs to the economy, and the fact that Canada is lagging far behind other nations when it comes to food innovation.

This study provides concrete evidence to support the widely-held view that Canada's food regulatory system is hurting Canada, and is in urgent need of reform.

The study:

- assesses the food regulatory environment in Canada, and compares its main components to the systems in the United States, the European Union, Japan and Australia/New Zealand (Section Two);
- details the experiences of food and beverage manufacturers with Canada's food regulatory system through 12 case studies (Section Three);
- highlights the broader spectrum of the innovation that Canadian consumers are missing out on, by showing what is available in many other countries (Section Four); and
- offers some general conclusions and recommendations for Canada's food regulatory system (Section Five).

Conclusions

Through an analysis of the performance of Canada's regulatory system compared to its competitors, a look at 12 actual cases, and a review of innovative products and use of health claims that are not available in Canada, the study draws the following key conclusions:

- **Canada is not competitive; our food regulatory system is far behind those of leading nations in the world**. There are substantial differences between Canada's regulatory system and those in a number of other countries. Canada's system is less accountable and has more lags. The problems exist in all three parts of the system – the legislation, regulations and administration/processes. As a result, timelines for approval of innovative products and the use of health claims in Canada are much longer than those in the other jurisdictions.
- **Canada's regulatory system needs to be brought into the 21st century**. Canada's system needs a legislative framework, as other countries have, that incorporates objectives for both health protection and food innovation. This would require regulators to explicitly consider the balance between protecting the safety of consumers and responding to demand for new, healthful products.
- **The costs associated with Canada's lagging system are very high and far-reaching**. Twelve case studies help to quantify the costs as a result of the lagging system. The costs were categorized into direct costs, opportunity costs to the food manufacturing companies looking to develop new food products and/or market products with health claims, potential lost sales for retailers because of lack of product availability and potential lost sales for primary producers. Overall opportunity costs to the economy were also examined; these losses include the food manufacturers and all upstream industries' output (lost sales), wages and salaries, foregone taxes, and employment that would have been created due to the economic activity. The costs along the whole value chain are significant.

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Summary of Direct, Indirect and Total Opportunity Costs

Case	Foregone Output, Wages and Salaries, Taxes on Products and Taxes on Production ($Cdn)			Foregone Employment (Individuals)		
	Direct	Indirect	Total	Direct	Indirect	Total
A	$13,435,680	$17,629,764	$31,065,720	39	98	137
B	$69,557,634	$91,270,756	$160,829,819	201	508	709
C	$2,799,100	$3,672,868	$6,472,025	8	20	29
E	$41,204,353	$54,066,710	$95,271,910	119	301	420
F[1]	$1,092,981	$1,434,167	$2,527,170	3	8	11
G	$31,676,589	$41,564,758	$73,241,998	91	231	323
H	$8,696,874	$11,411,692	$20,108,745	25	64	89
J	$14,824,104	$19,451,599	$34,276,007	43	108	151
K[1]	$3,147,881					
L[1]	$12,602,334					
TOTAL	**$200,013,720**	**$240,502,314**	**$440,519,799**	**529**	**1,338**	**1,869**

**Some totals may not exactly equal sum of direct and indirect impacts because of rounding*

Note:

i) these figures are based on only 12 cases. There are likely many more cases experienced by each of the companies who participated in the study, and many more companies who did not participate, who would have similar experiences. It is clear that if these results were extended to the entire system, the costs would be much higher.

ii) it is impossible to estimate all the costs because of the deleterious effects of the regulatory system on the underlying structure of the economy. When suppliers are continually penalized for innovation, they reduce investment in Canada, they undertake less research and development, and they do not provide Canadians with products that could improve their health.

- **Lack of commercialization opportunity fuels the decline of the sector**. The lack of a modern administrative and procedural infrastructure to respond effectively and efficiently to market demand creates a disincentive to commercialize food innovation in Canada and add value to the economy. At a time when Canada's traditional manufacturing sector is in decline due to global economic shifts and currency fluctuations, a strong food processing sector that is properly incented to innovate in Canada could stem the tide of plant closures and job losses that are endemic to the wider manufacturing sector and appearing with greater frequency within the food industry as well.
- **There is no evidence that the lags are the result of measures to help improve the health and safety of Canadians**. The lags identified in the study do not relate to food safety components but rather are the result of poor administrative processes and lack of a framework for decision-making. This contributes additional costs and uncertainty to food suppliers, adds to the time and cost for Canadians to obtain potentially healthier products, and reduces investment in the food industry.

The conclusions of this study are not new nor are they confined to this particular set of regulations. Many other studies, including on other aspects of Health Canada's and CFIA regulations, from plant health products to seed regulations, have drawn similar conclusions, for well over two decades.

Instead of adapting to today's needs, the system has become a growing burden on the Canadian industry, effectively dampening innovation and economic prosperity, and cheating Canadian consumers and users of inputs from access to the products that would allow them to improve their lot.

Canadian food law expert Ron Doering[2] noted that Health Canada has discussed and consulted on the "improvement" and "modernization" of the regulatory system for years, through initiatives such as: *Smart Regulation; Blueprint for Renewal: Transforming Canada's Approach to Regulating Health Products and Food; Blueprint for Renewal II: Modernizing Canada's Regulatory System for Health Products and Food; Towards a Regulatory Modernization Strategy for Food and Nutrition;* and the newest *Managing Health Claims for Foods in Canada: Towards a Modernized Framework*. Although the consultations seem to move in the right direction there is little evidence of any significant results. It is time to step up the effort to reform the system.

Recommendations

The following are recommendations:

- Establish the political will to urgently reform Canada's food regulatory system. Appoint an executive at the highest level of government to oversee and champion the process.
- Re-write the legislation to incorporate:
    - clear objectives so that regulators are given guidance on what the public wants from its health regulatory system;
    - an objective in the legislation to promote efficiency in the food system, as Australia/ New Zealand has;
    - the maximum length of time for regulators to make decisions and a requirement for them to be accountable to Cabinet when the time line is exceeded.

    The Cabinet Directive on Streamlining Regulation was published in April 2007. This Directive replaces the Government of Canada Regulatory Policy with a purpose to work "with Canadians and other governments to ensure that its regulatory activities result in the greatest overall benefit to current and future generations of Canadians". This Directive applies to the development and amendment of regulations under the authority of all federal departments and agencies.

    Along with protecting the health and safety of Canadians, under the Directive, the government must "create regulations through inclusiveness, transparency, accountability and public scrutiny" and "require timeliness" and "promote a fair and competitive market economy that encourages entrepreneurship, investment and innovation". This Directive may help to improve the environment for developing regulations and seems to be heading in the right direction but may simply result in more consultations.
- If the legislation were amended, the regulations would also need to be re-written to be compliant. The following are recommended improvements to the regulations:
    - Pursue administrative approval approaches for food additives and health claims rather than lengthy regulatory amendments after safety has been assessed.
    - Adjust the heavy reliance on the pre-market assessment process and fully explore the use of regulatory procedures in other countries that do not have excessive requirements or have tiered requirements, and assess how they can be adopted to be used in Canada. This would relieve many of the regulatory impediments mentioned in this report.
    - Given the regulatory system is so reliant on pre-market assessments, it requires a clear and transparent process and application requirements. Substantial changes in administrative procedures need to be made to speed up and improve this process at Health Canada, for example:
        - Develop a comprehensive submission guide for applicants to follow in developing a submission (Draft Guidance Document – Management of Pre-Market Submissions is currently in the consultation phase).
        - Hold meaningful pre-submission consultations with applicants with the intent of ensuring that applicants understand the process and complete their submissions with the right information for efficient decision-making.

- Adopt the legislated Australia/New Zealand policy that requires regular communication with applicants at each stage of the decision process.
- Ensure efficiency by accepting credible scientific reviews from other jurisdictions as part of an application and/or utilize third-party experts when resources within Health Canada are limited.
- Hold regulators accountable for meeting timelines. As already indicated, we recommend the legislation be amended to hold the government accountable. This should become part of normal performance evaluation within Health Canada.
- Develop performance indicators and conduct a self-assessment based on those indicators. Make Health Canada's performance on timelines and other measures public.
- Publish application decisions (positive or negative) so that the industry can learn from these experiences. This would also ensure that decisions are made consistently.

1 Cases K and L products and one product from Case F would be manufactured in the United States and therefore have not been run through the Statistics Canada Input-Output model (described in detail in Appendix I). However, the potential lost sales amounts are included in the total economy opportunity costs because these sales would be attributed to the companies' Canadian divisions.

2 Doering, R. (2008). More Talk, No Action: Yet Another Health Canada consultation on health claims in announced. Food in Canada. January/February 2008.

1 **Introduction** and Purpose

As is illustrated by the growth in the world market for natural health products, nutraceuticals and functional foods, consumers are placing greater value on and increasing their demand for foods that are differentiated by health and nutrition attributes.

Noted food industry expert Leatherhead Food International[1] estimates the global functional food market grew almost 10 per cent between 2005 and 2006 and will grow 50 per cent between 2005 and 2010. This growth is driven by changing demographics and economic and social trends. According to Leatherhead, a key market driver for the functional food industry has been the consumer desire to take a more active role in promoting and optimizing personal health and wellbeing. Interest tends to be focused on three main areas: optimizing current health; controlling specific health problems; and promoting future good health.

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Other thought-leaders say the trends that are driving the demand for natural health foods, nutraceuticals and functional foods include[2]:

- aging populations, particularly the large baby boom generation;
- increasing interest in 'healthy living';
- increasing affluence and education among world populations;
- increasing understanding of the link between nutrition and health;
- emphasis on preventative measures to control health care costs;
- increased acceptance and utilization of 'alternative' treatments;
- general consumer dissatisfaction with conventional treatments, therapies and drugs;
- rising acceptance among doctors, pharmacists and other health professionals;
- expanding body of scientific and clinical research to validate effectiveness and safety;
- expanding press coverage of such research;
- increased marketing and advertising activities by suppliers; and
- evolving public policy and regulatory environments.

In spite of the many anecdotal examples of lost opportunity that industry provides to government, the sector's ability to build an urgent case for change has been hampered by a lack of quantifiable data about the opportunity costs associated with Canada's poorly functioning regulatory system for food.

Canadians figure among the global population of consumers who have an increased focus on food for health and disease prevention. However, Canadians are not benefitting from many of the foods designed to deliver these benefits. Canada's outdated regulatory standards and practices limit, restrict and discourage innovation by food manufacturers that would ensure Canadians have access to a variety of foods with health benefits.

The *Food and Drugs Act* and its corresponding *Food and Drug Regulations* and *Natural Health Products Regulations* and the *Consumer Packaging and Labelling Act* impede food innovation and place limitations on health and nutrition claims. The food regulatory frameworks of other nations have more advanced regulatory processes that allow products to be presented in the market according to specific consumer segment demands. While the Canadian government publicly urges the sector to differentiate and diversify, it does nothing to change a regulatory system that rewards sameness and makes innovation costly.

The Canadian food industry is waiting for Health Canada to publish proposed amended regulations for fortification in the *Canada Gazette*. The proposed Canadian regulations will provide manufacturers with greater ability for discretionary fortification of foods than the current regulatory regime does. However, in order for the time and money invested in developing this policy to be worthwhile, the policy must reflect industry needs for innovation and needs to be flexible enough to adapt to future innovation.

In the meantime, the industry – and Canadians – are missing out on significant opportunities. This situation will only amplify as the Canadian system continues to lag, while the global functional food market experiences expected massive growth.

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This study provides the necessary evidence to support the growing assertion that the Canadian food regulatory system is inefficient and ineffective in terms of speed, clarity, transparency and accountability, and as a result, is hurting Canada's economic future and ability to prosper and compete globally. It draws attention to the fact that urgent reform is needed to meet the expectations of Canadians.

1 **Leatherhead Food International. 2006**. The International Market for Functional Foods: Moving into the Mainstream? Retrieved May 28, 2007.

2 **Scott Wolfe Management Inc. 2002**. Potential Benefits of Functional Foods and Nutraceuticals to the Agri-Food Industry in Canada. Research conducted for Agriculture and Agri-Food Canada. Retrieved Apr. 3, 2007 from: http://www.agr.gc.ca/misb/fb-ba/nutra/ben/pdf/Ag-rpt_e.pdf.

Purpose of the Study

The purpose of this study is to identify the impact of Canada's current food approval system on companies wanting to introduce new products, novel foods and/or make health claims relating to these foods. Ultimately the study's goal is to estimate the magnitude of the economic cost to the agri-food sector and the Canadian economy.

Specifically, the study:

- compares Canada's performance against other food regulatory systems around the world;
- estimates the direct losses as the result of a poorly functioning regulatory framework for innovative foods, including losses that stem from delays in the product approval and/or health claim approval process;
- quantifies the losses to food companies and retailers, and to the Canadian economy;
- estimates the potential lost market opportunities for Canadian primary agriculture; and
- recommends improvements to the Canadian food regulatory system.

The losses are quantified through information provided by Canadian food manufacturers about their experiences with the regulatory approvals process, which are written up in 12 case studies in this report. To strengthen the case for change and to press for the urgency of the situation, Canada's food and beverage industry elected to put forward actual examples of the various ways regulatory delays have impacted the ability to commercialize innovation in this country.

It is important to note that the food industry recognizes the need for high standards. The purpose of this research is not to diminish the importance of food safety standards or the reputation for safety that Health Canada enjoys; instead, the research assesses how inefficient regulatory systems have economically impacted the food industry in Canada in an attempt to make a business case for improvement.

2 **Assessment** Of The Canadian Food Regulatory System

To test and assess the widely-held view that the Canadian food regulatory system is inefficient and ineffective, the study examined the components of the system, and compared them to food regulatory systems in other jurisdictions. This review focused in particular on the approval processes for health claims, food additives, novel foods, natural health products and the discretionary fortification of food.

This section of the report outlines the most relevant findings. Appendices A through E[1] of the report contain the complete descriptions of each regulatory system. Summary comparative tables of this information can be found in Appendix G.

An Overview Of Canada's Food Regulatory System

The term "regulatory system" is used to describe a designed framework governing human interaction. The framework comprises prescribed formal rules, which are the objects of social goals, such as safety or economic growth, and delegated procedures and authority to ensure compliance to these rules. The components of the system include legislation, regulations, administration and enforcement.

Legislation and Regulations

Relevant Canadian legislation and regulations pertaining to foods are the *Food and Drugs Act and Regulations* and the *Consumer Packaging and Labelling Act and Regulations*.

The *Food and Drugs Act* prohibits the manufacture or sale of all dangerous or adulterated food products anywhere in Canada. The *Act*, which derives its authority from criminal law, is supplemented by regulations designed to ensure the safety and nutritional quality of foods. The *Food and Drugs Act* also contains *Natural Health Product Regulations* which were implemented in January 2004. Natural Health Products are regulated as a sub-category of drugs.

The *Consumer Packaging and Labelling Act* requires that prepackaged consumer products bear accurate and meaningful labelling information to help consumers make informed purchasing decisions. The *Act* prohibits false or misleading representations and sets out specifications for mandatory label information.

Administration and Enforcement

Health Canada and the Canadian Food Inspection Agency (CFIA) are the federal agencies responsible for the safety and regulation of food in Canada. Health Canada's responsibility is to administer the *Food and Drugs Act and Regulations*, while CFIA is responsible for enforcing the legislation.

Health Canada engages in research, risk assessment, pre-market review and evaluation of all issues related to food safety and nutrition. Health Canada is also responsible for assessing the effectiveness of CFIA's food safety activities. Along with federal inspection services related to food, the CFIA is also responsible for enforcing the *Consumer Packaging and Labelling Act and Regulations*.

Within Health Canada, the Health Products and Food Branch houses the Food Directorate and the Natural Health Products Directorate (NHPD).

The Food Directorate establishes policies, sets standards and provides advice and information on the safety and nutrition of food in Canada with respect to the *Food and Drugs Act and Regulations*. The Nutrition Evaluation Division of the Bureau of Nutritional Sciences works within the Food Directorate and is responsible for food fortification, nutrition labelling and food health claim petitions, policies and standards.

The NHPD regulates natural health products under the Natural Health Product Regulations.

Assessment Of The Canadian Food Product Market Approval System As Compared To Other Jurisdictions

The next section provides an assessment of how efficient the Canadian food product approval system is at getting safe products to market. It looks at the impact of the a) legislation; b) regulations; and c) administration; outlines best practices in other jurisdictions; and assesses Canada's position relative to them. The jurisdictions chosen for comparison are the United States, Australia/New Zealand, Japan, and the European Union, which are considered among the most advanced when it comes to both food safety and innovation.

A) Legislation

The stated purpose of legislation is what guides overall decision-making and formation of policy. The Canadian *Food and Drugs Act* does not appear to have a defined or stated purpose for food product market approval. By default, the focus of the legislation may be inferred by the fact that the *Act* and the *Packaging and Labelling Act* are based on criminal law. The *Food and Drugs Act* was established in 1953 and was designed to meet the challenges of the day. It was largely intended as a consumer protection statute. The *Act's* singular intent is to ensure high safety standards.

Objectives of Legislation in Some Other Jurisdictions

United States	No statement of purpose
Japan	Purpose pertains only to safety
Australia	Very prescriptive purpose, including the goal of ensuring "an effective, transparent and accountable regulatory framework within which the food industry can work efficiently" through Food Standards Australia New Zealand
European Union	Regulation on nutrition and health claims introduced in 2007 (Regulation 1924/2006) includes in its objectives "to ensure the effective functioning of the internal market whilst providing a high level of consumer protection and stimulation and protection of innovations"

The purpose of food legislation in other jurisdictions varies. The market approval processes in some of the other jurisdictions appear to be guided by twin objectives: to protect consumers and foster innovation.

B) Regulations

Health Claims

Regulatory Amendment Requirements Are Lengthy

The efficiency of the health claim approval process is affected by the level of regulatory oversight and regulatory amendments required for approval. Increased regulatory oversight can lead to a decreased number of health claims pursued and/or approved, which in turn leads to a more limited opportunity for innovation.

Health Canada recently compared the health claim regulatory framework in Canada to the United States, EU, Australia/New Zealand and Japan as part of its review of the current framework for the management of health claims on foods[1].

Health claim definitions differ among the countries and make comparison challenging. Although each jurisdiction has its own definition of a health claim, generally, health claims are a statement or representation (through graphics, brand name, trade name) on a food that states, suggests, or implies that a relationship exists between a food or a component of that food and health or disease risk-reduction. Generally, health claims do not refer to dietary information alone that quantitatively or qualitatively makes reference to the level of a nutrient in a food, for example, "zero fat" or "high in fibre". Such claims are referred to as nutrient content claims or nutritional claims.

Prior to regulatory amendments made in 2002, disease risk reduction (DRR) claims were not permitted in Canada. After a review of ten DRR claims allowed for use in the United States, Health Canada amended the *Food and Drug Regulations* to permit five generic DRR claims; a proposal to permit two additional disease risk reduction claims was published on Health Canada's website in 2006[2].

