

**Analysis of the Regulatory Framework  
Affecting Development and Commercialization  
of Dairy Products in Canada**

**Completed for**

**The Dairy Processors Association of Canada**

**by**

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## **Executive Summary**

This report and its appendices provide a comprehensive overview of federal and provincial statutes and regulations that apply to dairy processing and dairy products. The project was undertaken on behalf of the Dairy Processors Association of Canada.

The authors conducted a review of all federal and provincial regulation that applies to dairy production, processing, marketing and distribution with the objective of identifying all provisions that do or could affect dairy processing and products. However, no analysis was conducted, nor have observations been made on regulation dealing with supply management or price determination. We confined our analysis and recommendations to dairy processing and products.

The development of Canada's regulatory framework affecting the dairy industry and other food sub-sectors has taken place over a period of approximately 85 years, commencing with the coming into force of Canada's 1920 Food and Drugs Act. The early decades of food regulation relied primarily on food standards, in the absence of provisions to follow many years later dealing with food additives (1964), comprehensive labelling (1976) and addition of vitamins and minerals to foods (1972). Despite the refinement of these provisions and the emergence in Canada and at the international level of generally applicable and commodity-specific food safety requirement, compositional standards remain in place in both federal and provincial dairy processing and product regulations.

Court decisions over the past three decades have affirmed both a federal and provincial role in the regulation of foods, including dairy products. The courts have determined that the existence of federal regulation does not remove from provincial governments the authority to regulate food products within their respective provincial borders. The courts have also reaffirmed the federal role in food safety. The federal government (Health Canada and the Canadian Food Inspection Agency) retains authority over health related standards and severable components of food standards dealing with health, regardless of whether a product is traded (sold) interprovincially.

In the past 30 years, federal comprehensive labelling requirements for foods have been introduced, including the requirement for a complete list of ingredients for all foods, including standardized foods. Until 1976 and the introduction of the Consumer Packaging Act and Regulations, only optional ingredients were required on the list of ingredients for a standardized foods. Since 1976, we have seen the adoption of requirements for disclosure of ingredients of ingredients and most recently, mandatory nutrition labelling. The principal of the "consumer's right to know" has been the rationale for regulatory intervention in these areas. It can be argued that these comprehensive labelling requirements have to a great degree, rendered prescriptive compositional food standards redundant. This is being recognized by regulators in Canada and in other jurisdictions, notably the United States and by the Codex Alimentarius Commission.

Food processors are being increasingly influenced in their manufacturing activity by outcome-based regulatory policy and industry-led good manufacturing practices that are based on the principles of Hazard Analysis Critical Control Points (HACCP). Generally speaking, this trend

has confirmed the primary role of agencies such as the Canadian Food Inspection Agency as an auditor, performing random audits and in some cases audits and inspections by invitation. The more significant implication for regulators is that if they are to keep pace with societal, technological and consumer behavioural change, regulators must concentrate on outcome-based or performance-based regulation.

Our analysis of federal and provincial regulation affecting dairy products suggests that many provisions are of benefit in that they support the marketing interests of the dairy value chain. It can be argued that these contribute to consumer product recognition and understanding. This analysis is summarized in Appendix A.

On the other hand, food manufacturers have long been subject to authoritarian regulatory interpretations that are seated in regulatory culture that adheres to the view that compositional standards contribute to the “public good”. It is time for the processing sector to carefully examine these longstanding views about compositional standards that are based in history and regulatory culture. Regulators in the 21<sup>st</sup> century will have to give increased recognition to technological, cultural and societal change and design regulations and regulatory policy consistent with consumer demands. Standards must become sufficiently flexible to accommodate use of dairy and other ingredients derived from modern technology.

We would argue that compositional standards for dairy products have advanced to the point where no further refinement and no additional standards are necessary. A single set of identity and compositional standards, including provisions for addition of vitamins and minerals and food additives should exist within the Canadian federal regulatory framework readily available to be incorporated by reference into other federal and into provincial regulation.

We would also argue that best practices to be used in dairy production, storage, handling and transportation and processing have advanced to the point that these also need reside only in one place in the federal regulatory framework.

Our research revealed that there is a wide variation in the design, scope and composition of statutes and regulations affecting the dairy industry at the provincial level. The provincial frameworks vary from being as simple as one statute and one regulation pursuant to that statute affecting the entire dairy value chain to the other extreme, where as many as four statutes are in place and in excess of 20 regulatory instruments for the entire dairy value chain. Although the regulatory provisions that directly govern product composition, labelling and marketing are relatively few in number in most provinces, additional regulatory provisions do affect the operation of dairy processing facilities.

We also noted the limited extent to which provincial regulation has become transparently aligned with federal regulation, notwithstanding fairly recent reviews and amendments in some provinces. This is noteworthy, given the years of effort invested by the dairy value chain (industry) and provincial departments and agencies to develop the National Dairy Regulation and Code as a model. It is also noteworthy considering that all provinces, territories and the federal government are signatories to the 1995 Agreement on Internal Trade that calls for removal of

existing interprovincial trade barriers, preventing the establishment of new barriers and harmonizing standards in 11 sectors, including agriculture and food goods.

We would observe that in the absence of a single set of compositional standards at the federal regulatory level, it is not currently possible for provincial regulations to incorporate compositional standards by reference to reflect all that are being sold in these markets. There is clearly a need for a single set of federal compositional standards that lends itself to incorporation by reference in the interest of modernizing, harmonizing and abbreviating provincial regulations affecting dairy processing and products. This issue has been addressed in the drafting of Draft 9 of the proposed revised Dairy Product Regulations.

We suggest that the identity and compositional standards found in Division 8 of the *Food and Drug Regulations* be harmonized with the standards contained in Draft 9 of the *Dairy Product Regulations*. The standards found in Draft 9 of the *Dairy Product Regulations* are the result of several years of consultation and are thus more current and complete than those found in the *Food and Drug Regulations*.

The complete set of dairy standards found in the *Food and Drug Regulations* would include the “health and safety” provisions, namely permitted food additives and permitted or mandatory nutrient substances (vitamins and minerals). By having a complete set of standards in the *Food and Drug Regulations*, the user of these regulations would not have to carry out a cross-referencing to determine the totality of applicable provisions. Because Health Canada retains jurisdiction for health and safety requirements of food products, the compositional or identity standard, complete with “health and safety” provisions would be a “best fit” in the *Food and Drug Regulations*. The standards would be repeated as currently drafted in Draft 9 of the *Dairy Product Regulations* with referencing of “permitted food additives”, “permitted vitamins” and possibly other health and safety provisions.

Many provincial regulations affecting the dairy industry have the effect of sub-delegating regulatory power. In most cases some regulatory powers are delegated to commissions and supply management agencies. In one province, regulatory powers have been sub-delegated to the dairy producers. This does not exist in any other provincial jurisdiction for any food and beverage product outside of the dairy industry. Except in rare instances, regulatory powers are not sub-delegated to organizations outside of federal departments and agencies. This renders regulatory interpretation and change more predictable and transparent under federal regulatory policy.

Existing regulatory requirements for dairy products do not reflect the reality of competition at retail level and in foodservice from multi-ingredient unstandardized products. The formulation of competing products such as soy-based beverages and edible oil products is at the discretion of the manufacturer, so long as the products are compliant with the Food and Drugs Act and Regulations. Put in other terms, products that compete with dairy products, do not face the same degree of restrictions to innovation, formulation, labelling, distribution and marketing.

The interpretation of regulation and the potential for unanticipated changes in regulation present uncertainties for all food and beverage processing industries who invest and operate in Canada. Business decisions pertaining to investment in processing capacity and new product development are usually made in the belief that the investors have a reasonably complete and correct understanding of current regulatory requirements.

As outlined in this report and as identified in the appendices, there are anomalies and conflicts within and among provincial and federal regulations affecting dairy processing and products. As a result, it is difficult to achieve a reasonably complete and correct understanding of the totality of regulatory provisions and requirements in the dairy processing sector as opposed to other sub-sectors of the food industry. This, coupled with the sub-delegation of regulatory powers, contributes to a climate of uncertainty for dairy processors.