Health Claim Definitions in Canada

Specific Health Claims: claims about the effects of a food, or food constituent, on a specific organ, disease, biomarker or health condition.

1. Disease Risk Reduction Claims: link the consumption of foods or food constituents to a reduced risk of disease in the context of the total diet.
2. Function Claims:
   a. claims about the maintenance of body functions that are necessary to the maintenance of good health and normal growth and development;
   b. claims about maintaining or supporting body functions associated with the maintenance of good health or performance; and
   c. claims about restoring, correcting or modifying body functions.

General Health Claims: do not refer to a specific health effect, disease or health condition.

They include broad "healthy for you" or "healthy choice" claims that promote choosing a food for overall health, promote healthy eating, or provide dietary guidance.

(Health Canada, 2007f)

In Canada, disease risk reduction claims and certain function claims that are made about restoring, correcting or modifying body functions (2c in the Table above) bring a food product under the definition of a drug[3]. A food product that falls under the definition of a drug is then subject to the drug regulations under the *Food and Drug Regulations*. In order to permit the use of health claims, there are provisions in the regulations exempting food products with these claims from the drugs regulations[4]. This results in a great deal of effort to approve a new health claim as described above, and requires regulatory amendment following a pre-market assessment and review of submission[5].

Health Canada's international review of health claim mechanisms of approval and oversight found that the approach used in Canada to manage disease risk reduction and certain function claims is comparable to the other jurisdictions. Regulatory authorization is required for the use of disease risk reduction claims (or their equivalents) in all of the jurisdictions.

In Australia/New Zealand, a tiered system is being proposed whereby pre-approval would only be required for 'serious diseases' in disease risk reduction claims called High Level Health Claims (serious diseases would be defined in the regulations)[6]. Those claims for 'non-serious' diseases, called General Level claims, and nutrient content claims would not require regulatory approval.

In the United States, there are also a number of mechanisms used in approving disease risk reduction claims[7]. The FDA can authorize use of a health claim, the claim can be permitted under the 1997 *Food and Drug Administration Modernization Act* (FDAMA) if FDA makes no objection to the claim within 120 days of submission permitting that an authoritative statement from the US government or the National Academy of Science is included, and, lastly, if the FDA does not deem the claim to have a significant scientific agreement then it can issue a letter of enforcement discretion for a 'qualified' health claim.

With respect to function claims that include well-known nutrients, the use of a positive-list of acceptable claims is common among the reviewed countries. Differences arise in the regulatory oversight among the compared countries with the management of new function claims[8]. In Canada, any new claim requires pre-approval and its addition to the list. In Australia/New Zealand, it is proposed that General Level claims that are not on the pre-approved list not require pre-market approval as long as data are available upon request to prove the claim[9]. High Level health claims in Australia/New Zealand do require pre-approval and the relevant Code must change to accommodate them. In the United States, there is no positive listing process for function claims; under the *Federal Food, Drug and Cosmetic Act*, these claims must simply be truthful and not misleading[10].

Although the mechanisms for approval and oversight may be similar across the jurisdictions, most jurisdictions do not require formal regulatory amendments. When a regulatory amendment is required in Canada it involves formal consultations, drafting a new regulation, a Regulatory Impact Analysis Statement, taking it to Cabinet to authorize its publication in *Canada Gazette* Part I, more consultation, going back to Cabinet and publication in *Canada Gazette* Part II[11].

Canadian food law expert Ron Doering[12] suggests that this process is appropriate for large new regulatory initiatives that will impose new requirements on the industry. However, the regulatory amendments required in the food industry in this context are only required to 'refine existing regulations' after the safety has been assessed. This amendment can take anywhere from 40-120 weeks[13] to three years[14]. Due to this process, the system cannot respond quickly, thereby discouraging innovation in the industry[15].

In the United States, pre-market approval is also required for authorized and qualified health claims, but the FDA does not require statutory exemptions and therefore regulatory amendments, resulting in less time required to get a health claim to market. The United States has approved 16 health claims since 1993 under this process, compared to the five approved in Canada (and two pending review). These health claims have driven US market development in functional foods[16]. For example, development in the area of heart healthy cereal products began with FDA approval of the claim that products with oatmeal could lower cholesterol. Development in this area continued to grow with FDA approval of claims related to psyllium, soya protein and whole grains.[17]

Lag	Effective Practice	Assessment of Canada
Regulatory amendment requirements for certain health claims (DRR and certain function claims)	US: does not require regulatory amendment after pre-market approval. AUS/NZ: Proposed tiered system only requires a Code change for High Level Health Claims. Length of process is accountable to timelines.	Process and response rate to innovation are lengthy.

Cantox[18] also compared the depth and breadth of health claim regulations and processes in each of the five jurisdictions listed above and concluded that the scope of allowable claims linking foods to normal health conditions is more limited in Canada compared to the US. Cantox concluded that "Canada's current regulatory framework for health claims has limited the import of products approved for use in the US. With a more narrow scope of allowable diet and health or disease relationships on foods, food manufacturers are less able to capitalize on their research and innovation initiatives in Canada, many opting to export their ideas, services and products to the US."[19]

Food Additives

Positive List of Approved Additives and Regulatory Amendment Requirements

The efficiency of the food additive approval process is affected by the level of regulatory oversight and regulatory amendments required for approval. Increased regulatory oversight can lead to a decreased number of food additive submissions pursued and/or approved, which in turn leads to a more limited opportunity for innovation.

Food additives must undergo pre-market evaluation for safety and efficacy of their intended use and level of use. In Canada, permitted food additives, the foods in which they may be used and the maximum level of use must be listed in Table II, Division 16 of the *Food and Drug Regulations*. The tables are prescriptive and state exactly in what type of food an additive may be used and at what level. If a food additive or its specific use is not on the list of permitted substances then the additive and its use must be pre-market approved. An amendment to the regulations is required each time a food additive has successfully been approved.

Canadian Regulatory Policy requires that the public has an opportunity to comment on any regulatory amendments, including the *Food and Drug Regulations*. For example, under the proposed revisions, following positive review of a food additive by Health Canada's Food Directorate, the intention for approval is published in *Canada Gazette*, Part I and a minimum of 75 days are allowed for public review of the intention. Marketing of the food additive is only allowed after this review period, approval by the Governor-in-Council, registration of the amendment as regulations and its publication in Part II of the *Canada Gazette*[20].

As noted above, this is a lengthy process and Smith et al.[21] suggest that this has "resulted in numerous submissions and ultimately regulatory modification involving relatively trivial amendments". In an attempt to mitigate this issue of the length of time it takes to get a regulatory amendment, the Food Directorate has increased the use of Interim Marketing Authorizations that permit the use and sale of food products while the regulatory process to amend the regulations is undertaken[22].

The Canadian food additive approval process is similar to the process in Australia/New Zealand and the United States. Food Standards Australia New Zealand (FSANZ) also requires pre-market approval of additives and an amendment to the Food Standards Code that adds the additive to an approved list. The difference in the efficiencies in the processes is that FSANZ is legally accountable to timelines prescribed in the *Act* (this is discussed further below). In the United States, a new food additive must undergo pre-market approval and, once it is deemed safe, a regulation permitting its use is published in the Federal Register.

There is also a major difference within the US regulatory process as compared to the Canadian system. The US regulatory process for food additives is very flexible due to the Generally Recognized As Safe (GRAS) process which allows food additives with a history of safe use to be used without regulatory change. The US is the only jurisdiction with the GRAS process. Usually, the safety of the petitioned food additive has to be determined by the FDA, while the safety of the GRAS substance can be determined by the experts outside of government.

The GRAS and Prior Sanction processes (the latter which covers specific substances that were approved by the FDA prior to the enactment of the food additives amendment to the federal *Food, Drug, and Cosmetic Act*) permit greater flexibility in product marketing and relieve pressure on the regulatory system. GRAS and Prior Sanction substances are generally not specifically regulated in terms of product use or level of use and are not subject to legal review and approval by the FDA. According to Smith et al.[23], the GRAS process is the major difference between the regulation of food additives in Canada and the US and relieves pressure on the regulatory system when dealing with additives that have a history of safe use.

An example that best explains the difference between the Canadian process and the US process is the use of caffeine as a food additive. In Canada, caffeine is regulated as a food additive and is only permitted in cola-type beverages at a concentration level of 200 ppm[24]. In the United States, caffeine is considered a GRAS substance and, if used at a concentration level of 200 ppm, can be added to various beverages including waters and citrus-based beverages[25]. With the energy drink phenomenon in North America, products that use caffeine as their energy sources have sought status as Natural Health Products (NHPs) in Canada, rather than simply being marketed as foods as they are in most other countries[26].

Cheeseman and Wallrock[27] imply that only seven percent of food additive applications in the United States are not GRAS, which shows that the food additive system is substantially relieved of application pressures due to the GRAS process. Due to this relief on the system, the new food additive submissions in 2002 averaged a response rate of 180 days.[28]

Lag	Effective Practice	Assessment of Canada
Specific use listing system requiring continuous amendments to regulations	US: GRAS system which requires no regulation of food additives when there is history of comparable use. Relieves regulatory system and results in a more efficient approval process for new additive submissions. AUS/NZ: Similar process to Canada but length of process is accountable to timelines.	Very specific in prescribed food additive uses and levels. Greater flexibility would decrease pressure on system. Process is said to be lengthy, but the IMA streamlines the process for eligible submissions.

Novel Foods

Product Specific Pre-market Evaluations

A novel food in Canada is defined as a food that has no history of safe use as a food, is a food manufactured using a process not previously applied to that food or an existing food that has been genetically modified. The EU definition also encompasses genetically modified organism (GMO) novel food products, although it is uncertain what percentage of approvals are GMO related. On the other hand, the US has no specific novel food regulatory system and has developed regulations for GMOs specifically, instead of regulating these under the umbrella of novel foods. Since there is no explicit definition for novel foods', these foods fall under the definition of food additives. Therefore, if there is history of use in a like substance, the food can be processed through the GRAS process; if not, then it is considered a new food additive and the food additive market approval process applies.

The novel food regulations in Canada include a legal requirement for these foods to undergo a pre-market safety assessment. Similar to the food additive requirements, these submissions can only be used for the individual products in the submission and, therefore, there are no simplified procedures for novel foods that are substantially equivalent to existing foods – all companies must submit pre-market assessments even if the same food has already undergone an assessment and approval.[29]

In Australia/New Zealand, all novel foods permitted for sale must be included in a Table in the Code. If the food or ingredient is not included in the Table then it must undergo a pre-market safety assessment and, if approved, the Code must be amended.

In the European Union, pre-market assessment of novel foods is required only for those foods that are not substantially equivalent to an existing food.[30] Companies whose products or ingredients are substantially equivalent to an existing food or ingredient can undergo a simplified assessment and can simply notify the Commission that the food or ingredient has been placed on the market.[31] Therefore, it would seem that this allowance would reduce pressure on the regulators.

Unlike the food additive regulation, the pre-market assessment for novel foods in Canada is administrative only and does not require a regulatory amendment. Therefore, inefficiencies resulting from a regulatory amendment requirement do not apply to novel foods. Novel food approvals in the United States and EU also do not require regulatory amendments.

Lag	Effective Practice	Assessment of Canada
Product specific pre-market evaluations	US: Novel foods fall under food additives and therefore can be deemed GRAS if there is a history of use. EU: Simplified Assessment if there is a substantially equivalent food or ingredient. This eases burden on regulatory body.	Very specific in prescribed products. Greater flexibility would decrease pressure on system.

Lack of Discretionary Fortification Policy

In Canada, there are significant regulatory restrictions on the addition of vitamins and minerals to foods. This is likely one of the reasons for the large amount of food-like submissions under the NHPD as food manufacturers continue to innovate and adapt to the possibilities within the regulatory system.

Currently in Canada, the fortification of food is only approved to prevent and/or correct nutritional problems, such as adding Vitamin D to milk to prevent rickets. Foods can also be fortified if vitamins and minerals are depleted during the manufacturing process. The particular vitamins and minerals that can be used are available in a list similar to the one used for food additives in Canada, in *Part D of the Food and Drugs Regulations*. This current fortification policy is based on guidelines published more than 35 years ago.[32]

In 2005, Health Canada outlined a proposed policy in "*Addition of Vitamins and Minerals to Food, 2005: Health Canada's Proposed Policy and Implementation Plans*" to meet increasing demands for functional foods by consumers and to expand food development opportunities and reduce the differences in regulations between Canada and the United States.[33] The proposed policy lays out the following specifics for the discretionary fortification of food:[34]

- List of vitamins and minerals that can be added
- Levels of vitamins and minerals that can be added
- Those foods that cannot be fortified at the discretion of manufacturers

The levels of vitamins and minerals added to food products can vary allowing food manufacturers to indicate whether the product is 'a source', 'a good source' or 'an excellent source' of the nutrients. [35] Health Canada states that the proposed science-based vitamin and mineral levels laid out in the policy are "more conservative than the United States, but more liberal than some European countries".[36] The policy also includes a list of staple foods which will be excluded from fortification.

Although the proposed policy and implementation plan was created in 2005, the public has not yet had a chance to review a set of proposed regulations through *Canada Gazette* Part I. According to Health Canada, the process from *Canada Gazette* Part I to when the regulations would become law once they are published in *Canada Gazette* Part II usually takes 12-18 months.[37] Therefore, this policy is far from being implemented despite the process having started ten years ago.

In the United States, Fortification Policy is published under the Nutritional Quality Guidelines for Foods.[38] These guidelines have been interpreted liberally to permit discretionary fortification of many foods with vitamins and minerals in the United.[39] For example, calcium can be added to many products sold in the United States. However, in Canada, calcium can only be added to orange juice by obtaining an Interim Marketing Authorization (IMA) or by obtaining a Drug Identification Number (DIN).

In Australia/New Zealand, Policy Guidelines for the Fortification of Foods with Vitamins and Minerals were published in 2006. Food Standards Australia/New Zealand (FSANZ) concluded that vitamins and minerals may be added to foods as long as the fortification has demonstrated benefits and no resulting harm. In November 2003, the EU proposed a rule on the discretionary fortification of foods.[40] This rule is based on a positive list of vitamins and minerals that can be added to certain foods at various levels. Japan does not appear to have restrictions on food fortification;[41] instead, it relies on food labelling under FOSHU (foods for specific health use) as a form of control.

While the Canadian food industry is waiting for Health Canada's proposed fortification policy to be published in the *Canada Gazette*, it is missing out on significant opportunities. The proposed Canadian policy will provide manufacturers with greater ability for discretionary fortification of foods than the current regulatory regime does. However, in order for the time and money invested in developing this policy to be worthwhile, the policy must reflect industry needs for innovation and needs to be flexible enough to adapt to future innovation.

Lag	Effective Practice	Assessment of Canada
Restrictive list of pre-approved foods that can be fortified with vitamins and minerals	Canada: Publish the proposed policy for review in *Canada Gazette I*. Direct policy to reflect industry needs to encourage innovation.	Very little discretionary fortification of foods in Canada. Slow to publish proposed policy.

Natural Health Products

Lack of Clarity of Definition of NHPs

In January 2004, a new category of products was created under the *Food and Drugs Act* through the *Natural Health Products Regulations*. In all jurisdictions except for Canada, natural health products are basic synonyms for dietary supplements (natural medicines). In Canada, natural health products are defined much more broadly and can include foodstuffs. However, the *Canadian Food and Drugs Act* was never amended to include a definition of NHPs[42]; therefore, food-like NHPs are regulated as a subcategory of drugs but with their own set of regulations.

There are some food products which fit the definition of both a natural health product and a food. In these cases, it is up to the applicant company to choose under which regulatory process it will market the product. As a result, the Natural Health Products Directorate (NHPD) has received a number of product license applications for food-format NHPs which was never its original intent. There are also products that fall under the definition of NHPs in Canada that can be simply marketed as foods in other countries.

Discussion is taking place within Health Canada, in both the Food and Natural Health Products Directorates, as to whether food formats that fit the definition of both a natural health product and food should be marketed as NHPs under drug regulations or as foods. In October 2007, the NHPD issued a statement that product license and/or claim approvals for NHPs in food format would now be reviewed by the Food Directorate in order to address this issue.[43] Although this is an attempt to better regulate these products, the change has caused confusion for the food industry. The process and implementation issues that have plagued the NHPD, including lengthy submission timelines and capacity issues are likely to continue as, under the current system, these product submissions must pass through two Directorates.

NHPD's proposal is to amend the *Natural Health Products Regulations* (NHPR) to exclude food-like NHPs from the purview of the NHPR. This regulatory amendment would make it clear that these products are not regulated as NHPs and, therefore, would alleviate the confusion that the industry is currently facing. However, to support the innovation within the industry, the amendment implementation should only take place after Canada has implemented a functional and efficient health claims regulatory system for food products and a policy for discretionary food fortification so as not to cause another lag in the system and impede innovation. Many companies have taken advantage of the opportunity that the NHP regulations have provided for the development of innovative food products and health claims. For this innovation to continue, the proper regulatory system, including an effective route for companies to market fortified products and products with claims, must be in place.

Administrative/Process Impacts on Food Approval Process Efficiency

The following is an overview of how Canada compares to other jurisdictions in terms of the key administrative components that may impact food approval process efficiency (timeliness, transparency, clarity and accountability in the review and approval process). Since these administrative components generally apply to different food environments (common administering body, i.e., Health Canada administers regulations for health claims, novel foods and food additives), the administrative impacts on the system's efficiency are not separated by food environment.

No Clear Framework for Pre-market Assessment Submissions

A regulatory system that heavily utilizes pre-market assessment requires an understandable and transparent system for application requirements in order to function efficiently. This does not seem to be the case in Canada. It is not the regulatory requirement of the pre-market assessment that is often the lag. Rather, it is the inconsistent and unclear process in regulation administration that has caused the lags in approvals for food additives, novel foods and health claims in Canada.

Lack of Submission Guidance and Communication

A lack of guidance (framework, documents and consultation) may lead to extended approval process timelines if applicants are unaware of data and information requirements. Without a timely preliminary application assessment, applicants may be unaware of submission deficiencies for long periods of time, which prohibits timely commencement of the scientific review. The lack of guidance leads to a lack of clarity for applicants in terms of the process of approval and the requirements for pre-market assessment.

In October 2007, Health Canada undertook a consultation on a Draft Guidance Document for the Management of Pre-Market Submissions for food additives, novel foods and infant formulas. The document provides instructions for submissions, describes pre-submission consultation and the submission management process, and provides performance standards for the Food Directorate. This document is long overdue, as there appears that there has never been a submission guidance document for food additives as there is for novel foods.