### **Summary of Recommendations**

- 1. With respect to the National Dairy Regulation and Codes, we recommend:**
  - **Removal of the word “Regulations” from the title of the “*National Dairy Regulation and Codes*” as this is a non-regulatory guidance document. Thus the title becomes the “*National Dairy Code*”.**
  - **removal of all compositional standards from the Code**
  - **retaining and editing of existing text to create one chapter or division for each of primary production and on-farm storage, farm-to-processor handling and transportation, good manufacturing practices for processing**
- 2. With respect to the Food and Drugs Act and Regulations, we recommend that:**
  - **the identity and compositional standards found in Division 8 of the *Food and Drug Regulations* be harmonized with the standards contained in Draft 9 of the *Dairy Product Regulations*. This would require the addition to Division 8 of the Draft 9 standards for the following products: cultured butter, whipped butter, (naming the added ingredient) butter, whipped whey butter, (naming the added ingredient) whey butter, butter oil, anhydrous butter oil, buttermilk powder, whey powder, acid-type whey powder, blended skim milk and whey powder, edible casein, edible caseinate, eggnog, yoghurt, (naming the flavour) yoghurt, yoghurt drink and cultured cream.**
- 3. With respect to the federal Dairy Product Regulations, we recommend the prompt promulgation and coming into force of Draft 9, amended to;**
  - **harmonize the provisions of the existing National Dairy Regulation and Codes dealing with microbial count limits, testing and analytical methods with those of "Draft 9"**

- **incorporate by reference, the best practices for dairy processing as found in the relevant chapter of the revised National Dairy Code**
  - **include the definition of “milk product” found in section B.08.001.1 of the Food and Drug Regulations.** Although Draft 9 includes a definition for “dairy product” that could be interpreted to include B.08.001.1, clarity of the text would be improved with this addition.
- 4. With respect to discretionary fortification, we recommend that:**
- **discretionary fortification of standardized dairy products (packaged for retail sale) be permitted subject to labelling requirements for treating these as non-standardized foods intended to provide informed consumer choice of safe alternative sources of nutrition**
- 5. With respect to provincial regulations, we recommend that provincial regulators:**
- **delete prescriptive text (specific clauses and sections) dealing with location, design, construction and operation of dairy production, storage and handling and processing facilities, to be replaced through incorporation by reference of the relevant chapters of the revised National Dairy Code**
  - **adopt common definitions for “milk product” and “dairy product”, being the definitions that would be included in the revised federal Dairy Product Regulations**
  - **delete all compositional standards for dairy products to be replaced through incorporation by reference of the compositional standards included in Division 8 of the Food and Drug Regulations (amended as noted above)**
  - **delete prescriptive text and tables all provisions dealing with inspection, testing, analytical methods, standards and tolerances for microbial content unless such text aligns with the content of the revised National Dairy Code and the content is deemed necessary for compliance and enforcement activity falling under the purview of the provincial agency or office to whom compliance and enforcement responsibility have been delegated**
  - **harmonize measures dealing with the manufacture, importation and sale of edible oil products through a recommitment to the measures stipulated in the Agreement on Internal Trade (Chapter Nine – Agricultural and Food Goods), particularly with reference to the adoption of recommendations concerning imitation dairy blends and butter blends (Annex 902.5, Work Programs, Section 8)**

Included in this report are a number of appendices in table format to illustrate the analysis and highlight examples that form the basis for the above recommendations.

## **I Project Overview**

The Dairy Processors Association of Canada (DPAC/ATLC) is Canada's national industry association representing the public policy and regulatory interests of the Canadian dairy processing industry. DPAC/ATLC engaged B.L. Smith & Associates to conduct a comprehensive analysis of all federal and provincial legislation (statutes) and regulations affecting dairy processing and products. The project was initiated in January, 2005 and culminated with the completion of this report in July, 2005.

### **Project Rationale**

Among developed countries, Canada has one of the most prescriptive regulatory frameworks governing processed dairy foods.

Most processed dairy foods are treated as “standardized” products under applicable federal and provincial regulations. Regulatory standards are generally very prescriptive and thus do not allow the manufacturer to deviate from legally compliant product formulations and prescribed labelling requirements, even where innovation improves the product and better serves changing consumer demands.

The extensive nature of Canadian regulations has been recognized by the dairy sector and governments for many years. It is noteworthy that Agriculture and Agri-Food Canada has developed a compendium of federal and provincial regulation affecting the sector. This recognition is also evidenced by industry efforts to develop and adopt the National Dairy Regulation and Code.

The prescriptive regulatory requirements are not exclusive to the processed dairy food sector in that all food sub-sectors are subject to extensive regulation and related compliance guidance documents. The food industry and the research community generally characterize the Canadian food regulatory framework as being unduly restrictive in comparison with other developed countries and trading partners. However, the regulatory framework governing the dairy sector is complicated by overlapping jurisdictions and sometimes differing requirements at the federal and provincial levels.

Food ingredient research, the linkage between diet and disease, product and process innovation and changes in demographics and consumer dietary behavior are all outpacing the adaptation of the regulatory system to new market realities and opportunities.

Recent amendments to the *Food & Drug Regulations* (nutrition labelling, nutrient content claims, generic health claims and Natural Health Product regulations) have further narrowed room for interpretation in product formulation, labelling and advertising. Future changes that could result from a comprehensive parliamentary review of the *Food & Drugs Act* will present both risks and opportunities to the Canadian dairy sector.

In 2003 the dairy sector conducted a Visionary exercise which identified a key area of focus -- "growth through innovation". In 2004 a Dairy Regulation Advisory Committee was struck with representatives from Dairy Farmers of Canada (DFC), DPAC/ATLC and the Canadian Dairy Commission (CDC) because federal and provincial dairy regulations were seen by many stakeholders as an impediment to market growth.

## **Research Scope and Methodology**

In completing this project, the authors conducted a review and analysis of all federal and provincial legislation and regulations containing provisions that affect production and processing of bovine milk and cream into fluid milk products and other dairy products.

It should be noted that legislation or statutes (enacted by federal and provincial parliaments) generally deal with broad public policy principles. Most legislation permits the promulgation of specific regulations pursuant to the statute to interpret a broad power or principle. The process of developing regulations is done by federal and provincial bureaucracies (public servants) and then authorized for promulgation as law by a committee of parliamentarians or another body as authorized in a particular statute. Thus, new regulations or amendments to existing regulations do not have to be debated before Parliament.

In terms of an example, the *Canada Agricultural Products Act (CAP Act)* is "umbrella" legislation that has been enacted by the Canadian Parliament. The *Dairy Product Regulations* are authorized as specific regulations within the scope of the *CAP Act* and may be amended by "The Special Committee of Council" which is, in reality, a Cabinet Committee.

Departments and agencies of both the federal and provincial governments frequently develop non-regulatory guidance documents that provide administrative interpretations about both legislative provisions and specific regulations. The Canadian Food Inspection Agency (CFIA) *Guide to Food Labelling and Advertising* is a good example of such a document. There is a relatively common misperception in the food industry that the *CFIA Guide to Food Labelling and Advertising* has regulatory status and can be enforced as such. This is not the case as manufacturers can challenge administrative rulings and interpretations that have not been subject to the legislative or regulatory process.

The many provincial statutes and regulations pertaining to supply management, quota allocation, primary production, storage and handling, transportation and marketing of milk and cream were examined with the objective of identifying provisions that affect or have the potential to affect dairy processors and dairy products. For the purposes of this study, this did not include regulations pertaining to the establishment and adjustments of prices to be paid to producers by processors or the fees for various licenses required by processors and their employees.

Readers of this report should note that although all regulation affecting dairy production and processing was examined, **the focus of this project was on regulation affecting dairy processing and dairy products.** Provisions of federal regulation, existing and proposed, are

compared and contrasted in Appendices A through F. Provisions of provincial regulation are summarized in a common format in Appendices G through P, where apparent conflicts and anomalies are also noted. In conducting the analysis of provincial regulations, we attempted to identify provisions that either aligned with or conflicted with the intent of the Agreement on Internal Trade.

We also examined the most recent drafts of the National Dairy Code and Regulations and Health Canada's April, 2005 proposed Policy on Addition of Vitamins and Minerals to Foods, for possible implications to the dairy processing industry.

Other than considering Canada's involvement as a signatory to the Codex Alimentarius Commission, we did not consider the legislative and regulatory systems of other jurisdictions. This was outside the scope of this project.

We conducted interviews with a number of individuals in both federal and provincial departments and agencies, seeking perspectives on recent and pending regulatory changes

A compendium of all statutes and regulation identified and reviewed is included as Appendix Q.