An interim guidance document is provided for health claim submissions however, based on a review by Cantox[44], this document is unclear and incomprehensive. Cantox provides a number of recommendations on how to improve and simplify the health claim approval process in Canada in terms of submission guidance including mandating consultations with government and industry and creating user-friendly guidance documents and websites. Based on industry feedback, it appears that this lack of comprehensive guidance and a clear framework applies to the whole food approval process in Canada. Cantox also states that although health claim applicants are encouraged to discuss proposals with Health Canada, this is not required and contact information is difficult to find. These issues were also mentioned by representatives within the industry as part of this research study.

The US and Australia/New Zealand both have comprehensive submission guidance documents. Australia/New Zealand's guidance document[45] applies to all food product applications; it increases clarity for applicants since only one document encompasses all aspects of the submissions.

Australia/New Zealand has recently changed its approval process to include an Administrative Assessment with a statutory timeframe of 15 business days. The goal of this assessment is "to identify any gaps in the applications to decrease the number of rejections." The statutory timeframe on this assessment ensures that applicants are informed quickly of deficiencies in their submissions, so that there is no delay in the commencement of the application review and submissions are not rejected on the basis of insufficient data or information. Australia/New Zealand strongly urges pre-submission consultations. According to Cantox, FSANZ provides a "clear and unambiguous explanation of regulatory processes for health claim approvals." FSANZ is also obliged to communicate with applicants at various stages throughout the approval process ensuring that communication is maintained .[46]

Lag	Effective Practice	Assessment of Canada
Lack of guidance	US and AUS/NZ: Comprehensive submission guidance documents. AUS/NZ: Pre-submission consultations. US and AUS/NZ: Preliminary application assessment.	Incomprehensive guidance documents for novel foods and health claims. No clear framework for application procedures. Voluntary pre-submission consultation. Initial submission verification for novel foods and food additives under proposed process revisions.
Lack of communication between Health Canada and applicant	AUS/NZ: Legislated obligation for approval body to formally notify applicants of decisions; Review stage updates to applicants.	Legislated notification of decision. No other communication required.

Lack of Accountability to Timelines

While the *Food and Drug Regulations* prescribe timelines for decisions on applications relating to food additives and novel foods, in reality, Health Canada does not adhere to these guidelines. There is no mechanism for holding the agency accountable for its failure to do so. Anecdotal evidence suggests that the process may take 20 to 30 times longer than expected based on the regulatory prescriptions.[47] Clearly prescribing timelines is no guarantee of timeliness in decision-making. Because the clock on an application only begins to "tick" once that application is in full compliance with requirements, some food industry personnel feel that Health Canada exploits this provision by continually requesting more information.

On the other hand, Australia/New Zealand's *FSANZ Act* requires FSANZ to make decisions about food additives and novel foods within stipulated time frames. This requirement will extend to health claims applications once the new policy is implemented. Timelines for General Procedure applications under the Act are measured from the start of assessment (within 15 business days) or receipt of fees, to the date of approval of the draft food regulatory measure (i.e. amendment to the *Food Standards Code*). Time is stopped when further data are requested by FSANZ (dictated by s.108 of the FSANZ Act), however, FSANZ is held accountable to these timelines since it is required to indicate where it has extended the timeframe for completion of an assessment or where it has failed to meet its statutory timeframes and the reasons why in its Annual Report.[48]

In the US, the FDA is accountable to the timelines prescribed with respect to health claim submissions. If timelines are not met, the FDA must provide the Committee on Commerce of the House of Representatives and the Committee on Labor and Human Resources of the Senate with a written explanation.[49]

In Japan, the Ministry application guidelines specify "the standard period of time required for processing" to be one year. This timeframe begins when the Ministry receives the applications and ends with the designation or revision of standards of use of the food additive.

Lag	Effective Practice	Assessment of Canada
No accountability to timelines	AUS/NZ: Timeframes to approval prescribed in legislation and accountability through necessary documentation of performance.	Prescribed timelines but no accountability leads to inability of industry to plan marketing initiatives for products in approval process.

Requirement for Enhanced Research Capacity

Administrative inefficiencies in the market approval process arise when bodies responsible for review are strapped with respect to research resource capacity. In its 2005/2006 Fall/Winter Quarterly, the NHPD acknowledged that backlogs occurred as a result of a lack of human resource capacity.

Two potential solutions exist in response to this lag. The first is that Health Canada could share scientific research analysis with other regulators (i.e., in other jurisdictions). Second, Health Canada could free up research capacity when overwhelmed with submissions by outsourcing scientific assessments to external experts.

Health Canada still does not accept novel foods and food additive pre-market evaluations performed and approved in other jurisdictions for pre-market assessment of efficacy of health claims.[50] Health Canada requests scientific reviews and supporting data from applicants, and reviews it internally regardless of whether the same type of review has been conducted in other jurisdictions or external to the government by credible sources.

Health Canada's Guidance Document for Food Additive Submissions states that an applicant can include evaluations conducted by other domestic, foreign or international scientific bodies such as the US FDA, FSANZ, Codex and the EU, but "such evaluations do not replace the requisite national assessments by Canadian authorities" and "it is expected that some of the efficacy data be procured in institutions in Canada or at least ensure that the data is relevant to Canadian manufacturing conditions and practices".

Cantox suggests that allowing the use of credible reviews that already exist for substantiation of health claims would help to simplify and speed up the approval process and decrease resources required from industry and government parties. For example, FSANZ allows applicants to use relevant assessments conducted by a list of credible authorities.[51]

The US GRAS process also works to free up regulator resources. Usually, the safety of the petitioned food additive has to be determined by the FDA, while the safety of the GRAS substance can be determined by experts outside of government. Both regular food additive and GRAS submissions require the same level of scientific evidence; therefore, the level of safety is not compromised.

Lag	Effective Practice	Assessment of Canada
Research and resource capacity is limited	US: GRAS allows for review by external scientific experts. AUS/NZ: Previously conducted credible assessments to be included in submissions.	No allowances for external review or third party assessment. Puts pressure on resources.

Summary: Identified Lags Affecting Food Approval in Canada

Based on the discussion above, the Table below summarizes the identified major lags affecting food approval in Canada and the international best practices corresponding to these lags. There is substantial potential improvement in efficiency of the food approval process that could result from the adoption of best practices and implementation of more efficient processes to improve the lags in the Canadian system. Improved speed, transparency, clarity and accountability will allow the Canadian industry to move forward with its innovation.

Identified Lags Affecting Food Approvals in Canada, Corresponding International Best Practices

Identified Lags in Canadian Food Regulatory System	International Practices/Potential Improvements
Legislation	
Purpose of Legislation: Current focus solely on safety. No mention of consumer choice or innovation	AUS/NZ and EU: Clear statements of purpose in legislation encompassing goals of ensuring consumer safety and fostering food industry innovation and consumer access to choice.
Regulation	
Health Claims: Regulatory amendment required for certain health claims (DRR and certain function claims)	US: Does not require regulatory amendment after pre-market approval. AUS/NZ: Proposed tiered system only requires a pre-approval and Code change for High Level Health Claims. Length of process is accountable to timelines.
Food Additives: Specific use listing system requires continuous amendments to regulations to add new additives or to add existing additives to new products	US: GRAS system which requires no regulation of food additives when there is history of comparable use.
Novel Foods: Pre-market evaluations required for each product containing a novel ingredient	US: Novel foods fall under food additives and therefore can be deemed GRAS if there is a history of use. EU: Simplified pre-market procedure if there is a substantially equivalent food.
Restrictive list of pre-approved foods that can be fortified with vitamins and minerals	Canada: Publish proposed fortification policy in *Canada Gazette I*. Ensure that the policy reflects innovation of present and future.
Administration	
Lack of guidance	US and AUS/NZ: Comprehensive submission guidance documents; AUS/NZ: Pre-submission consultations; US and AUS/NZ: Preliminary application assessment.
Lack of communication between approval body and applicant	AUS/NZ: Legislated obligation for approval body to formally notify applicants of decisions; Review stage updates provided to applicants.
Limited research and resource capacity	US: GRAS allows for review by external scientific experts. AUS/NZ: Allows review by external scientific experts.
No accountability to timelines	AUS/NZ: Timeframes to approval prescribed in legislation and accountability through necessary documentation of performance.

Global Comparison of Scientific Requirements for Food Approval

Having detail of the inefficiency built into all levels of the Canadian food regulatory system – legislation, regulation as wells as administrative processes – brings us to the question: is the lack of efficiency a result of higher scientific requirements for food approval that make Canada safer? The following compares the scientific requirements for approvals of food products, food additives, novel foods and health claims across the jurisdictions examined in the previous pages.

In each of the jurisdictions reviewed in this study, scientific requirements for health claim substantiation in particular, address the same three areas: efficacy, safety and quality assurance. In 2007, Cantox compared the scientific requirements in these three areas and found that Canada's requirements are most similar to Australia/New Zealand, more comprehensive than the US and less comprehensive than the EU. Overall, despite differences of degree, the requirements are generally comparable.[52]

Efficacy

Cantox reviewed a number of efficacy factors considered in the approval assessments and found Canada's requirements to be adequate and comparable to the other jurisdictions. All of the jurisdictions required human studies, dose-response information, a consistency of findings across studies, relevance of studies to the target group or general population and effective intake information.

Safety

Cantox also found that the safety requirements across the jurisdictions were similar. The primary difference being that safety requirements are not always required to be addressed in health claim applications. For example, Japan requires all aspects of safety to be covered in health claim applications, whereas Australia/New Zealand and the EU cover food safety requirements in their novel food applications. The United States also covers food safety requirements under its GRAS process or food additive applications. Safety requirements in Canada differ depending on whether safety has already been assessed by Health Canada. Overall, Cantox concluded that Canada's scientific requirements for health claim substantiation are similar and adequate compared to the other jurisdictions, but the guidance and communication through the application process is lacking in the Canadian system.

Cantox also reviewed the quality and safety information requirements for novel food applications across the jurisdictions. Although novel foods are defined and regulated very differently across the jurisdictions (a novel food in the United States for example would be regulated as a food additive), the safety and quality requirements are comparable with respect to the depth and quality of information required. Information requirements include manufacturing details, dietary intake estimates, toxicology information and nutritional implications. Again, Cantox found that the major difference was not with the requirements themselves, but with the process that is used to assess the information and its *efficiency*.

A review of the scientific information required for food additive applications (see Appendix G, Table G.2) shows that the requirements are similar. Safety information dominates the requirements and efficacy information is required in Canada and Australia/New Zealand. In the United States, food additives can be declared GRAS or go through the food additive application process if there is less common knowledge regarding the additive. Under either process, the quality of the scientific evidence required is the same.[53]

The reviews predominantly show that Canada's scientific requirements for food approvals are comparable to other jurisdictions, suggesting that they are no higher than those of Canada's competitors. Therefore, it appears that the Canadian system does not result in safer products. It must be noted that while Canada's regulatory system is regarded as one of the safest and most credible in the world, it is those provisions extraneous to safety that are holding up the marketing of innovative food products in Canada.

Canada's regulatory system may in fact contribute to less safe and healthful outcomes for Canadians. If Canadian standards are no higher and do not lead to safer products, yet the system is slow and restrictive, Canadian consumers cannot benefit from products that would improve their health and do not receive them as quickly as they could. Given current demographics of aging populations and rising health care costs, a sclerotic regulatory system creates an overall reduction in social good. This is consistent with the recent analysis of Malla *et al*.[54], and of Parvavolidaki.[55]

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[44] **Cantox. 2007**. *International Comparison on the Management of Health Claims and Novel Foods*. CANTOX Health Science International. from: http://www4.agr.gc.ca/AAFC-AAC/display-afficher.do?id=1178736813119

[45] http://www.foodstandards.gov.au/_srcfiles/Application%20Handbook%20as%20at%2027%20August%2007%20_2_.pdf

[46] **Cantox. 2007**. *International Comparison on the Management of Health Claims and Novel Foods*. CANTOX Health Science International. from: http://www4.agr.gc.ca/AAFC-AAC/display-afficher.do?id=1178736813119

[47] The regulations suggest 90 days to decision, whereas Smith et al. (2007) suggest that the process takes between 40 and 120 weeks and that "the food industry continues to be concerned about the length of time required to promulgate a regulation permitting a new food additive or an amendment dealing a new use for an existing food additive."

[48] **Food Standards Australia New Zealand. 2007a**. Food Matters. Retrieved Oct. 13, 2007a from: http://www.foodstandards.gov.au/foodmatters/.

[49] **Cantox. 2007**. *International Comparison on the Management of Health Claims and Novel Foods*. CANTOX Health Science International. from: http://www4.agr.gc.ca/AAFC-AAC/display-afficher.do?id=1178736813119

[50] **Smith, B. et al. 2007**. *Comprehensive Summary of Canadian Federal Statutes and Regulations Governing Pre-Market Evaluation, Labelling, Advertising and Health Claims for Functional Food in the Canadian Market*. Prepared for the Office of Science and Innovation, Agriculture Policy Framework, Agriculture and Agri-food Canada by Inter/Sect Alliance Inc.

[51] **Cantox. 2007**. *International Comparison on the Management of Health Claims and Novel Foods*. CANTOX Health Science International. from: http://www4.agr.gc.ca/AAFC-AAC/display-afficher.do?id=1178736813119

[52] **Cantox. 2007**. *International Comparison on the Management of Health Claims and Novel Foods*. Cantox Health Science International. from: http://www4.agr.gc.ca/AAFC-AAC/display-afficher.do?id=1178736813119

[53] **US Food and Drug Administration. 2004**. *Frequently Asked Questions About GRAS*. Centre for Food Safety and Applied Nutrition. Retrieved Feb. 15, 2008 from: http://www.cfsan.fda.gov/~dms/grasguid.html#Q2.

[54] **Malla, S. et al. 2007**. Valuing the Health Benefits of a Novel Functional Food. *Canadian Journal of Agricultural Economics* 55: 115-136

[55] **Paravolidaki, C. 2008**. Labelling Information Asymmetry and Functional Foods: A Case Study of Omega-3 Enriched Eggs. A Thesis Submitted to the College of Graduate Studies and Research, in Partial Fulfillment of the Requirements for the Degree of Master of Science, University of Saskatchewan. Master of Science thesis. University of Saskatchewan.

3 **Actual Experiences** With Canada's Food Regulatory System:

Case Study Examples

This section provides evidence through twelve actual examples provided by Canadian food manufacturers that the food regulatory system in Canada presents problems and lengthy lags for companies seeking approvals for health claims and new food products into the Canadian market.

Having a measure of direct costs and opportunity costs is vital in explaining to regulators why the system is urgently in need of reform.

It also quantifies the impact of these deficiencies in the system. The case studies detail the high opportunity costs for the entire supply chain including the manufacturers but also retailers seeking to benefit from the sale of innovative products as well as a wide variety of input suppliers, including primary agriculture producers.

Having a measure of direct costs and opportunity costs is vital in explaining to regulators why the system is urgently in need of reform. Raising awareness of the urgency for change has been challenging in the absence of comprehensive data that quantifies the real costs caused by delays and inefficiencies within the Canadian food regulatory system.

About the Case Studies

Anonymity of the product and manufacturer in each case is retained, due to the proprietary information that was provided during the interview process, unless permission was given by the participating company. The methodology for estimating the economic impacts is described in Appendix I.

The case studies relate to the pursuit of approval from Health Canada for one of four categories:

1. To use health claims in the Canadian marketplace or market products without claims that are approved in other jurisdictions.

Food manufacturers are continually developing and adding "functional foods" to their product lines – foods that have additional nutrients, minerals, cultures or other substances that have positive health benefits when consumed – in order to provide products that have a benefit beyond the traditional nutrients they contain.

Manufacturers would like the ability to communicate these health benefits to consumers by adding health claims to the packaging of these products. Health claims clearly connect the relationship between a nutrient or other substance, and a disease or other health-related condition, and allow consumers to make informed purchasing decisions. Ultimately the ability to use health claims justifies the additional investment required by companies to bring innovative products to the market.

A recent on-line survey conducted by National Starch found that consumers would be 10-26 per cent more likely to consume products with proven health claims, which may translate into a 20 per cent increase in sales.

Today, Canadian consumers are looking for foods with health benefits and exhibit a high level of awareness of functional foods and the diseases they are related to. Two in three Canadians choose foods to maintain health, according to the National Institute of Nutrition and Canadian Food Information Council, 2004. A Decima Research study in 2004, found that overall, Canadians are very positive about functional foods.

Awareness of functional foods is increasing around the world. Datamonitor (2007) found that sales of functional food and beverage products are rising across categories in the US and Europe alike, and growth rates continue to outperform growth in the food and drink categories overall.

Food manufacturers serving the Canadian market would like to take advantage of this demand but would also like to effectively market these new and innovative products to consumers. They are missing opportunities to educate consumers by not being able to effectively communicate the benefits of their products. The use of health claims on food products has been proven to increase consumption of healthy products[1]. For manufacturers, health claims can cause consumers to switch to nutritionally enhanced products in a category or they may attract new consumers who would not otherwise buy a product without an explicitly stated health benefit.

2. To introduce new food products and/or additives

These case studies illustrate the experiences of companies seeking to gain approval in Canada for ingredients/additives that have never been approved in Canada but are currently approved in other countries where they have been proven to be safe and effective.

3. To introduce fortified food products

Food fortification, sometimes called 'enrichment', refers to the addition of one or more vitamins or minerals to a food product. The Canadian food regulations approve food fortification only to prevent and/or correct nutritional deficiencies. For example, Vitamin D is allowed to be added to milk to prevent rickets. Foods can also be fortified if vitamins and minerals are depleted during the manufacturing process.

The Canadian food regulations do not have a definition for or a framework to approve functional foods. Regulations to allow for the discretionary use of food fortification by manufacturers have been in development for the past ten years and are pending publication in *Canada Gazette I*.

4. To introduce natural health products

Natural health products (NHP) are a subcategory of drugs with their own regulations under the *Food and Drugs Act* and defined by Health Canada. They refer to homeopathic and traditional medicines and other substances such as vitamins, minerals, amino acids, probiotics, essential fatty acids, and plant extracts/isolates that, similar to drugs, are represented for use in the diagnosis, treatment, mitigation or prevention of a disease/disorder/abnormal physical state or its symptoms; or, restoring, correcting, or modifying organic functions in humans.

Because the regulatory definition of NHPs does not specify the form or matrix of NHPs, for example, tablets, capsules, powders, conventional food form, the NHPD has received product license applications for NHPs in conventional food form, in other words functional foods.

Case A:
Product Marketed in Canada Without a Health Claim

Summary

Case A is a dairy-based product, currently sold in all major grocery chains in Canada. This product contains non-novel food additives which have recognized benefits for maintaining health. Company A does not require approval to manufacture and sell this product containing these additives in Canada, but is prohibited from making health claims about it. In the United States, similar products are permitted to carry labels with an explanation of the health benefits of the ingredients.