## **II Key Findings and Observations Arising from Analysis of Existing Federal and Provincial Regulatory Framework**

### **Historical Context - Food Regulation in Canada**

*The Inland Revenue Act of 1875 (later called the Adulteration Act and finally the Food and Drugs Act in 1920) contained basic prohibitions against the sale of adulterated foods. Early attempts to prosecute under the statute were often unsuccessful because there were no recognized standards. In order to counter this legal problem, standards were gradually introduced over a period of time starting in the late 1800s. Many of the food standards in existence today were in place by 1920.*

The following types of standards may be found in various sections of the *Food and Drug Regulations*:

**Standards of Identity** which tend to be absolute in that the commodity being defined must be from a specified source. Examples include milk, coffee, spices, cocoa beans and fats and oils.

**Standards of Composition** that tend to be arbitrary and prescriptive in nature in that they generally refer to multi-ingredient products and reflect historical expectations for products sold under a particular name or designation. Examples include the requirement for 45 percent raspberries in “raspberry jam” and 10 percent milk fat in “ice cream”.

**Performance Standards** that require that a particular food conform to certain performance requirements such as minimum protein quality and quantity. The regulatory requirements for “Infant Formulae” is a good example of a performance standard which is based on nutritional outcome rather than a prescriptive formulation defined by regulation.

**Quality Standards** that pertain to only those provisions in standards not directly associated with compositional or identity criteria. Examples include total plate count limits for “Ice Cream” and limits for crude fibre and total ash in “Chocolate”.

Food standards were introduced during a simpler era when the Canadian food supply was essentially limited to the standardized foods that were defined by regulation. With the passage of time, standards were used not only for purposes of identity and composition but also as a convenient mechanism to control the addition of food additives, vitamins and minerals.

In 1964, the introduction of a formalized pre-market control system for food additives together with the inclusion of tables of acceptable food additives in the regulations, reduced the former reliance on standards as a method of prescriptive control.

1976 was another landmark year as major regulatory amendments mandated a complete listing of ingredients on all pre-packaged foods products. Up to this time, standardized foods were exempt from a list of ingredients as conventional wisdom of the time felt that prescribed composition in federal regulations was an adequate alternative to a label declaration of ingredients.

Readers should note that two sets of standards for dairy products were developed for valid reasons. The standards found in Division 8 of the *Food and Drug Regulations* were intended to cover standardized dairy products at all points of sale. The standards included in the *Dairy Product Regulations* were developed for the purposes of plant registration and marketing of products interprovincially and for export. The standards are similar but not identical as the *Dairy Product Regulations* do not contain standards for fluid milk products.

The December, 1979, Supreme Court of Canada ruling in the “Labatt Lite Beer” case was a landmark decision in terms of the applicability of food standards promulgated under the authority of the *Food and Drugs Act*. In effect, the Supreme Court decided that the promulgation of “recipe-type” or compositional standards was an “over-reach” of a statute that finds its authority in the criminal law power of the constitution.

As a result of the 1979 decision, federal food standards dealing with prescriptive composition requirements became enforceable only if the product was involved in international or interprovincial commerce. Thus, compositional standards found in the *Food and Drug Regulations* became entirely comparable in terms of enforcement to similar standards found in “commodity statutes” (e.g. CAP Act) enforced by Agriculture Canada and as of 1997, the Canadian Food Inspection Agency.

While the decision specifically invalidated only the malt liquor standards, its implications were much broader in that it placed the validity of some 300 other food composition and identity standards in jeopardy.

Following protracted legal analysis, it was concluded that the Supreme Court decision did not affect existing provisions of food standards in the *Food and Drug Regulations* that are directly related to protecting consumers from potential health hazards. For example, in the case of food additives and nutritional requirements found in food standards, legal wisdom has always held that these provisions are enforceable at any level of sale as they are still within the jurisdiction of the Criminal Law. This means that health and food safety aspects of food standards are not limited by considerations of interprovincial commerce.

In its 1993 publication entitled *A Strategic Direction for Change – A Review of the Regulations under the Food and Drugs Act, Volume 2*, Health Canada officials concluded the following about the issue of food standards in a modern context:

*The inflexibility of food standards and the difficulty in making amendments to reflect advances in technology is a concern to staff who have responsibility for food standards.*

*The fact that standards are duplicated in other regulations (Processed Product Regulations, Meat Inspection Regulations, etc.) creates a certain amount of confusion, particularly when the standards are not identical in the two sets of regulations.*

*Prior to the Labatt Decision, it could be argued that standards were essential in the Food and Drug Regulations so that enforcement could take place down to the local level of sale. However, the Supreme Court of Canada changed the application of food standards and the revalidated Section 6 is not operative under the Trade and Commerce power of the constitution in exactly the same fashion as the commodity regulations enforced by Department of Fisheries and Oceans and Agriculture Canada. In other words, for a standard found in the Food and Drugs Regulations to become operative, the product must be involved in international or interprovincial commerce.*

*As noted previously, the limitation on enforceability of food standards is confined only to the compositional and identity features of the standard as directed by the Supreme Court decision. For example, a compositional parameter such as the milk fat content prescribed in the standard for Ice Cream could not be enforced except if the product has moved in interprovincial commerce. However, because health related, severable, provisions in standards are still considered to be part of the Criminal Law, the optional provisions for the use of certain food additives (stabilizers, food colours) in Ice Cream Mix would be enforceable at any level of trade including intra-provincial sale. Similarly, the mandatory addition of Vitamin D to milk and milk products is considered to be enforceable regardless of the level of sale.*

In the same report, Health Canada officials also presented the following additional views about food standards as a regulatory tool:

*All non-health related standards should be deleted or transferred to the regulations of other agencies having jurisdiction;*

*The regulatory process is ponderous and slow. There needs to be a mechanism that provides for increased flexibility. Current standards interfere with product development and delivery of products that consumers want;*

*Food standards are generally difficult to amend and many are duplicated in regulations administered by Agriculture Canada and Fisheries and Oceans Canada. Regulations could be amalgamated into a "Food Standards Compendium" which could be maintained by an agency such as the Standards Council of Canada. Departments could establish mandatory standards, as required, by referencing.*

In considering the issue of standards for cheese products found in both the *Food and Drug Regulations* and the *Dairy Product Regulations*, Health Canada officials offered the following views:

*In the 1970s, revised standards for cheese products were developed and entered in both the Food and Drug Regulations and the Dairy Product Regulations under the CAP Act. By this time, the Department of Agriculture had adopted the attitude that they would merely reference provisions for food additive use to the Food and Drug Regulations and would not repeat these provisions in their own regulations.*

It is clear that officials in Health Canada and Agriculture Canada had accepted the principle of maintaining compositional standards for dairy, meat and processed fruits and vegetables exclusively in the “commodity regulations” some 12 years ago. Those aspects of standards clearly dealing with health and safety should be retained in the *Food and Drug Regulations* and should be referenced as required in the “commodity regulations”. Despite the broad consultation that took place following the release of the 1993 regulatory review, little concrete action has taken place to implement the recommendations found in the reports.

Labelling of dairy products took a somewhat surprising turn during the review of Bill C-27 (a government bill entitled *The Canadian Food Inspection Agency Enforcement Act*) by the Standing Committee on Agriculture and Agri-Food. On June 2, 2005, the Committee members agreed to amend the Bill by adding the following section which would make a consequential amendment to Section 18 of the *Canada Agricultural Products Act*:

**18.1** *(1) No person shall market an agricultural product using a dairy term on the label unless that product contains the dairy ingredient represented by the dairy term*

*(2) No person shall market an agricultural product that has a dairy term on the label if the agricultural product is intended to substitute for a dairy product.*

*For the purpose of this section, “dairy ingredient” means butter, buttermilk, butter oil, cream, cheese, ice cream, milk, sour cream, whey, yogourt or any other prescribed thing;*

*“dairy term” means a word, name, designation, symbol or pictorial which refers to a dairy ingredient and “milk” means the normal lacteal secretion obtained from the mammary gland of an animal*

If proposed Section 18.1(2) became law and were enforced as currently written, it could result in the removal of a large number of food items from sale. This would include foods such as chip dips, calcium fortified orange juice containing a dairy ingredient as a source of calcium, margarine and dairy spreads containing dairy ingredients and specialty items such as coffee creamers. At the time of writing this report, the Dairy Processors Association of Canada (DPAC/ATLC) and other sectors of the food industry were making representation to the Standing Committee on Agriculture and Agri-Food to either withdraw or substantially amend the provision in question.