Prior to launching the product in Canada, Company A conducted substantial research and development on the food ingredient levels in the product. It wanted to ensure the levels were maintained throughout the shelf-life of the product and that there were sufficient numbers of clinical studies to support the desired health benefit. In spite of the restrictions on health claims, the company elected to manufacture this product with the added ingredients for the benefit of consumers.

Company A chose to support the launch of the product in the Canadian marketplace with an effective marketing campaign that would refer to the added benefits of this product. This is a common approach taken by companies in the absence of a health claim approval.

In order to compensate for the inability to make health claims on the package, many food companies develop extremely intricate print advertisements designed to communicate product benefits indirectly. Print advertising does not require pre-market approval by Health Canada.

As a result of the restrictions on health claims, Company A was forced to pursue a more arduous and time-consuming creative process. This required more investment by the company and ultimately delayed the product launch, costing the company lost sales opportunities.

In taking extra care not to breach the regulations, the marketing team ended up creating approximately 50 different commercials and campaigns designed to infer the benefits of the product appropriately. Company A estimates that the direct costs of developing this product's nuanced marketing campaign were $500,000 more than that normally spent on more effective marketing campaigns for comparable products. These costs comprise marketing expertise, legal counsel evaluations and approvals, technical expertise to re-test the science, media relations, and expert endorsements from doctors, dieticians and nutritionists as to the benefits of certain functional foods.

Company A estimated an additional three to four months was required to get the product to market as the result of the additional work required to finalize the advertisements. The lost time, coupled with the inability to directly inform the consumer about the benefits has resulted in significant potential lost sales, conservatively estimated to be between $12 and $20 million. Losses would have been reduced had Company A been granted the flexibility to fully discuss product attributes in a more direct manner, using clearer language and using broadcast media to a greater degree to communicate more effectively to a larger audience.

The Opportunity Costs

- Lost sales at the food manufacturer level would translate into potential lost sales for retailers of $15 – $25 million, based on company estimates of retailer mark-ups for this product. This translates to retailer margin losses of $3 – $5 million.
- Dairy producers in Canada have also faced potential lost sales on an estimated 3 – 4 million litres of milk. Based on the current average Canadian price of Class 3B milk of $71.43/hL, the producers' losses are between $2.1 and $2.9 million since the product launch.
- The total opportunity costs to the Canadian economy due to these foregone impacts are $31.1 million, assuming $12 million in lost sales. The total opportunity costs assume $20 million in lost sales.

Case A: Direct, Indirect and Total Opportunity Costs – Low Potential Sales

Impact Category	Impact Type		
	Direct	Indirect	Total
Output	$12,000,000	$14,638,920	$26,638,920
Wage and Salary	$1,353,960	$2,581,680	$3,935,640
Taxes on Products	$19,080	$118,440	$137,520
Taxes on Production	$62,640	$290,724	$353,640
Total Dollar Losses	**$13,435,680**	**$17,629,764**	**$31,065,720**
Employment (Individuals)	39	98	137

**Some totals may not exactly equal sum of direct and indirect impacts because of rounding*

Case A: Direct, Indirect and Total Opportunity Costs – High Potential Sales

Impact Category	Impact Type		
	Direct	Indirect	Total
Output	$20,000,000	$24,398,200	$44,398,200
Wage and Salary	$2,256,600	$4,302,800	$6,559,400
Taxes on Products	$31,800	$197,400	$229,200
Taxes on Production	$104,400	$484,540	$589,400
Total Dollar Losses	**$22,392,800**	**$29,382,940**	**$51,776,200**
Employment (Individuals)	65	164	228

**Some totals may not exactly equal sum of direct and indirect impacts because of rounding*

CASE B:
Product Line Marketed in Canada Without a Health Claim

Summary

Case B involves an ingredient with scientifically proven health benefits which is included in a large number of Company B's products. These products are available in many countries, including Canada. In the United States, UK , and Malaysia, products containing a minimum level of this ingredient can be labeled with a health benefit explanation.

Based on the substantial literature that exists showing the health-related benefits of this ingredient, Company B began in 1999 to consider applying to have a health/function claim approved in Canada for this ingredient. Upon further investigation, including reviewing Canada's regulations and Health Canada's Guidance Document on health claims, Company B decided not to pursue the application. Due to Health Canada's lack of performance targets and accountability, Company B did not have confidence the claim application would be successful, and felt there was too much uncertainty associated with regulatory inefficiency to warrant the human and financial resources, estimated to be $300,000, required for the application.

Company B acknowledges that if Health Canada had a 'buttoned-down' process, including transparency and accountability, it might have submitted an application. The company also said it is scaling back its R&D in Canada due to the sclerotic regulatory system which is stifling innovation and unable to develop an educated health-savvy consumer.

Company B is of the opinion that food manufacturing in Canada as it stands today will disappear if companies can't invest in products of the future and/or communicate their benefits to the consumer. This is especially true now that the majority of food innovation involves health/function claims and the fortification of food.

Company B estimates that, based on sales of products containing this ingredient in other countries where claims are permitted, an approved claim in Canada would lead to a sales increase of 15 per cent. This equates to potential lost sales of $62,124,999.

The Opportunity Costs

- Lost sales at the food manufacturer level would translate into potential lost sales for retailers of approximately $72,721,039, based on company estimates of retailer mark-ups for these products.
- Lost sales at the primary producer level, based on the volume of the ingredient required and historical prices received, total $2,458,803.
- The total opportunity costs to the Canadian economy due to this foregone activity are $160.8 million.

Case B: Direct, Indirect and Total Opportunity Costs

Impact Category	Impact Type		
	Direct	Indirect	Total
Output	$62,124,999	$75,786,908	$137,911,907
Wage and Salary	$7,009,564	$13,365,572	$20,375,136
Taxes on Products	$98,779	$613,174	$711,952
Taxes on Production	$324,292	$1,505,102	$1,830,824
Total Dollar Losses	**$69,557,634**	**$91,270,756**	**$160,829,819**
Employment (Individuals)	201	508	709

**Some totals may not exactly equal sum of direct and indirect impacts because of rounding*

CASE C:
Product Marketed in Canada Without a Claim

Summary

Case C involves a dairy-based product that is sold in all major grocery chains in Canada. This product contains live probiotic culture, a non-novel food additive that has recognized benefits for digestive health. Company C does not require approval to manufacture and sell a product with an added probiotic culture but is prohibited from making claims in association with the benefits of probiotics and this food product

Company C developed, pioneered, and launched this product in Canada. It then introduced similar products into other countries; in some jurisdictions such as the United States, this product's label can include an explanation that the live cultures are beneficial for maintaining digestive health.

Company C knows it could increase sales of the product, attract new consumers and enhance its marketing efforts if it were able to implement a communication plan and design packaging to inform consumers of the benefits of live cultures.

From its market research the company conservatively projects growth of 70 per cent in the first year of being able to communicate health claims. This translates to a loss of $2.5 million in potential sales since the product was launched.

The Opportunity Costs

- Based on wholesale losses of $2.5 million and estimates of retailer mark-ups for this product, retailer margin losses of $1.0 million were calculated.
- The estimated potential sales lost as a result of being unable to educate consumers effectively, has also had a significant impact on Canadian dairy producers. The potential lost sales equate to lost demand of 1.83 million litres of milk.
- Based on the current average Canadian price of Class 3B milk of $71.43/hL, dairy producers have lost the opportunity to sell $1,310,706 of milk to Company C since the launch of this product.
- The total opportunity costs to the Canadian economy due to these foregone sales are $6.47 million.

Case C: Direct, Indirect and Total Opportunity Costs

Impact Category	Impact Type		
	Direct	Indirect	Total
Output	$2,500,000	$3,049,775	$5,549,775
Wage and Salary	$282,075	$537,850	$819,925
Taxes on Products	$3,975	$24,675	$28,650
Taxes on Production	$13,050	$60,568	$73,675
Total Dollar Losses	**$2,799,100**	**$3,672,868**	**$6,472,025**
Employment (Individuals)	8	20	29

**Some totals may not exactly equal sum of direct and indirect impacts because of rounding*

CASE D:
Natural Health Product Approval

Summary

Case D involves a line of teas that contain vitamins, minerals and herbal ingredients, some of which are considered medicinal ingredients in Canada. Company D includes these ingredients at low levels for appearance and flavour rather than for their medicinal properties.

In the United States, these teas are sold as food items and fall under the general food regulations. However, in Canada, the presence of the "medicinal" ingredients in the product requires that they be regulated as natural health products (NHP). Company D is awaiting approval for product licenses and Natural Product Numbers (NPNs) from the Natural Health Products Directorate.

In 2006, Company D took over the importation of the teas from its US counterpart. To gain an understanding of the newly implemented NHP regulations and the application process for its products, Company D attended training seminars hosted by the Natural Health Product Directorate (NHPD).

Through this training, Company D determined that a number of its beverages would require Natural Product Numbers (NPNs) and that its Canadian distribution centre would require a site license number. To be granted a license, sites must demonstrate compliance with good manufacturing practices (GMPs). The company also determined that a site license was not required for the US manufacturer, so terminated the application process which the US operation had initiated prior to the new business arrangement.

In spite of the training seminars, Company D found the site license application process unclear and the NHPD unhelpful. It hired a regulatory consultant to prepare the site license application and NPN applications for the teas to ensure the applications were comprehensive, and ultimately to expedite the process.

Company D has experienced many challenges throughout this process. The site license was initially denied because of a mix-up about the US site (for which the application had been withdrawn) and the Canadian distribution centre. Health Canada had misplaced some of the information Company D included in the application due to personnel changes at the NHPD and did not contact the regulatory consultant who submitted the application to address the issue; it eventually contacted Company D directly. Following this period of inactivity and delay, Company D ended up submitting a second site license application.

Although the site license submission number was sent to Company D within 30 days, to date it has not received an actual site license number. In anticipation of receiving the site license, Company D had the consultant proceed with NPN applications as required for the teas. Company D cannot estimate how long it will take. NHPD guidance documents provide estimated approval timelines for single-ingredient products but not for combination-ingredient products such as the Case D teas.

Given that the site license application is still under review, Company D submitted the applications without the site license, using the submission number instead.

In October 2007 the NHPD announced that product license and/or claim approvals for products in food format would need to be reviewed by the Food Directorate. Company D is currently unclear what effect this change will have on the process or its product license applications. Due to this change in process as well as the fact that the NHPD has been overwhelmed with applications since its inception, Company D does not expect to have approval for its teas for at least another year.

Such extensive and unclear regulations have substantially increased costs for food manufacturers such as Company D who are looking to produce and/or import NHP products into the Canadian market. Company D strongly recommends that NHPD increase its resources so that applicants have access to consultation and advice regarding their applications.

While the NHPD is working to catch up on applications in the queue, new innovation, research and development are taking place. There is legitimate concern that in ten years time there will be another ten years' worth of backlogged applications waiting for approval. As companies become increasingly aware of the enormity of the backlog, the system represents a serious disincentive to food and beverage innovation in Canada.

With the site license number and product applications submitted, Company D can continue to sell the teas as long as it does not make any natural health product claims. However it is missing out on the potential to increase sales. And it has invested substantially in financial and human resources to proceed with the extensive site license application and product number application processes under the NHPD, which required the company to hire a regulatory consultant at a cost to date of $10,000.

CASE E:
Unilever – Becel Pro.Activ

Summary

Case E involves a margarine fortified with plant sterols, developed by Unilever. It is not approved for sale in Canada.

Plant sterols are naturally occurring compounds found in many whole foods such as fruits, vegetables, nuts, seeds and legumes. The cholesterol lowering effect of plant sterols has been studied extensively.

Based on its own extensive research confirming plant sterols represent a significant health benefit because they lower blood cholesterol, Unilever decided to develop a margarine that contains plant sterols to provide a functional benefit to consumers.

Unilever has launched similar products in approximately 19 other countries, including Australia, and the European Union. For the launch of Take Control in 1999 in the United States, plant sterols went through the GRAS process; the product includes the claim "contains natural plant sterols that can help lower LDL cholesterol levels, and may decrease your risk of heart disease". In Australia the product includes a nutrient function claim; "This product contains sterols. Sterols reduce cholesterol absorption".

In August 2001 Unilever introduced Becel Pro.Activ into the Canadian market. The margarine is fortified with plant sterols from soybeans and is designed to lower blood cholesterol levels. The product was marketed as a 'heart-healthier' food.

In October 2001 Health Canada released a statement advising consumers that Becel Pro.Activ was not in compliance with the *Food and Drugs Act and Regulations*. Health Canada contends that Unilever did not receive the required pre-market approval to launch the product. Unilever maintains that Health Canada reviewed scientific data provided by the company under a Novel Foods application for two years and the process was complete.

Under the *Act and Regulations*, any food that makes a health claim is considered a drug. Health Canada's view is that since managing cholesterol is considered a claim, Pro.Activ should have been approved as a drug. Health Canada also stated in its advisory that there was evidence to suggest that Pro.Activ was not safe for all Canadian consumers. To support this assertion, Health Canada released a study that suggested 0.001% of the population would experience red blood cell issues if they consumed plant sterols.

Unilever was caught in a regulatory quandary and, instead of waiting to be ordered to take Pro.Activ out of the market by Health Canada, voluntarily withdrew the product.

Now that the Natural Health Products Directorate has approved a plant sterol pill called ModuChol, from Purity Life Health Products, the safety and efficacy issues about plant sterols can no longer be used to argue against products containing plant sterols. Today, Health Canada no longer references the study linking plant sterol consumption with red blood cell issues.

With the introduction of the Natural Health Products Directorate in 2004, Unilever restarted the approval process, this time to register Pro.Activ as a NHP. Unilever submitted its application in the fall of 2004. NHP applications for "products in food format" have been variously shuffled between the NHPD and the Food Directorate. This lack of coordination within Health Canada is unduly delaying applications.

Health Canada remains apprehensive about the labelling of food products containing plant sterols, as well as the manner in which the dosage in the product is stated. The agency says it is concerned that consumers could eat too much of the product, possibly over-consuming the active ingredient. But instead of discussing labelling options to deal with this concern, Health Canada is simply withholding product approval.

Unilever has found it extremely frustrating to communicate with Health Canada because there is no formal mechanism or framework for reviewing the status of applications. The absence of a clear approval framework also means there are no timelines for which the government is accountable for making decisions.

The company feels that a framework with clear accountability is essential in order for companies to be able to forecast sales and create marketing campaigns. Lack of clarity with respect to process and timelines is exploited by Health Canada officials who face no penalties for arbitrarily drawing out the process by continuing to request more data and information as way to avoid making any decisions.

It also suggests that the lack of a plan for effective collaboration between industry and Health Canada contributes to the agency's lack of understanding of the food formulation and marketing processes in commercial enterprises. Given the criminal law focus of the *Food and Drugs Act and Regulations*, Health Canada is preoccupied mostly with a safety and health protection mandate and as a result, is forfeiting the opportunity to enhance the overall health and well-being of Canadians.

Unilever has begun an 'educational' campaign on plant sterols with key stakeholders (health professionals, governments and NGO's). In 2007, Unilever invited Health Canada and the Heart and Stroke Foundation to learn more about plant sterols in foods. While the sessions have been informative, the approach is not advancing the issue, as Unilever continues to meet with the Food Directorate and its license application is tied up in the NHPD.

In the meantime, Unilever is at a competitive disadvantage because the NHPD has already approved the plant sterol pill – ModuChol. This has effectively eliminated the competitive advantage Unilever had by launching Becel Pro.Activ as a first-to market plant sterol product.

Unilever continues to be prevented from selling and marketing a product that was available for launch in Canada as far back as 2001, not because of concerns about the safety of plant sterols but because Health Canada has not designed a framework under which to approve it.

Unilever has estimated annual sales of $5 million since August 2001 due to first-to market advantage, which translates to a total loss of $36,801,430 in potential sales.

The Opportunity Costs

- Based on company estimates of lost sales and retailer mark-ups, the potential lost sales would result in just over $46 million compounded at the retail level.
- Although figures were not calculated, soybean oil demand (a primary input) would increase if this product were approved in Canada, resulting in current potential lost sales for primary producers.
- The total opportunity costs to the Canadian economy due to these foregone impacts are $95.3 million.

Case E: Direct, Indirect and Total Opportunity Costs

Impact Category	Impact Type		
	Direct	Indirect	Total
Output	$36,801,430	$44,894,432	$81,695,862
Wage and Salary	$4,152,305	$7,917,460	$12,069,765
Taxes on Products	$58,514	$363,230	$421,744
Taxes on Production	$192,103	$891,588	$1,084,538
Total Dollar Losses	**$41,204,353**	**$54,066,710**	**$95,271,910**
Employment (Individuals)	119	301	420

**Some totals may not exactly equal sum of direct and indirect impacts because of rounding*

CASE F:
Health Claim Approval

Summary

Case F involves an application for a health claim related to an ingredient in two similar food products manufactured by Company F and sold in Canada. While one is manufactured in Canada and the other in the US, both are manufactured for the Canadian market. Company F manufactures similar products containing the same primary food ingredient for other international markets.

Company F has submitted an application in Canada for a disease risk reduction claim related to the food ingredient. Approval of the health claim application will require an amendment to one of the five approved health claims for disease reduction (the current claim is attributed to the ingredient in question). The health claim in question has been allowed in the United States since 1998, and is pending approval in the UK. The Australian equivalent to this product is marketed with a structure function claim regarding the food ingredient in question and has been allowed in that country for three years.

Company F initiated discussions with Health Canada for several years and in 2005 commenced the health claim application process. The company hired a consultant to pursue the application process and provide advice on the scientific requirements and regulatory process.

A pre-application meeting between Health Canada and Company F left the company feeling encouraged by Health Canada's suggestion to pursue an application. Originally, the company intended to seek a product specific health claim regarding the food ingredient. However, Health Canada suggested that a disease risk reduction claim would be the best route for the company. Health Canada gave strong signals that an application in the latter category would be more straight-forward and more likely to be successful.

The company submitted the initial required data. A lengthy period of back and forth ensued, with Health Canada requesting further data. The company complied, submitting further data and addressing a seemingly endless series of issues raised by Health Canada. Requests for further data and information continued even after the company felt confident that it had fulfilled all conceivable requirements (meta-analysis studies, literature, research trials etc.).

In August 2007, the company received notice that the application was in preliminary review by Health Canada's nutrition division, pending further information from the company. The company once again complied. In late October 2007, the company was notified that additional questions could arise once Health Canada initiated its detailed scientific review which is not due to commence until late 2008 because of resource/staffing shortages. Company F was discouraged by this notification. Given the many issues that it had already addressed in response to Health Canada requests, the company was under the impression that a detailed review of the application was already underway.

The company's consultant has since asked Health Canada to provide more information about the process and next steps in the approval process including details relating to timelines, the evaluation team, and the components of the scientific review. In response, Health Canada has provided the company with steps and proposed timelines for a health claim application. The company is skeptical that Health Canada will abide by these timelines.