## **Provincial Authority in Regulation of Dairy Products**

With the evolution of federal food regulations in recent years to provide more complete information to the consumer, one might question the need for any provincial regulations that specifically applies to dairy products. The federal regulatory framework deals with standards of identity and composition, quality standards, and health and safety requirements involving food additives, nutrient addition and prohibition of pathogenic microbes. Federal requirements also deal with complete listing of ingredients, mandatory nutrition labelling, nutrient content claims, generic health claims, food safety, inspection, compliance and enforcement.

Notwithstanding the detailed and comprehensive federal framework, provincial regulations do contain many of the same kinds of provisions. These include standards of identity, compositional standards, quality standards, provisions dealing with vitamin addition, package sizes, labelling, processing methods and marketing. As noted in the historical context outlined above, where provincial jurisdiction in some of these areas has been challenged, the courts have determined that the existence of federal regulation does not remove from provincial governments the authority to regulate food product within their respective provincial borders.

## **Federal Authority in Regulation of Dairy Products**

As noted above, notwithstanding the “*Labatt Lite Beer Decision*”, the federal government (Minister of Health and through delegation of enforcement authority, to the Minister of Agriculture) retains authority over health related standards and severable components of food standards dealing with health, regardless of whether a product is traded (sold) interprovincially. This authority includes mandatory addition of vitamins and minerals to foods, including standardized dairy products, use of authorized food additives, disclosure of ingredients on food labels and mandatory nutrition labelling. The health and safety provisions are enforceable at any point of sale because the Food and Drugs Act and Regulations are considered to be part of criminal law, a federal constitutional power.

A second federal constitutional power, trade and commerce, resides with the Minister of Agriculture in terms of interprovincial and export movement of agricultural products. This authority is articulated in part in the Canadian Agricultural Products Act and the subsidiary Dairy Product Regulations.

## **Modern Regulatory Principles and Practices**

The drafting of legislation and regulation is an art, not a science. That is to say, there are a number of ways of pursuing an outcome in society, industry behaviour or the economy. In recent years, views on the design and use of regulation to effect an outcome have shifted significantly.

A fundamental tenet of regulatory theory is that regulatory intervention is justified when the consumer has insufficient information about product characteristics to make an informed choice

among competing products. In regulation of food and beverage products, this applies to matters such as microbial and chemical contamination, food additives and addition of nutrient substances.

In addition, the principal of the “consumer’s right to know” has been the rationale for regulatory intervention in the areas of declaration of ingredients, declaration of “ingredients of ingredients”, listing of potential allergens and mandatory nutrition labelling.

It can be argued that these comprehensive labelling requirements have to a great degree, rendered prescriptive compositional food standards redundant. This is being recognized by regulators in Canada and other jurisdictions. For example, Canada’s major trading partner, the U.S.A., released a regulatory proposal respecting the modernization of food standards dated May 17, 2005. This proposal was jointly issued by the Food and Drug Administration (FDA) and the Department of Agriculture, Food Safety and Inspection Service (FSIS).

In this proposal, the FDA and the FSIS propose to establish a set of general principles for food standards. The following is the text found in the summary section of the proposal:

*The adherence to these principles will result in standards that will better promote honesty and fair dealing in the interest of consumers and protect the public, allow for technological advances in food products, be consistent with international food standards to the extent feasible, and be clear, simple and easy to use for both manufacturers and the agencies that enforce compliance with the standards. The proposed general principles will establish the criteria that the agencies will use in considering whether a petition to establish, revise, or eliminate a food standard will be the basis for a proposed rule. In addition, each agency may propose to establish, revise, or eliminate a food standard on its own initiative or may propose revisions to a food standard in addition to those a petitioner has requested. These proposed general principles are the agencies’ first step in instituting a process to modernize their standards of identity (and accompanying standards of quality and fill of containers) and standards of composition.*

Comments in response to the 85 page joint FDA/FSIS food standards modernization proposal will be accepted until August 19, 2005.

### **Federal Regulatory Policy**

Canada's Federal Regulatory Policy was developed, approved by Cabinet and first published by Treasury Board in 1994. The policy was amended in 1999 to reflect Canada’s obligations under international and internal trade agreements and now resides under the purview of the Privy Council Office ([www.pco-bcp.gc.ca](http://www.pco-bcp.gc.ca)).