As of April 2008, the company had yet to receive notice from Health Canada that the science submitted by the company for the claim had been approved.

Company F's experience with Health Canada's approval process has been fraught with delay, lack of clarity around administrative and process issues and endless procrastination on the part of officials who lack either the capability or the authority to make decisions. The Health Canada representatives who had encouraged the application have since left their positions, rendering the process more confusing and disjointed for the applicant.

Because the health claim approval process under Health Canada has not been formalized, neither the applicants nor Health Canada have a good grasp of what it entails. This lack of transparency and a formalized approval framework yield a lack of confidence. At this point in time the company is questioning the marketing and sales investment in this product given they cannot make a relevant consumer health claim. Eventually this product may be withdrawn, essentially putting an end to any subsequent product innovation using this ingredient.

The research trials to support the application began in the 1990s. The company estimates that the costs of research to support the application were approximately $2.5 million over 7-8 years. The last substantial trial related to the food ingredient cost $1.2 million.

Furthermore, the company has invested $100,000 to $150,000 over the last two years on a consultant to assist in assembling and addressing issues relating to the scientific evidence and a further $50,000 to $100,000 per year (for the last two years) for a policy consultant to assist with regulatory issues.

The Opportunity Costs

- The losses in the form of foregone sales due to the inability to use the disease risk reduction claim are estimated to be $0.5 million per year per product. Due to the fact that it would be reasonable for an approval decision to be made within one year, this company has experienced potential lost sales over the last year. One year of potential future lost sales are also included in the opportunity costs calculation since Health Canada has advised Company F that the scientific review will not commence until later in 2008. This results in potential lost sales of approximately $2 million for these two products.
- Although the company cannot quantify losses to market development and R&D, it noted that production would have increased at the Canadian manufacturing facility as a result of the expected increases in sales for this product. In the absence of an approved health claim the company is unlikely to invest in additional R&D related to this food product.
- The potential lost sales at the food manufacturer level would translate into potential lost sales for retailers of $2,635,714, based on company estimates of retailer mark-ups for this product. This would result in retailer margin losses of $683,333.

- Although the exact volume has not been calculated, the estimated foregone sales from the inability to market this product using a disease risk reduction claim also results in a significant lost opportunity for grain producers in Canada.
- The table below outlines the direct, indirect and total output, wage and salary, taxes on products, taxes on production and employment opportunity costs to the Canadian economy resulting from regulatory barriers on Case F product marketing. These losses are calculated based on the lost sales of the product that would be manufactured in Canada. The total economic opportunity costs to the Canadian economy due to these foregone impacts are $2.53 million.

Case F: Direct, Indirect and Total Losses

Impact Category	Impact Type		
	Direct	Indirect	Total
Output	$976,190	$1,190,864	$2,167,054
Wage and Salary	$110,144	$210,018	$320,161
Taxes on Products	$1,552	$9,635	$11,187
Taxes on Production	$5,096	$23,650	$28,768
Total Dollar Losses	**$1,092,981**	**$1,434,167**	**$2,527,170**
Employment (Individuals)	3	8	11

**Some totals may not exactly equal sum of direct and indirect impacts because of rounding*

CASE G:
Discretionary Fortification Approval

Summary

Case G involves a product fortified with calcium, which cannot be marketed in Canada, but is sold in major grocery chains across the United States.

Several years ago, Company G initiated discussions with Health Canada to investigate the requirements for approval of this product in Canada. At the time (and to this day) Health Canada was reviewing a proposed policy and plans for the addition of vitamins and minerals to foods. Company G was told to submit an Interim Marketing Authorization (IMA) application. IMAs are a regulatory tool whereby one can request dispensation from existing regulations in anticipation of a change to regulations that would eventually remove an existing prohibition.

The submissions and scientific evidence required by Health Canada to obtain an approval decision and receive an IMA seemed clear. Company G had positive initial meetings with the agency and the process seemed straightforward and transparent. It submitted existing scientific data and Health Canada population survey data to provide a scientific rationale for the fortification of this product.

Company G has not found information from Health Canada forthcoming. The agency has not indicated how long the application process would take or when Company G would learn of the decision. When asked, Health Canada has responded to requests for clarity and explanations, but Company G must initiate all communication with the agency.

After a period of time, Company G was asked to a re-submit its IMA application. Health Canada then changed its position and denied the approval in writing. Prior to the written response from Health Canada, Company G had expected relatively quick approval, given the pre-submission face-to-face meetings with Health Canada.

Health Canada began a review of its fortification policy in 1998. In 2005 it released its amended policy and subsequently developed draft regulations for publication in *Canada Gazette I*. There is no indication when those regulations will actually be published.

Company G has found the Canadian regulatory system to be extremely time consuming, restrictive and prescriptive. Company G suggested that the inability to fortify food products in Canada has resulted in less innovation in food products here.

Company G estimated the cost of the IMA application, including the compilation of data and the time and labour required for consultations to be $30,000.

The Opportunity Costs

- Company G has experienced lost potential sales of approximately $28 million as a result of the inability to market fortified products in Canada. These figures are based on the product's US sales history.
- Based on wholesale losses of just over $28 million and estimated retailer mark-ups for this product, retailer margin losses of $5.65 million were calculated.
- The estimated potential sales losses at the food manufacturing level have also resulted in opportunity costs for Canadian dairy producers. Based on potential lost food sales, dairy producers have lost an opportunity to sell $12,838,279 of milk to Company G.
- The total opportunity costs to the Canadian economy due to these foregone impacts are $73.2 million.

Case G: Direct, Indirect and Total Opportunity Costs

Impact Category	Impact Type		
	Direct	Indirect	Total
Output	$28,291,763	$34,513,404	$62,805,166
Wage and Salary	$3,192,160	$6,086,690	$9,278,849
Taxes on Products	$44,984	$279,240	$324,224
Taxes on Production	$147,683	$685,425	$833,758
Total Dollar Losses	**$31,676,589**	**$41,564,758**	**$73,241,998**
Employment (Individuals)	91	231	323

**Some totals may not exactly equal sum of direct and indirect impacts because of rounding*

CASE H:
Natural Health Product Approval

Summary

Case H involves a beverage fortified with vitamins and minerals for which Company H has applied for a product license and Natural Product Number (NPN) and is awaiting a response from Health Canada.

Company H submitted its application for an NPN for this line of beverages in March, 2004. Under the NHPD, if a line of beverages has varying flavours, only one approval is required, unlike Drug Identification Numbers (DINs). Company H provided the NHPD with all the information requested.

At one point NHPD suggested that Company H wait for the proposed discretionary fortification regulations to be enacted. These proposed regulations have yet to be published in *Canada Gazette I*, which means enactment is still a long time away.

Six months later, and after much dialogue, Company H received a submission number. Company H suggests that the NHPD was undergoing too many changes in early 2004 to be effective. They did not have an adequate number of staff to review the products waiting to transfer from DINs to NPNs, along with all the new products being developed by food manufacturing companies in anticipation of the new process. There was also a lack of expertise in the Directorate as staff members were transferred to the NHPD from other Directorates. Company H continued to follow up during the assessment phase to see whether there was any progress made on the NPN.

In December 2004, Company H decided to put a hold on producing products that would require going through the NHP approval process. Around the same time, Company H received a letter from its contact at NHPD to say that a working group had been created to look for a solution to food-like applications. Six to eight months later Company H received a phone message from NHPD stating that they were proceeding with an evaluation to assign an NPN to these types of fortified beverages.

Companies wishing to market products registered under the Natural Health Products Directorate must obtain site licenses for those facilities where NHPs will be manufactured. With the submission number received, Company H was able to obtain a site license from a separate group under the NHPD. Company H continued to ask the NHPD whether they required any additional information. The Company was told that the application was sufficient, and that the assessment process was moving along. Then staffing changes occurred at the NHPD and Company H lost its original contact person; this contact was not replaced.

The product has now been in the assessment phase for four years. NHPD cannot tell Company H where the application stands in the queue. Company H feels the NHPD has no ability to estimate decision-making timelines and no accountability for adhering to them.

This waiting has resulted in a substantial amount of lost opportunity for Company H. Since marketers at Company H are judged on the success of their campaigns, they do not want to start a campaign for any of the fortified products until they are certain the product will be approved. For this reason, market launch of the product will inevitably be delayed even should the NPN materialize in the future.

In order to remain in step with consumer demands and emerging trends, Company H plans development of and launches new products within a one to two year timeframe. However, based on this experience Company H would need four to five years to work

with the NHPD and therefore be launching products too late to remain on top of consumer trends. The slow process within the NHPD diminishes timely innovation.

The NHPD announcement in October 2007 that product license and/or claim approvals for products in food format would be reviewed by the Food Directorate, has left Company H unclear what effect this will have on the process and Company H's application.

As a result of its frustration, Company H has placed a moratorium on introducing any more products into the Canadian marketplace that require approval from Health Canada. Company H is currently marketing a product similar to the one outlined in this case study which has a DIN due to expire in 2009. Afterwards, this product will need to be either converted to an NPN or withdrawn from the market. Company H has made the business decision to discontinue marketing the product. Company H acknowledges that this is a drastic measure that stifles the innovation and growth of its product line in Canada and may review its decision if discretionary fortification regulations are ever implemented.

Company H would have preferred the NHPD to come back immediately with a definitive rejection of the application. Instead Company H continues to wait.

Company H has been continually monitoring its NPN application through phone calls and emails for more than four years which has added many hours in follow up activity for its staff.

The Opportunity Costs

- Company H has estimated that growth in business and market share through sales of this beverage would have been substantial. Company H planned to launch this product in the second quarter of 2005, figuring on more than one year for the NHPD approval process. This application represents a line of three flavoured beverages. Based on the estimated annual sales for cases of each flavour, Company H has lost a total of $7.8 million in potential sales compounded over the last three years.
- Based on company estimates for lost sales of just under $7.8 million, and estimated retailer mark-ups for this product, retailer margin losses of $3.1 million were calculated.
- The ingredients for these juices would likely come from imported sources. Although Company H sources all of the Canadian produce it can for its fresh juices, the supply of juice-grade produce is declining in Canada due to new technologies and production practices used by producers. Supply is also an issue in Canada since many orchards have been converted to other, more profitable horticultural products, or have disappeared as producers exit the business.
- The total opportunity costs to the Canadian economy due to these foregone impacts are $20.1 million.

Case H: Direct, Indirect and Total Opportunity Costs

Impact Category	Impact Type		
	Direct	Indirect	Total
Output	$7,767,563	$9,475,728	$17,243,291
Wage and Salary	$876,414	$1,671,114	$2,547,528
Taxes on Products	$12,350	$76,666	$89,016
Taxes on Production	$40,547	$188,185	$228,910
Total Dollar Losses	**$8,696,874**	**$11,411,692**	**$20,108,745**
Employment (Individuals)	25	64	89

**Some totals may not exactly equal sum of direct and indirect impacts because of rounding*

CASE I:
Minute Maid Company Canada Inc.: Calcium-Fortified Orange Juice

Summary

Case I describes the experience that The Minute Maid Company Canada Inc. ("Minute Maid") had in launching a calcium-fortified orange juice for the Canadian marketplace – Minute Maid Calcium Rich Orange Juice from Concentrate with modified milk ingredients. Minute Maid's parent corporation, The Minute Maid Company, has marketed a similar type of calcium-fortified orange juice in the United States since 1986.

Research indicates many Canadians do not get the appropriate daily amount of calcium. The Minute Maid product was designed to provide between 25 and 30 per cent of the recommended daily intake (RDI) of calcium. It was seen as a good way to provide much needed calcium to consumers who do not drink milk for a variety of reasons including allergies, lactose intolerance and personal taste preferences.

Minute Maid viewed this product as an important opportunity to provide a functional beverage option to Canadian consumers and meet a market demand. In fact, Minute Maid had received a number of calls from consumers asking where this product was sold in Canada after seeing it or consuming it in the United States. At the time, there was considerable competitive pressure to market this product; most manufacturers of orange juice products saw this as the next logical orange juice product extension in Canada. As the majority of the international manufacturers were already selling a product like this elsewhere, they were poised with existing formulations that could easily be used in Canada had the regulations permitted it.

Prior to Minute Maid launching this product on the market, calcium was only permitted to be added to certain food products such as cereal products, meal replacements, nutritional supplements, flour, and a variety of egg products. The regulatory provisions list the types of foods that can be fortified and specify the nutrients that can be added and at what levels, and how to meet the labelling requirements.

Minute Maid invested a significant amount of time, energy and money in order to determine a method by which it could launch the product and remain compliant with the provisions of the *Food and Drugs Act and Regulations*. Minute Maid devised a formulation that contained modified milk ingredients in order to produce a finished product that contained sufficient amounts of calcium. This formulation proved to be much more expensive and complex to manufacture, distribute and sell, than the calcium salts that the company was using in the United States.

The first calcium-fortified orange juice product was launched in 1999 by Industries Lassonde. Minute Maid then launched Minute Maid Calcium Rich Orange Juice and modified milk ingredients. Shortly thereafter several other manufacturers entered the marketplace with calcium rich products; the most notable was the launch by Tropicana of a mineral supplement with a Drug Identification Number (DIN) which contained orange juice and calcium.

In March of 1999, the company was notified in writing that Health Canada objected to the sale of the product on the basis that it contravened the provisions of the *Food and Drug Act and Regulations*. According to the regulator, the use of modified milk ingredients was deemed to be a form of calcium fortification not permitted by the *Act and Regulations*.

In addition the company was put on notice by the Canadian Food Inspection Agency (CFIA) that if sales of the product continued, the product could be detained, resulting in considerable embarrassment in front of retail customers.

After the notice from Health Canada, the Food Directorate Division put Minute Maid (and likely other similarly situated manufacturers) on notice that in order for Minute Maid to continue to market the product pending regulatory review, it would have to apply for a Temporary Marketing Authorization Letter (TMAL). Minute Maid met with Health Canada officials over the spring of 1999 to review the TMAL requirements and related implications for the marketing of the product. Minute Maid also made changes to the packaging and advertising of the product which ultimately was marketed as a special purpose food "specifically designed as a source of calcium for people who do not drink milk".

In addition, Health Canada imposed a variety of advertising restrictions, including that the product must not be represented for consumption by children under the age of 12 years. The imposition of additional marketing and packaging requirements affected only manufacturers selling the product as a food. Products marketed with a drug identification number (DIN) were not affected by these terms and conditions. The terms of the TMAL allowed for the use of the less expensive calcium salt ingredient ultimately permitting closer alignment with the existing US formulation.

Health Canada provided Minute Maid and all other manufacturers of like products who applied for the authorization with a TMAL for a period of two years. At the conclusion of the two-year period, each company and would be required to conduct post-market research regarding consumers' understanding of the label statement and the product benefits and to assess consumer calcium intakes. This information would then be used to support a regulatory amendment to allow for calcium fortification of orange juice in Canada. This additional requirement had not been imposed in any other jurisdiction where the product was sold. This study required the company to hire an outside consultant. What's more, the TMAL, being temporary in nature, had to be renewed every two years.

After Health Canada received sufficient post-market research, it indicated to industry that the regulations would be amended to allow for the sale of calcium-fortified orange juice. Many years later, Minute Maid applied for a TMAL to market a calcium and vitamin D formulation and was advised by Health Canada that since the regulations had not yet been amended, the new proper regulatory authorization would henceforth be an interim marketing authorization (IMA). Since that time, calcium-fortified orange and tangerine juice products have been approved for sale in Canada as IMAs.

It has been a decade since the launch of these products and the regulatory reform has yet to be completed as it is part of the overall food fortification regulations which are pending publication in *Canada Gazette I*.

Given that the company was unable to use calcium salts initially, it allocated significant resources and time to developing and validating a formula that fit within the parameters of the regulations. Ultimately, it chose a formula with modified milk ingredients that scored lower with consumers on various taste attributes in comparison with the lower cost US Minute Maid formula utilizing calcium salts. In order to optimize the modified milk ingredient formulation, two rounds of consumer research were conducted in Canada at a cost of $65,000 per study. The modified

milk ingredient product was launched despite it being a more complex formulation and having a less appealing taste profile. If the salts formula had been allowed, no consumer taste research would have been required.

The launch of modified milk ingredients was technically complex from a manufacturing perspective and as a result of the milk protein component, significant capital investments were necessary to modify production equipment in the plant facilities belonging to the company as well as its co-packers. Once calcium salts were permitted to be used, this investment was lost.

Due to the high level of perceived regulatory risk in launching this formulation in Canada, Minute Maid was conservative in its approach and prepared an in-depth public relations campaign in preparation for the possibility of action from Health Canada and the CFIA.

Once the product was on the market under the TMAL, post-market research was conducted to meet its requirements. A specialized consultant was hired to properly formulate the research study and to obtain the data that Health Canada required. Additional internal resources from the market research, regulatory and legal departments were needed to advise and supervise the research study and to finalize and report the findings to Health Canada. Much of this work was also likely duplicated by other manufacturers who had the same TMAL and therefore the same post-market research requirements. Money spent on the post market research was approximately $75,000.

The Opportunity Costs

- A core product for Minute Maid is frozen concentrated orange juice. Due to technical difficulties, the modified milk formula could not be utilized in the frozen orange juice format and therefore Minute Maid was not able to capitalize on that market with the modified milk formulation. The introduction of a frozen product was delayed until approval was secured to use calcium salts in the formula under the TMAL, thus resulting in considerable lost sales and opportunity costs.

CASE J:
Ocean Nutrition Canada: Novel Food and Health Claims Approvals

Summary

Case J involves a novel food approval, a nutrient content claim and a biological role claim approval for a microencapsulated gelatin EPA and DHA (omega-3) powder produced in Canada and marketed globally including in the US, Mexico, the EU and certain Asian countries.

Ocean Nutrition Canada (ONC) specializes in research and development of omega-3 supplements and food components. Its supplements are sold in health food and grocery stores and its food ingredients are sold to food processors for addition to 'better for you' food products marketed in all major grocery stores.

The stabilizing agents and fish oils used in the ingredient are not novel. However, the ingredient was considered novel by Health Canada because its production process conceals the taste of the fish oil. As such, Health Canada was concerned that a lack of taste could lead to large amounts of consumption of the ingredient, since its consumption would not be inhibited by the "fish" taste of the food products containing it.

While the ingredient is currently available for sale in Canada having cleared the necessary regulatory approvals for a novel food, the process leading up to the approval was a difficult one. ONC is now seeking nutrient content and biological role claim approvals for the product. This process has taken four years so far and has yielded no success to date.

The current labels for products containing this ingredient can only make factual statements indicating that omega-3 ingredient is contained within the food, but cannot claim that the food is rich in omega-3, or a good source of omega-3. This would be considered a nutrient content claim which the ingredient is currently not authorized to make. A label on a product containing this ingredient cannot state that it offers any cardiovascular health benefits which constitutes the biological role claim also currently under review.

Discussions with Health Canada regarding this ingredient began in January 2003 and a submission for a novel food approval of the ingredient was made in May 2003. The novel food was approved more than three years after the original submission, in June 2006.

The company felt that the process was not transparent in terms of timelines or data requirements, which resulted in an unnecessarily lengthy process and unexpected costs to the company.

The submission process was challenging because the Canadian novel food approval process is geared toward the review of genetically modified organisms. The company did not find the novel food submission requirements helpful in guiding this particular ingredient submission. ONC was unsure about data requirements and, as a consequence, ended up having to make several additional submissions of data, and spent much more time than if Health Canada had provided a more clear understanding of the submission requirements upfront. In fact, ONC was required to generate new evaluations of safety related to estimated average daily consumption which required that toxicological consultants be retained to meet these requirements.

The approval process for the novel food component was protracted, due to the debate with Health Canada regarding the range of foods that would be allowed to use the ingredient. ONC submitted an application for a broad range of foods. The breadth of food in the submission was based on a similar submission ONC was making in the United States. Health Canada asked

the company to shorten the list, claiming that this would result in a shorter approval process. ONC obliged, short-listing six to ten foods, which it had prioritized according to envisioned consumer demand.

The outcome of this discussion was that Health Canada approved the novel food for all foods with the exception of commodity foods (foods that are fundamental to many products and, as such, tend to be consumed often and in large quantities) such as flours, pastas, rice, butter and some other foods such as infant formula, tea, coffee and maple syrup (the basis of these choices being unknown to ONC). ONC was satisfied with this outcome, with the exception of the prohibition of the ingredient for use in pasta products, which company clients like to work with. However, the original Health Canada request for a short-list of products, which did not play a role in the final choice of approved foods, was wasteful in terms of time and finances invested by ONC.

The approval process was further delayed by discussion with Health Canada regarding the quantity of the novel food component that would be allowed in the final food product. Currently, one nutrient content claim exists for omega-3 in Canada that requires the presence of 300 mg of omega-3 per serving[2]. ONC submitted its application requesting a 300 mg per serving quantity for the novel food component, since it intended to use a nutrient content claim along with the novel food component application. However, Health Canada was not comfortable with this quantity. The original 300 mg nutrient content claim, according to Health Canada, was intended for plant-based omega-3 only (flax seed source from ALA)[3].

The company representative interviewed for this report stated that this narrow restriction to plant-based sources of omega-3 appears to be a retrospective prescription on the part of Health Canada. In fact, the nutrient content claim omits any such limitation and there is no suggestion that there was any intent to impose such a restriction on that Health Canada's claim of its limitation was retrospective. Following a series of lengthy discussions, Health Canada finally set a limit of 100 mg per serving (50 mg was the proposed quantity at one point in the discussion).

ONC did submit a nutrient content claim application in December 2003. As of January 2008, Health Canada had not approved the claim and there has been no resolution regarding what quantity of fish source omega-3 would ultimately be required (or permitted) in order to make such a claim. The interviewees point out that even if Health Canada were to approve the nutrient content claim application immediately, 18-24 months would be required to complete the regulatory process. Even under the best case scenario, ONC would not be able to label food with a nutrient content claim until approximately 2010 posing significant concern to the company.

ONC continues to pursue a biological role claim approval. Currently, one biological role claim for DHA is allowed in Canada connecting the benefits of DHA to brain, eye and nerve health. ONC also submitted an application for a second biological role claim in March 2004 that would allow the company to claim the benefits of omega-3 for cardiovascular health[4]. As of January 2008, this claim had not been approved.

The company contends that Canadian consumers have the right to know the health benefits of foods they are eating. Although the awareness of omega-3 health benefits has been growing among consumers, the company is concerned that the hype is misleading. The omega-3 used in most products offering health claims, especially in cereal products, is plant-based, even though research has been based on fish-based omega-3 benefits. Therefore, according to the company, the next step in increasing consumer awareness in this health food area is to familiarize the consumer with the distinction between plant-based and fish-based omega-3.

The company made the point that ONC is seeking approval in Canada, even though it has been very successfully marketing its products globally because it wants to market the product properly in its home country. The company and its employees feel passionate about Canadian consumer awareness of health benefits of certain foods and about increasing the affordability of healthy products to all Canadian consumers. They believe that consumers have a right to the health benefits of omega-3 through omega-3 enriched foods, especially those who are unable to afford seafood or supplements. This is especially true in light of the fact that ONC offers fish oil benefits without the taste of fish (a draw for those individuals who would not consume seafood otherwise) and purified of contaminants associated with many kinds of seafood (such as lead and mercury).

In addition, the company feels that the regulatory system in Canada creates a disincentive for domestic companies to commercialize their R&D and leverage new technology and innovation.

In terms of resources expended seeking the three approvals (including the two outstanding claim submissions) ONC invested a lot in travel to Ottawa and time in discussions with Health Canada. ONC also hired government relations advisors to try to speed up the process. External toxicological consultants were also hired to help gather the safety evaluations requested by Health Canada during the process.

The estimate of direct costs to ONC for the novel food component approval is $1.2 million ($250,000 for the first dossier, plus additional costs throughout the approval process). In addition, ONC estimates that the time and effort being spent on the claims approvals has cost the company $800,000 to date.

The company noted that although these costs are very high, they will continue to pursue approval because they want to sell their product in the country in which it is produced.

The Opportunity Costs

- The lengthy novel food approval process resulted in significant lost sales for ONC between June 2004 and June 2006. Based on estimated annual sales ONC lost a total of $2.2 million compounded over that time period.
- In addition, because the claims have not been approved, food manufacturers intending to produce products containing the ingredient have cancelled product market launches. These food manufacturers acknowledge the benefits of omega-3 in their food products but will not add the ingredient to their food products if they cannot alert consumers to the benefits of the ingredient on the food package.

- As a result, the company conservatively estimates that, in the Canadian market, it has experienced lost sales of $3.5 million annually while awaiting the health claims approvals – a total of $11 million over the last three years.
- In total, for both the lost sales experienced during the novel food approval process and the health claims processes, ONC has experienced potential lost sales of $13.2 million.
- Companies wishing to use the microencapsulated powder in food products have likely also experienced potential lost sales as a result of not launching the products using the ingredient because of the inability to inform the consumer of its benefits.
- The total opportunity costs to the Canadian economy are $34.3 million.

Ocean Nutrition: Direct, Indirect and Total Losses

Impact Category	Impact Type		
	Direct	Indirect	Total
Output	$13,240,063	$16,151,685	$29,391,748
Wage and Salary	$1,493,876	$2,848,467	$4,342,343
Taxes on Products	$21,051	$130,679	$151,731
Taxes on Production	$69,113	$320,767	$390,185
Total Dollar Losses	**$14,824,104**	**$19,451,599**	**$34,276,007**
Employment (Individuals)	43	108	151

**Some totals may not exactly equal sum of direct and indirect impacts because of rounding*

CASE K:
Discretionary Fortification

Summary

Case K involves a beverage line marketed and sold in Canada but produced in the United States. In the United States, this line includes products fortified with vitamins and minerals in order to meet consumer demands for healthier or 'Better for You' products. However, Canadian regulations prohibit discretionary fortification of all but a small number of products. The US parent company producing these products wishes to export the same fortified products to the Canadian market and inform consumers of the benefits of the fortified ingredients.

The lack of regulatory synchronization between the two countries means that items destined for sale in Canada require a separate production run, leading to inefficiencies and increased production costs. In some cases, a US manufacturing plant may not be able to accommodate the extra changeovers for Canada because of the negative impact on efficiency. Conversely, Canadian manufacturing plants cannot compete for the North American product mandates that they otherwise might if product formulations were harmonized.

This case study addresses the serious limitations on innovation when public policy makers forfeit their responsibilities to ensure that regulatory infrastructure is renewed to enable business to flourish and meet emerging market needs. In 1998, Health Canada began reviewing its current food fortification policy, in light of concerns from stakeholders suggesting that the current policy limited consumer access to fortified foods and limited the development of new food products. Health Canada released a policy for the discretionary fortification in 2005. Regulations to give that policy effect were drafted; yet, despite repeated urgings that the government proceed with promulgating the regulations, they have yet to proceed to *Canada Gazette I*.

Company K estimates that consumer demand for 'Better for You' products is the same in Canada as in the United States. Based on this assumption, Company K is forfeiting significant sales revenues in Canada with related economic impacts.

Product line K has been on the market less than a year in the United States and a smaller, non-fortified version of the product line is sold in Canada. Sales of the US product line have been growing substantially.

Company K has investigated how to bring this product line into Canada and is assessing whether to submit an Interim Marketing Authorization (IMA) application. The application would require a scientific rationale for the desired fortification process. IMAs are a regulatory tool whereby one can request dispensation from existing regulations in anticipation of new regulations that would eventually revoke the existing prohibition.

Until discretionary fortification regulations in Canada are promulgated, the process that companies must undergo in order to add vitamins and minerals to food is long, complicated and quite expensive, making such products largely unavailable to Canadian consumers. Even if the regulations are eventually implemented, the criteria that foods will be required to meet in order to be fortified raises uncertainty for Company K as to whether its product could ever be marketed in Canada.

Not only does Company K want to fortify these products, it wants to inform consumers about their benefits, letting them know that these products are 'better for you' through a nutrient content claim.

If fortified products were allowed in Canada and consumers could be educated about the benefits, Company K has indicated that it would launch a line of products fortified with vitamins and minerals. This launch could immediately double Company

K's business for this product line. Due to consumer appeal for 'Better for You' products in the United States, and the growth in sales of these products, Company K estimates a growth rate of 10 per cent per year for these products, compared to the current growth rate of 2.5 per cent for traditional products.

The Opportunity Costs

- Based on this estimate, potential future lost sales for the next five years[5] have been calculated at $3.1 million. The ability to sell this product line in Canada would be significant for Company K and would contribute significantly to consumer choice for these functional foods.
- Based on company estimates of lost sales of just over $3 million and estimated retailer mark-ups for this product across all retail chains, retailer margin losses of $771,231 were calculated.
- Due to the fact that these products would be produced in the United States and imported into Canada, the potential Canadian value chain impacts cannot be calculated using the Statistics Canada food industry multipliers. However, spin-off effects from the sales of these products in Canada cannot be overlooked, including the economic effects on those involved in transporting and marketing the product.
- Although Case K involves a product that will be produced in the United States, it is an example of the inability to market a functional food product line to Canadian consumers.

CASE L:
Food Additive Approval

Summary

Case L is an innovative and 'healthier for you' food product produced, marketed and sold in the United States. Company L cannot bring this product to Canada as it contains a food additive that is not currently approved for use in Canada. This product is experiencing strong growth in the United States and Company L is aware, through consumer research, that there would be a demand for the product from Canadian consumers and a strong business case for introducing it into Canada.

When it began investigating the possibility of bringing the product into Canada a number of years ago, Company L discovered that one of the enzymes used in the United States product has not been approved for use in Canada.

Food additives permitted for use in Canada are listed in Part B, Division 16 of the Food and Drug Regulations. All new additives must first be approved for use by Health Canada and subsequently listed.

This additive has been chosen by the ingredient company that supplies Company L because it is the most appropriate for the product and production process. The easy fix would be to exchange the additive for one that has already been approved in Canada for products destined for the Canadian marketplace. As this product would be produced in the same plant as the US product, Company L examined the economics of conducting short production runs of Product L using an additive already approved in Canada for the Canadian market, and determined it would not be economical. Substituting the additive would also result in an inferior product. Therefore, Company L initiated a discussion with Health Canada to discuss its options.

Company L was advised that it had a number of options including:

1. Initiate the standard regulatory approval process. Company L and the food ingredient company have estimated that this process will take six years to complete. Despite the long time frame, the company plans to commence this process in 2008. The approval process would be initiated by the food ingredient company that provides Company L with the additive since it would have the appropriate food safety research. The first step in the approval process of new food additives is the safety assessment which the food ingredient company has already completed. Company L would help facilitate the process.
2. After the scientific evaluation has been completed, Company L could apply for an Interim Marketing Authorization (IMA) in order to 'bridge the time between the completion of the scientific evaluation of certain enabling amendment and publication of the approved amendments in the Canada Gazette, Part II'. Company L will be looking into this expedited option as well.
3. The last option would be to explore a "work around" approach that would allow the additive to be approved in Canada if it qualified as a food processing aid.

The food ingredient company working with Company L continually conducts research regarding the development of new and better additives for food production processes and products. With respect to this case study, their research includes investigating improvements in performance of 'generations of enzymes'. Each time the research yields an improved additive for use in Product L, the regulatory system in Canada would require that this additive undergo the approval process all over again because there is no mechanism for approving "families of enzymes" that are essentially very similar. Again, this leads to

slower food innovation in Canada, and explains why undergoing the Health Canada food additive approval process is a low priority for the ingredient company.

Company L is frustrated with the lack of protocol for the introduction of food additives in Canada. The process is not clearly laid out for applicants so they do not know what to expect as the process unfolds. Company L believes that Health Canada delays progress by issuing continuous ad hoc requests for information rather than spelling out the data and information requirements at the outset. Company L noted that in the United States the process to approve a new food additive is clear and transparent and applicants are aware of the information requirements and their responsibilities.

The Opportunity Costs

- Company L has calculated projected sales of this product in Canada, based on current sales in the United States and the appeal of convenient and 'healthier for you' products in Canada. Potential future lost sales for the next five years[7] are calculated at $12.6 million. The ability to sell this product in Canada would mean significant sales for Company L, and would provide Canadian consumers with another convenient and 'healthier for you' food choice.
- Based on company estimates of lost sales of just under $12.6 million and estimated retailer mark-ups for this product, potential retailer margin losses of $5.04 million were calculated.
- Because these products would be produced in the United States and imported into Canada, the potential value chain impacts cannot be calculated using the Statistics Canada food industry multipliers. However, there would be spin-off effects from the sales of these products in Canada that cannot be overlooked.

Summary of the Lags and Challenges Experienced by Case Study Companies

The case studies profiled in this report provide ample evidence that the Canadian regulatory system is not equipped to deal with the needs of the food industry seeking regulatory approvals for their products, nor is it accountable or responsive. The majority of the cases highlight the inefficiencies within the system as a result of: poor administration including a lack of guidance and clear framework for the processes; communication; transparency; and accountability to timelines. A regulatory system that relies heavily on pre-market assessment and regulatory amendments requires a clear, understandable, transparent system.

Lags Identified Through the Case Studies

Of the twelve case studies:

- All 12 experienced lags because there is no expressed purpose of the legislation that is guiding decisions to deal with their submissions
- One quarter are facing obstacles for approval of certain types of health claims because a regulatory amendment is required first
- One cannot obtain approval for use of a food additive because a regulatory amendment is required to add it to the approved list
- Two are facing lags due to product-specific requirements in pre-market evaluations for their submissions for approval of novel foods
- One third cannot obtain approval to fortify their foods with vitamins and minerals because of the restrictive list
- Three quarters have faced significant lags because of a lack of guidance in the system
- Half say the lack of communication with the approval body has caused lags
- Seven have experienced obstacles because of Health Canada's limited research capacity
- Nine cite lack of accountability to timelines for causing significant lags

Direct Costs for Manufacturers

The following table shows some of the direct costs that participants incurred while working within the Canadian regulatory system to get their products, food additives or health claims approved. It should be noted that the companies accept that there are costs associated with food approval applications in Canada, but they have issues with the costs that are deemed unnecessary or excessive. Some of the direct costs listed below include initial and additional research requirements requested throughout the process, consultant fees to aid in the application process, the cost of monitoring the progress of submissions in the queue, and marketing costs to companies that cannot utilize health claims allowed in other jurisdictions.

Direct Costs to Food Manufacturers

Case	Estimated Cost	Reason/Explanation
A	$500,000	• Above and beyond what is normally spent on more effective marketing campaigns
B	N/A	• Research conducted to determine feasibility of approval submission
D	$10,000	• Regulatory consultant fees
E	$millions	• Launched a product, voluntarily recalled a product and resubmitted application under another process
F	• $2,500,000 • $275,000	• Research to support application • Chemistry and policy consultant fees
G	$30,000	• Submission of IMA application, encouraged by Health Canada and then rejected
H	50 hours of work	• Continual monitoring of application progress
I	• $130,000 • $75,000	• Consumer research on modified milk ingredient formulation • Post-market research requested by Health Canada
J	• $1,200,000 • $800,000	• Novel food submission: research, consultants, lobbyists, personnel time • Health claims submissions: research, personnel time

Potential Lost Sales along the Food Value Chain

The table below shows the total potential sales losses to food manufacturers, retailers and primary producers (where the information was available and/or relevant) as a result of delays by Health Canada (in excess of a reasonable processing time of one year) in rendering approval/rejection decisions. In some cases, sales losses include an estimate of the foregone additional sales of products that could have been realized had the company been able use health claims on these products. In other words, sales were expected to be higher if manufacturers were able to better communicate the health benefits of the innovation to Canadian consumers.

Potential Lost Sales along the Food Value Chain

Case	Potential Lost Sales		
	Food Manufacturers	Retail	Primary Producers
A – low	$12,000,000	$15,000,000	$2,142,900
A – high	$20,000,000	$25,000,000	$2,857,200
B	$62,124,999	$72,721,039	2,458,803
C	$2,500,000	$3,500,000	$1,310,706
E	$36,801,430	$46,001,787	N/A
F	$1,952,381	$2,635,714	N/A
G	$28,291,763	$33,950,115	$12,838,279
H	$7,767,563	$10,874,588	N/A
J	$13,240,063	N/A	N/A
K	$3,147,881	$771,231	N/A
L	$12,602,334	$5,040,934	N/A

Summary of Potential Direct, Indirect and Total Opportunity Costs

The potential sales losses of products that would be (are) manufactured in Canada were used to calculate the potential direct and indirect opportunity costs to the overall Canadian economy in the form of direct and indirect foregone output, employment, wages and salaries, and taxes. Direct opportunity costs are those corresponding to the final product manufacture (i.e., the foregone economic value of potential sales, related employment, wages and salaries, and tax revenue generation) while the indirect opportunity costs reflect the economic value of industries supporting the production of the food product (i.e., food ingredients, transportation). The indirect losses to all upstream stakeholders include the primary producer impacts as shown in the table, as well as other input suppliers and transport providers in terms of foregone sales, wages and salaries, and tax revenues due to stifled economic activity.

The total opportunity costs in the table below are a total of direct and indirect opportunity costs including the foregone direct output (potential sales losses to manufacturers shown in the above table), foregone indirect output, foregone direct and indirect wages and salaries and forgone direct and indirect taxes as a result of the lessened economic activity. Direct and indirect employment losses are shown separately in the table below as they reflect the number of individuals employed, rather than a monetary value.

General Conclusion

The foregone economic activity resulting from the impediments faced by food manufacturers working within the Canadian food regulatory system includes foregone economic activity of $440 million and foregone employment of 1,869 individuals for only these 12 case studies. This represents a significant loss to the economy.

Summary of Potential Direct, Indirect and Total Opportunity Costs

Case	Foregone Output, Wages and Salaries, Taxes on Products and Taxes on Production ($Cdn)			Foregone Employment (Individuals)		
	Direct	Indirect	Total	Direct	Indirect	Total
A	$13,435,680	$17,629,764	$31,065,720	39	98	137
B	$69,557,634	$91,270,756	$160,829,819	201	508	709
C	$2,799,100	$3,672,868	$6,472,025	8	20	29
E	$41,204,353	$54,066,710	$95,271,910	119	301	420
F[7]	$1,092,981	$1,434,167	$2,527,170	3	8	11
G	$31,676,589	$41,564,758	$73,241,998	91	231	323
H	$8,696,874	$11,411,692	$20,108,745	25	64	89
J	$14,824,104	$19,451,599	$34,276,007	43	108	151
K[7]	$3,147,881					
L[7]	$12,602,334					
TOTAL	**$200,013,720**	**$240,502,314**	**$440,519,799**	**529**	**1,338**	**1,869**

**Some totals may not exactly equal sum of direct and indirect impacts because of rounding*

In interpreting the results using the multipliers, it should be understood that losses to the broader economy represent a *potential,* rather than a point estimate. This is true because the approval of the product would not necessarily have generated entirely new sales. Depending on the case, some consumers already purchasing the product would continue to do so, and other consumers purchasing substitute products would switch to consume the newly approved product. In other cases, consumers would continue consumption of all other foods but increase consumption of the newly approved product due to the health claim and or new functionality. In practice it is impossible to disaggregate these effects, so this caveat should be observed in interpreting the broader economy benefits.

These case studies are merely the tip of the iceberg. For many companies who participated in this research, these cases represent just one example from a number of challenges they are experiencing with the Canadian food regulatory system. The magnitude of lost opportunity from these cases is conservative and represents a mere sampling of the impact that the current regulatory system has had on Canadian-based companies seeking to commercialize better-for-you innovation.

It is important to consider that the significant and varied costs represented in the above tables are short term. In the longer term, the costs will be higher; case study participants agreed that research and development and new product introductions in the industry will decrease if these new products cannot be marketed in Canada.

Conclusions from the Case Studies

The message from the case studies is clear: the ad hoc and unstructured administrative processes within Health Canada prevent Canadians from accessing new and innovative products that could meet their demands and improve their health, and has resulted in significant foregone economic activity.

In addition to the hard economic data, case study participants provided observations and anecdotes that lead to the following general conclusions:

1. **The *Food and Drugs Act* should include an objective to "enhance the health of Canadians"**

   One of the fundamental problems with Canada's food regulatory system is that the *Food and Drugs Act* does not have objectives for which regulators are accountable, not even those related to public health protection. Particularly dismaying to food and beverage companies is the fact that the *Act* does not include an objective to ensure efficient operations or to contribute to efficiency in the food system. This is in direct contrast to the *Food Standards Australia New Zealand Act* which in addition to providing for accountability, acknowledges that the food industry plays a role in enhancing the health of its citizens. The Australia New Zealand Food Regulation Ministerial Council reformed its health claim approach based on its acknowledgment that industry requires a regulatory landscape that enables new product development.

2. **Inefficiencies are created by "patchwork of regulatory processes"**

   In Health Canada's Blueprint for Renewal II, the agency acknowledges that the "current patchwork" of regulatory processes creates inefficiencies in the system. This fact was confirmed in a thorough and wide-ranging study by Cantox in 2007. For the food and beverage industry these inefficiencies stem from a lack of clarity and understanding of the requirements that must be met in order to secure approvals. Industry is often unclear as to how processes and frameworks vary depending upon the type of approval being sought, for example for applications for novel foods versus for food additives, and which directorate (Food Directorate or Natural Health Products Directorate) is charged with overseeing different types of applications.

   Australia/New Zealand's food authority (FSANZ) has one application handbook for all types of applications which ensures transparency and efficiency for applications with FSANZ. Applications are assessed under one of three procedures – minor, general or major.

3. **Natural Health Product Regulations create a 'work around' to market certain food products with claims**

   Since the implementation of the Natural Health Products Directorate (NHPD) in January 2004, food products can come under the definition of both a food and a natural health product (NHP). In fact applicants can now choose whether to market these products as foods or drugs. While Health Canada has a clear preference that products in food format be marketed as food, the implementation of the NHP regulations has provided a whole new avenue of market access for food manufacturing companies.

   However for those in the industry who would prefer to market their functional foods as "foods", the NHP route is viewed as a 'work-around'. Although the requirements that must be met in order to market foods as NHPs are relatively onerous, some companies are more than willing to work within the confines of the 'work-around' if it means being better able to market their products by including claims.

   There is now discussion within Health Canada, in both the Food and Natural Health Products Directorates as to whether food-format NHPs should be marketed as NHPs or foods. In October 2007 NHPD issued a statement that product license and/or claim approvals for products in food format would now be reviewed by the Food Directorate in order to address this issue. Although this is an effort on behalf of Health Canada and the NHPD to improve its processes, some companies suggested that this will initially lead to further elongated application processes as both directorates review food-like NHPs.

   Due to the demand for fortified foods as well as companies' desire to gain access to health claims for their products, the NHPD route offered an attractive option and opened the floodgates for thousands of applications once the Directorate was launched in 2004. Despite the window that has been afforded, the system is now hopelessly backlogged and many companies interviewed acknowledged that a regulatory framework for discretionary fortification and a better administrative process for health claims approvals could mitigate the current burden on the NHPD. Not only is the NHPD completely overwhelmed and under-resourced due to the amount of food-like product applications it has received, it is also dealing with products that are currently marketed with Drug Identification Numbers that are required to migrate to NPNs by December 31st, 2009.

4. **Administrative and process improvements within Health Canada are urgently needed to improve the management of food applications and reviews**

   The lack of clear and transparent frameworks for regulatory approvals has created huge frustration within the industry. In addition to being confusing and unclear, the approval process often results in unexpected requests for additional information as well as repeated and chronic delays. Loose and imprecise processes lead to inconsistency in the manner in which applications are assessed. Without consistent application reviews, companies cannot benefit from experience in previous applications. Participants suggested that transparency within the system through the use of a comprehensive guidance document would be beneficial.

However, the lack of accountability within Health Canada for meeting performance targets for communication with applicants, scientific reviews and decision-making creates huge uncertainties for companies who have increasingly given up on commercializing innovation in Canada.

5. Stakeholder collaboration is needed

There is currently no mechanism requiring government, industry, the scientific community and medical communities, consumers or other relevant stakeholders to discuss or exchange ideas about the enhancement of health through food and the protection of the health of Canadians through food regulation. Currently, the stakeholders along the value chain whose activities are independent of each other work in silos.

On-going stakeholder collaboration, where parties cooperatively work together, rather than industry consultation, would result in a better understanding on behalf of all parties regarding each stakeholder's responsibilities and views for the future of food in Canada. If more collaboration occurred, Health Canada could be made aware of the range of products in the pipeline and gain a greater understanding of the innovation taking place in the marketplace today. Industry would be made aware of the regulatory processes and procedures new innovations will face, resulting in a mutually beneficial working relationship.

6. The inefficient regulatory framework has created a disincentive for R&D

The implications from the experiences of the participants are that fewer innovative and functional foods will be available in the marketplace if the regulations and their administration provide a disincentive for R&D. Innovation must keep up with market trends, however the uncertain and protracted processes in the Canadian food regulatory system does not allow Canadian food manufacturers to stay ahead of the innovation curve. In order to conduct R&D, companies must receive a sufficient return on their investment; this return is impeded by lengthy delays.

It is clear from the case studies and conversations with participants that companies will not avail themselves of opportunities to commercialize innovation if the resulting products cannot be labelled and health claims cannot be made to communicate benefits to consumers.

The experiences of other countries as well clearly demonstrate that product sales increase when consumers are made aware of the functional benefits through health claims. If companies cannot get a sufficient return on the development of new innovative products, research and innovation will decline with fewer innovative and functional foods appearing in the marketplace.

Instead of utilizing health claims to promote the health benefits of food products companies are having to invest in expensive and convoluted marketing campaigns to convey the benefits of their products indirectly. Some participants acknowledged that as a result, marketing campaigns are less effective because health claims cannot be used.

Although the current regulations were established decades ago, and some of the products and science are new. Therefore, a regulatory framework for health claims that evolves with the industry would be beneficial for both industry and consumers.

7. Consumers are confused

Messages allowed on packaging and in advertisements differ from one country to another and have resulted in consumer confusion. In today's global world, with TV, magazines, the internet and travel, borders are porous and food manufacturers have acknowledged their desire for uniform and consistent messages across the countries in which they market their products. Participants suggested that due to the proximity of Canada and the United States and the heavy movement of people between the countries, a uniform message, if not a global one, should span the Canada-US border. It was also suggested that the majority of information consumers obtain about food products CFIA has no control over, such as on the internet, word of mouth etc.

Consumers see the 'latest and greatest' products on the internet and US TV stations – however in many instances the products are the same but are marketed differently in the various jurisdictions. Consumers see products available in other jurisdictions but not in Canada and call food manufacturer's hotlines to ask about the differences. This can be especially confusing if consumers hear about the benefits of food products from many sources but not the food manufacturing companies themselves.

With respect to mixed messages, Canadian-owned companies are competing with multinational companies that have other tools to use in getting messages to consumers. Some participants suggested that Canadian-owned companies are put at a disadvantage of having no spillover advertising from the United States, in which they can more effectively communicate the benefits of their food products.

Participants acknowledged that there is concern that consumers will begin to assume that food manufacturing companies in Canada are less innovative than those in other jurisdictions. While this may be the case, it is not for a lack of trying.

Although these food companies acknowledge that they sell food products to make money and that because there is less effective education of the consumer, messages don't get through and sales are stifled, they also underline the importance of consumer awareness regarding the added benefits of certain innovative food products.

8. The current system has created significant lost opportunities

It is widely agreed that the fastest growing component of the food business today is the 'functional', convenient and 'healthier for you' foods. As food companies want to improve their product offerings in this area, Health Canada represents a significant blockade.

The experiences that food companies have had working within the regulatory system in Canada have led them to seriously reconsider developing products that would require regulatory approval. Unfortunately, this will lead to stifled innovation and therefore less growth and investment in Canada. Canada is losing its capital attraction capabilities, and curtailing business opportunities for food manufacturing companies.

[1] (Paul et al. 1999; Marquant, 2001 as cited in (Williams, 2005)

[2] The current fish-source omega-3 content requirement for source claims in the United States is 32 mg per serving.

[3] According to the interviewees, there is currently a misconception among consumers regarding the difference between fish-based and plant-based omega-3. Many consumers believe that omega-3 contains the same fatty acids, regardless of its source. However, according to the interviewees, plant-based (flax seed) omega-3 source claims are based on ALA content, whereas fish-based omega 3 contains DHA and EPA. The 300 mg source claim approved by Health Canada is based on plant-sourced ALA. As a matter of fact, many of the established health benefits from this source of omega-3 are based on the assumption that the body converts ALA to DHA and EPA. Although this conversion is scientifically established, the conversion rate is very low. Therefore, much more ALA is required to produce the health benefits of DHA and EPA. As such, the interviewees claim that, even if Health Canada is uncomfortable with the 300 mg per serving quantity of EPA and DHA for a source claim, a lower quantity of EPA and DHA should be sufficient to make a source claim. However, the interviewees also submitted that there is no established risk of overconsumption of DHA and EPA (based on internal clinical studies and external research) and that Health Canada has already set a precedent for the 300 mg amount by recommending that Canadians consume at least 2 servings of fish per week. Furthermore, since the novel food component is purified of contaminants, which are often a cause of concern in setting recommendations for seafood consumption, contaminants cannot be a justifiable cause for prohibiting a source claim for this novel food.

[4] The omega-3 components being proposed for the heart health claim differ from the brain, eye and nerve health claim in that they contain different ratios of EPA and DHA. According to the interviewees, both health benefits, with their respective EPA and DHA ratios, have been scientifically established. As a matter of fact, the interviewees claimed that there is more research supporting the heart health claim than the previously approved brain, eye and nerve health claim.

[5] Five years of potential future lost sales was chosen as a standard time frame.

[6] Five years of potential future lost sales was chosen as a standard time frame.

[7] Cases K and L products and one product from Case F would be manufactured in the United States and therefore have not been run through the Statistics Canada Input-Output model (described in detail in Appendix I). However, the potential lost sales amounts are included in the total economy opportunity costs because these sales would be attributed to the companies' Canadian divisions.

4 **What Consumers** Are Missing

The 12 cases highlighted in Section Three of this report provide a small sampling of the impact the Canadian food approval system has had on food innovation and access to new products with health benefits that consumers desire.

There are many more examples of lost opportunities related to food products. A search of the internet, food journals and a comparison of international company websites found numerous innovative and new products that are not available in Canada, as well as more effective advertising of products with beneficial attributes in other countries than in Canada, undoubtedly due to Canada's health claim restrictions.

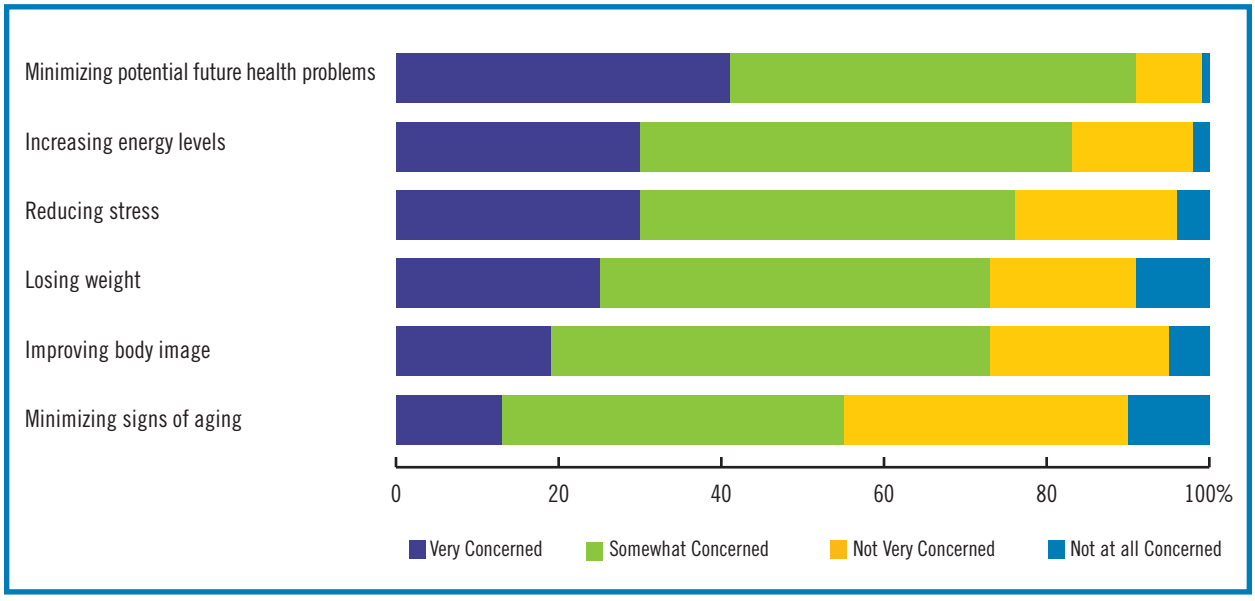
This section provides a broader perspective on the innovations that Canadian consumers are missing out on. In some instances it may be that the manufacturer has not attempted to have the product approved in Canada, the product may not fit the Canadian market or the Canadian food regulatory system has impeded its approval in Canada.

Canadian Consumer Health and Wellness and Food Purchasing Trends

Canadians want access to foods with health benefits. According to the Nielsen PanelTrack Health and Wellness Survey, 2007, Canadian households' primary health and wellness concern is preventing potential future health problems. Canadians are becoming proactive in managing their health today to stay healthy in the future through exercise and diet. Twenty-seven per cent of Canadians are exercising to stay healthy and 31 per cent of consumers purchase functional or fortified foods to prevent future health issues.

The survey results also show that Canadian consumers are increasingly using health symbols and logos on food packaging as an important information source in order to make healthier food choices. Canadian consumer awareness of the benefits of functional foods and ingredients, including awareness of the benefits of omega-3's, probiotic cultures, whole grains and fibres, has also been increasing.

Canadian consumer response to the question: How concerned are you about?



(Source: Nielsen PanelTrack Health and Wellness Survey, 2007)

Food Innovations Missing in Canada

Foods that Minimize Future Health Conditions Heart Health and Cholesterol Reduction – Plant Sterols and Stanols

Two food innovation trends to minimize potential future health conditions that have really taken off are foods that help to improve digestion and gut health through the use of probiotics and heart healthy foods that help to lower cholesterol.

Health Canada permits probiotics to be added to food sold in Canada but they can be marketed with limited claims. A number of products that have been developed to reduce cholesterol through the use of plant sterols and stanols are available in many countries but not approved in Canada.

Plant sterols (phytosterols) are naturally occurring plant compounds which have a similar chemical structure and biological functions as cholesterol. There is "broad based efficacy and safety support of plant sterols in the treatment of high cholesterol and heart disease from key third parties" including the British Heart Foundation, American Heart Foundation, International Atherosclerosis Society, Dutch Heart Foundation, World Heart Foundation, Finnish Medical Society, Finnish Nutritionist Association and the Spanish Atherosclerosis Society.

Studies have shown that individuals may lower their LDL-cholesterol levels by about 10 per cent with plant sterols depending on the age and individual metabolism of the person. In addition to the benefits for individuals with high blood cholesterol, plant sterols may also provide anti-cancer, anti-inflammatory, anti-atherogenicity, and anti-oxidation benefits to the average consumer, according to the Australian Heart Foundation.[1,2]

Furthermore, plant stanols have been proven to reduce harmful cholesterol and lower the risk of heart disease. There are a myriad of food products available that contain plant sterols and stanols and millions of consumers worldwide have access to these products, which are convenient to include in one's diet without having to resort to supplements and other means. In Europe, plant sterols can be found in products such as table spreads, dairy products (milk, yogurt and cheese), cereal, spicy sauces, and rye bread (pumpernickel). In the US, they are also permitted in orange juice. In Australia/New Zealand, they can be added to table spreads, low fat yogurt and milk, and breakfast cereals.

> In spite of their safe history of use in other countries, plant sterols are not approved in Canada. Canadian consumers are again missing out on health benefits of these products due to our regulatory system.

In spite of their safe history of use in other countries, plant sterols are not approved in Canada. Canadian consumers are again missing out on health benefits of these products due to our regulatory system.

The table on the next page lists a number of food products proven to reduce cholesterol through the use of plant sterols and starols the countries in which they can be found, and corresponding allowable health claims.

Food Products Containing Plant Sterols/Stanols to Reduce Cholesterol

Company/Product	Description	Countries Available (year approved)	Health Claims/Comments
Unilever: Flora/Becel Pro.Activ products	Margarine Spread 	US (1999) Australia (1999) EU (2000) New Zealand, Switzerland, Brazil, South Africa, Japan, Czech Republic	Food products containing vegetable oil sterol esters. **Health Claims:** US: "…contains natural plant sterols that can help lower LDL cholesterol levels, and may decrease your risk of heart disease…' Australia: "This product contains sterols. Sterols reduce cholesterol consumption." EU: "Becel pro.activ is clinically proven to significantly lower cholesterol as part of a healthy diet." 
	Yogurts	US (2004) EU (2004) Australia (2006)	
	Milk Beverages 	EU (2004) Australia (2006)	
	Breakfast Cereals	Australia (2006)	
Kroger Company: Active Lifestyle Fat Free Milk	Milk containing *Corowise* brand (from Cargill) of plant sterols to reduce LDL cholesterol	US (2007)	Package states: "Helps Reduce Cholesterol."
Minute Maid: Heart Wise Juice	Juice/juice drink containing 1g per 8 fl. Oz of naturally sourced plant sterols proven to reduce LDL cholesterol	US 	Proven to help reduce cholesterol.
Raisio Group: Benecol 	Cream Cheese	Belgium Ireland UK Luxembourg	Benecol is a range of foods that contain plant stanol esters. Package states "Proven to Reduce Cholesterol." 
	Dairy Free (Soya-based) Drink	UK (2007) Ireland (2007) Belgium (2007)	

Company/Product	Description	Countries Available (year approved)	Health Claims/Comments
Tropicana Orange Juice with Benecol	Orange juice with added plant stanols	England (2006)	Helps to reduce cholesterol.
Hain Celestial: Rice Dream Heart Wise	Rice milk beverage that contains *Corowise brand* (from Cargill) of plant sterols that help reduce cholesterol and the risk of cardiovascular disease	United States (2004) Europe 	US package states: Can Help Lower Cholesterol. "Foods containing at least 0.65g per serving of vegetable sterol esters, eaten twice a day with meals for a daily total intake of at least 1.3g, as part of a diet low in saturated fat and cholesterol, may reduce the risk of heart disease."
General Mills, Nature Valley: Healthy Heart Chewy Granola Bars	Granola bars that contain cholesterol-lowering plant sterols	United States 	Package states: Helps Lower Cholesterol. Plant sterols eaten twice a day with meals for a 0.8g daily total, may reduce heart disease risk in a diet low in saturated fat and cholesterol. Nature Valley has 0.4g per bar.
Kesko Food and Scanvit Ltd.: Pirkka Reducol Rye Bread	Rye bread that contains Reducol (from Forbes Medi-Tech); a plant stanol and sterol mixture processed from tall oil that reduces cholesterol	Finland (2007) 	There is a Pirkka Reducol line of products including: rye bread, Buckthorn yogurt, vegetable-oil spread and low-fat yogurt.

Increasing Energy Levels

As is outlined in some of the case studies described in Section Three, companies are experiencing foregone economic opportunities as a result of not being able to enrich certain food and beverage products with increased amounts of vitamins and minerals. At the same time, 86 per cent of Canadian consumers are concerned about increasing their energy levels in order to maintain or gain an active and healthy lifestyle.[3] Certain vitamins and minerals can play important roles in energy metabolism and tissue formation; discretionary fortification could help provide Canadians with additional vitamins and minerals in convenient food and beverage products.

86 per cent of Canadian consumers are concerned about increasing their energy levels in order to maintain or gain an active and healthy lifestyle.[3]

According to Health Canada, with fortification, "the nutrients available in our food supply will increase (within the safe limits set by Health Canada). Canadians would enjoy the freedom to make choices from a wider range and variety of fortified foods while knowing that they have been protected from the health hazards of consuming too much of a given nutrient"[4]. However, it has been a decade since Health Canada began a review of its discretionary fortification policy and the proposed amended reglautions are yet to be published in *Canada Gazette I*.

The Table on the next page lists a number of beverages and energy drinks that are currently not available in Canada but based on current health and wellness and food purchasing trends, could be popular among Canadian consumers.

Beverages and Energy Drinks Currently Not Available in Canada

Company/Product	Description	Countries Available (year approved)	Health Claims/Comments
Coca Cola Company: Diet Coke Plus	A sparkling, calorie-free beverage with vitamins B3, B6, and B12, and the minerals zinc and magnesium.	US (2007)	
Coca Cola Company: Dasani Plus	Vitamin enhanced flavoured water	United States 	Three flavours: Refresh & Revive: Vitamins B3, B6, B12 Cleanse & Restore: Vitamins E,B3, B6, B12, 1g fibre Defend & Protect: Vitamin E, Zinc
DDO: FullProtein energy drink	The world's first egg-white drink. An energy drink for athletes.	Portugal Spain UK	
Ocean Spray: Cranergy Energy Juice Drink	Cranberry juice enhanced with green tea extract and Vitamin B.	United States	This product is currently not available in Canada because Ocean Spray is currently investigating how to apply for a Natural Health Product Number

Weight Management and Body Image

The top six health and wellness concerns of Canadian consumers are rounded out by weight management and body image concerns. According to the Nielsen research, 29 per cent of Canadian consumers exercise portion control as a way to manage weight. Again, food manufacturers have kept on top of consumer trends and have developed a variety of food and beverage products to help mitigate hunger, burn calories and fat, and prevent skin dehydration, to name a few. However, due to Canada's antiquated regulatory system, many of these products are not available in Canada.

The following are just some innovative food and beverage products that contribute to weight management and body image.

Naturlinea

Corporación Alimentaria Peñasanta (CAPSA), a Spanish dairy group, was the first company to launch dairy products with added conjugated linoleic acid (CLA), under the Tonalin brand from Germany. CAPSA's range of dairy products includes milk, yogurt and daily-dose yogurt drinks that are marketed with a claim to inhibit body fat formation and encourage the breakdown of body fat. CAPSA launched these products in 2004, and in two years brand sales reached $60 million (US) in Spain alone.

Celsius, Sparkling Beverage

Celsius Inc., an innovative sports nutrition company from the United States, markets Celsius as the "original calorie burning sparkling beverage". The drink is marketed with a claim to burn up to 100 calories, raise metabolism and provide sustained energy for up to three hours. The drink contains a unique blend of natural ingredients such as green tea with EGCG, ginger, calcium, chromium, B vitamins and vitamin C. It is proving very successful in the United States and won the 2007 Global Beverage Innovation Award in Madrid, Spain for the Best New Functional Drink.

Kellogg's Special K2O Protein Water

Kellogg's has developed flavoured water that contains 5g of protein in a 16 oz. bottle in order to manage hunger. Kellogg's is targeting those consumers interested in weight management and has come out with a whole line of protein-fortified products, including snack bars. This product was released in the United States in 2006, and Kellogg's then released single serve packets in 2007. The packages of the various flavours state: "Takes the edge off hunger" and "Feel full longer". These drinks also contain a combination of calcium and B vitamins. Currently, this product is not available in Canada.

Essensis Yogurt, Danone

Danone has introduced a number of products in recent years that have the added benefit of some health attributes, most notably Activia yogurt enhanced with probiotics. In 2007, Danone launched a yogurt aimed at beauty. Essensis is marketed to nourish skin from the inside and prevent skin dehydration. It contains a combination of probiotics, antioxidants, green tea, omega-6 fatty acids from borage oil and vitamin E called the Pronutris Complex. Again, this is an example of an innovative food company meeting consumer demand for foods that are cosmetically beneficial.

Missing Food Packaging Messages in Canada

In 1992, a National Institute of Nutrition study on consumer use and understanding of nutrition found that health claims were a key element that influenced product choice of consumers when health issues were a concern. Health claims have become even more important in the last decade due to the growth in the availability of functional foods and consumers looking to attain health from foods. Therefore, manufacturers want the ability to communicate the benefits of food products to consumers.

health claims were a key element that influenced product choice of consumers when health issues were a concern

To date, Canada has approved only five science-based disease risk reduction health claims. As a result of a recent review of health claims in other jurisdictions, Health Canada is looking to approve two more. The US, by comparison, has approved twelve health claims. The following are only a few examples of the different messages that can be used on packaged foods in the United States and other countries, but are limited in Canada.

Oatmeal/Oat bran and Heart Health

A popular health claim in the United States relates to oat (bran, meal, whole oat flour) intake and reduced risk of coronary heart disease. This claim has been well substantiated in the scientific literature, was the first approved health claim for specific foods and has been approved in the United States since 1998. The claim states that "soluble fibre from oatmeal, as part of a low saturated fat, low cholesterol diet, may reduce the risk of heart disease."

Similar health claims have been approved in several European countries with respect to oats and cholesterol reduction, including in the United Kingdom, Sweden, Finland and the Netherlands. Finland was the first country to recognize the cholesterol lowering ability of oats – its claim states "soluble fibre helps to control blood cholesterol. X amount of oat bran/rolled oats is rich in soluble fibre".

In Canada, however, manufacturers have been limited in their ability to make health claims on oat products in particular and their benefits in reducing heart disease.

Products that Contain Oat and Heart Disease Claims

Probiotics and Gut Health/Digestion

The inclusion of probiotics in food products has really taken off and demand for these products will continue to grow as awareness of their health benefits increases. Some of the proven benefits include immune stimulation, enhancement of bowel mobility, and the reduction of inflammatory or allergic reactions.

In the United States, there are no approved health claims for probiotics yet, but manufacturers can promote their benefits on food packages through structure/function claims, qualified health claims or significant scientific agreement claims. A structure/function claim describes the role of an ingredient, such as probiotics, intended to affect the normal structure or functioning of the body. These claims do not require FDA pre-approval but scientific substantiation by the manufacturer is required. Products containing probiotics in the United States can include statements such as "Supports Immune Function" or "Supports Healthy Intestinal Balance", whereas in Canada, these statements are not allowed.

[1] **Australian Heart Foundation. 2007**. *Position Statement: Questions and Answers*. Australian Heart Foundation.

[2] Berger, A., Jones, P.J.H., & Abumweis, S.S. 2004. Plant Sterols: factors affecting their efficacy and safety as functional food ingredients. Lipids in Health and Disease. 3: 5. Retrieved from http://www.lipidworld.com/content/3/1/5 <http://www.lipidworld.com/content/3/1/5> , (May 7, 2008).

[3] Nielsen PanelTrack Health and Wellness Survey, 2007

[4] **Health Canada. 2005a**. *Information Sheet – Food Fortification in Canada – Updating the Policy*. Health Canada. Retrieved Jan. 10, 2008a from: http://www.hc-sc.gc.ca/fn-an/nutrition/vitamin/fortification_factsheet2-fiche2_e.html.

5 **Conclusions** and Recommendations

Through an analysis of the performance of Canada's regulatory system compared to its competitors, a look at 12 actual cases, and a review of innovative products and use of health claims that are not available in Canada, the study draws the following key conclusions:

- **Canada is not competitive; our food regulatory system is far behind those of leading nations in the world**. There are substantial differences between Canada's regulatory system and those in a number of other countries. Canada's system is less accountable and has more lags. The problems exist in all three parts of the system – the legislation, regulations and administration/ processes. As a result, timelines for approval of innovative products and the use of health claims in Canada are much longer than those in the other jurisdictions.
- **Canada's regulatory system needs to be brought into the 21st century**. Canada's system needs a legislative framework, as other countries have, that incorporates objectives for both health protection and food innovation. This would require regulators to explicitly consider the balance between protecting the safety of consumers and responding to demand for new, healthful products.

- **The costs associated with Canada's lagging system are very high and far-reaching**. Twelve case studies help to quantify the costs as a result of the lagging system. The costs were categorized into direct costs, opportunity costs to the food manufacturing companies looking to develop new food products and/or market products with health claims, potential lost sales for retailers because of lack of product availability and potential lost sales for primary producers.

  Overall opportunity costs to the economy were also examined; these losses include the food manufacturers and all upstream industries' output (lost sales), wages and salaries, foregone taxes, and employment that would have been created due to the economic activity. The costs along the whole value chain are significant.

Estimated costs associated with the lags outlined in just 12 case studies are more than $440 million.

Summary of Potential Direct, Indirect and Total Opportunity Costs

Case	Foregone Output, Wages and Salaries, Taxes on Products and Taxes on Production ($Cdn)			Foregone Employment (Individuals)		
	Direct	Indirect	Total	Direct	Indirect	Total
A	$13,435,680	$17,629,764	$31,065,720	39	98	137
B	$69,557,634	$91,270,756	$160,829,819	201	508	709
C	$2,799,100	$3,672,868	$6,472,025	8	20	29
E	$41,204,353	$54,066,710	$95,271,910	119	301	420
F[1]	$1,092,981	$1,434,167	$2,527,170	3	8	11
G	$31,676,589	$41,564,758	$73,241,998	91	231	323
H	$8,696,874	$11,411,692	$20,108,745	25	64	89
J	$14,824,104	$19,451,599	$34,276,007	43	108	151
K[1]	$3,147,881					
L[1]	$12,602,334					
TOTAL	**$200,013,720**	**$240,502,314**	**$440,519,799**	**529**	**1,338**	**1,869**

**Some totals may not exactly equal sum of direct and indirect impacts because of rounding*

Note:

i) these figures are based on only 12 cases. There are likely many more cases experienced by each of the companies who participated in the study, and many more companies who did not participate, who would have similar experiences. It is clear that if these results were extended to the entire system, the costs would be much higher.

ii) it is impossible to estimate all the costs because of the deleterious effects of the regulatory system on the underlying structure of the economy. When suppliers are continually penalized for innovation, they reduce investment in Canada, they undertake less research and development, and they do not provide Canadians with products that could improve their health.

- **Lack of commercialization opportunity fuels the decline of the sector**. The lack of a modern administrative and procedural infrastructure to respond effectively and efficiently to market demand creates a disincentive to commercialize food innovation in Canada and add value to the economy. At a time when Canada's traditional manufacturing sector is in decline due to global economic shifts and currency fluctuations, a strong food processing sector that is properly incented to innovate in Canada could stem the tide of plant closures and job losses that are endemic to the wider manufacturing sector and appearing with greater frequency within the food industry as well.
- **There is no evidence that the lags are the result of measures to help improve the health and safety of Canadians.** The lags identified in the study do not relate to food safety components but rather are the result of poor administrative processes and lack of a framework for decision-making. This contributes additional costs and uncertainty to food suppliers, adds to the time and cost for Canadians to obtain potentially healthier products, and reduces investment in the food industry.

The conclusions of this study are not new nor are they confined to this particular set of regulations. Many other studies, including on other aspects of Health Canada's and CFIA regulations, from plant health products to seed regulations, have drawn similar conclusions, for well over two decades.

Instead of adapting to today's needs, the system has become a growing burden on the Canadian industry, effectively dampening innovation and economic prosperity, and cheating Canadian consumers and users of inputs from access to the products that would allow them to improve their lot.

Canadian food law expert Ron Doering[2] noted that Health Canada has discussed and consulted on the "improvement" and "modernization" of the regulatory system for years, through initiatives such as: *Smart Regulation; Blueprint for Renewal: Transforming Canada's Approach to Regulating Health Products and Food; Blueprint for Renewal II: Modernizing Canada's Regulatory System for Health Products and Food; Towards a Regulatory Modernization Strategy for Food and Nutrition;* and the newest *Managing Health Claims for Foods in Canada: Towards a Modernized Framework*. Although the consultations seem to move in the right direction there is little evidence of any significant results. It is time to step up the effort to reform the system.

Recommendations

The following are recommendations:

- Establish the political will to urgently reform Canada's food regulatory system. Appoint an executive at the highest level of government to oversee and champion the process.
- Re-write the legislation to incorporate:
    - clear objectives so that regulators are given guidance on what the public wants from its health regulatory system;
    - an objective in the legislation to promote efficiency in the food system, as Australia/New Zealand has; and
    - the maximum length of time for regulators to make decisions and a requirement for them to be accountable to Cabinet when the time line is exceeded.

    The Cabinet Directive on Streamlining Regulation was published in April 2007. This Directive replaces the Government of Canada Regulatory Policy with a purpose to work "with Canadians and other governments to ensure that its regulatory activities result in the greatest overall benefit to current and future generations of Canadians". This Directive applies to the development and amendment of regulations under the authority of all federal departments and agencies. Along with protecting the health and safety of Canadians, under the Directive, the government must "create regulations through inclusiveness, transparency, accountability" and public scrutiny and "require timeliness" and "promote a fair and competitive market economy that encourages entrepreneurship, investment and innovation". This Directive may help to improve the environment for developing regulations and seems to be heading in the right direction but may simply result in more consultations.
- If the legislation were amended, the regulations would also need to be re-written to be compliant. The following are recommended improvements to the regulations:
    - Pursue administrative approval approaches for food additives and health claims rather than lengthy regulatory amendments after safety has been assessed.
    - Adjust the heavy reliance on the pre-market assessment process and fully explore the use of regulatory procedures in other countries that do not have excessive requirements or have tiered requirements, and assess how they can be adopted to be used in Canada. This would relieve many of the regulatory impediments mentioned in this report.
    - Given the regulatory system is so reliant on pre-market assessments, it requires a clear and transparent process and application requirements. Substantial changes in administrative procedures need to be made to speed up and improve this process at Health Canada, for example:
        - Develop a comprehensive submission guide for applicants to follow in developing a submission (Draft Guidance Document – Management of Pre-Market Submissions is currently in the consultation phase).
        - Hold meaningful pre-submission consultations with applicants with the intent of ensuring that applicants understand the process and complete their submissions with the right information for efficient decision-making.
        - Adopt the legislated Australia/New Zealand policy that requires regular communication with applicants at each stage of the decision process.

- Ensure efficiency by accepting credible scientific reviews from other jurisdictions as part of an application and/or utilize third-party experts when resources within Health Canada are limited.
- Hold regulators accountable for meeting timelines. As already indicated, we recommend the legislation be amended to hold the government accountable. This should become part of normal performance evaluation within Health Canada.
- Develop performance indicators and conduct a self-assessment based on those indicators. Make Health Canada's performance on timelines and other measures public.
- Publish application decisions (positive or negative) so that the industry can learn from these experiences. This would also ensure that decisions are made consistently.

1 Cases K and L products and one product from Case F would be manufactured in the United States and therefore have not been run through the Statistics Canada Input-Output model (described in detail in Appendix I). However, the potential lost sales amounts are included in the total economy opportunity costs because these sales would be attributed to the companies' Canadian divisions.

2 Doering, R. (2008). More Talk, No Action: Yet Another Health Canada consultation on health claims in announced. Food in Canada. January/February 2008.

Notes

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