The policy objective of the federal regulatory policy is “*to ensure that use of the government’s regulatory powers results in the greatest net benefit to Canadian society.*”

The policy statements are:

*Canadians view health, safety, the quality of the environment, and economic and social well-being as important concerns. The government's regulatory activity in these areas is part of its responsibility to serve the public interest.*

*Ensuring that the public's money is spent wisely is also in the public interest. The government will weigh the benefits of alternatives to regulation, and of alternative regulations, against their cost and focus resources where they can do the most good.*

*To these ends, the federal government is committed to working in partnership with industry, labour, interest groups, professional organisations, other governments and interested individuals.*

A companion document to the federal regulatory policy entitled *A Framework for the Application of Precaution in Science-based Decision Making About Risk* has been issued. This document builds on the federal regulatory policy. Guiding principles of note are:

*Precautionary measures should be cost-effective, with the goal of generating (i) an overall net benefit for society at least cost, and (ii) efficiency in the choice of measures.*

*Where more than one option reasonably meets the above characteristics, then the least trade-restrictive measure should be applied.*

The fact that there is a comprehensive federal government policy regarding regulation is surprisingly not widely known among federal public servants. This is despite the fact that the policy contains a section dealing with regulatory process management standards. The policy states that it is the responsibility of regulatory authorities to develop and maintain a system to manage the regulatory process that meets the standards, and to document clearly how they are met for each proposal to create or amend regulations.

### **Smart Regulation**

The federal government appointed an External Advisory Committee on Smart Regulation (EACSR) in May 2003. The EASC report entitled *Smart Regulation: A Regulatory Strategy for Canada* was released in 2004. It identified sectors and areas requiring regulatory reform and provided recommendations on a regulatory strategy for Canada,

The federal government (PCO) defines “smart regulation” as:

*“ a government-wide initiative aimed at improving the government of Canada's regulatory performance. It involves a series of projects that strengthen the policy, processes, tools and regulatory community that are needed to sustain high levels of regulatory performance and facilitate continuous improvement.”*

In addition, the federal government has published a series of principles and strategic objectives for work to be undertaken under the Smart Regulation initiative. These are identified as building upon the existing federal regulatory policy. In particular, the principle dealing with protection of the public interest states that:

*“government regulates to improve Canadian quality of life and serve the broader needs of society to achieve the greatest net benefit for Canadians, not just a single group, sector or industry.”*

This principle is strongly reflected in the recently published document entitled *Guidelines for Effective Regulatory Consultations*. The purpose of this guidance document is to ensure that departments and agencies with regulatory responsibilities abide by the objectives and principles articulated in the Smart Regulation policy.

In order for the Smart Regulation initiative to succeed, it must acknowledge that market-driven and innovation-driven changes in industry behaviour usually outpace the ability of regulators to amend regulation. This has certainly been true in the agri-food sector generally and in food and beverage processing industries in particular, where industry-led quality assurance and food safety initiatives go beyond requirements that are based in regulation.

In 2005, food processors who are suppliers of food ingredients and finished food products to the foodservice industry and retail grocery industry find themselves subject to HACCP-based inspection and certification programs in order to achieve and maintain qualification as suppliers. These programs are almost entirely private sector designed and managed and typically use "third party auditors" (neither vendor nor purchaser) who are as often as not, accredited by non-government organizations who are recognized and welcomed by industry as organizations qualified to accredit inspectors and auditors.

What are the implications of this trend for government inspection agencies and programs? Generally speaking, this trend has confirmed the primary role of agencies such as the Canadian Food Inspection Agency as an auditor, performing random audits and in some cases audits and inspections by invitation.

The more significant implication for regulators is that if they are to keep pace with societal, technological and consumer behavioural change, regulators must concentrate on outcome-based or performance-based regulation. Such regulation typically defines only the essential characteristics of consumer-ready food products and largely defers to industry (the whole value chain, including processors) as to the means to achieve these characteristics.

## **The Use of Standards in an Outcome-based Regulatory Framework - “Thinking Outside of the Standardized Food Box”**

Our analysis of federal and provincial regulation affecting dairy products suggests that many provisions are of benefit in that they support the marketing interests of the dairy value chain. It can be argued that these contribute to consumer product recognition and understanding. This analysis is summarized in Appendix A.

On the other hand, food manufacturers have long been subject to authoritarian regulatory interpretations that are seated in regulatory culture that adheres to the view that compositional standards contribute to the “public good”. It is time for the processing sector to carefully examine these longstanding views about compositional standards that are based in history and regulatory culture. Regulators in the 21<sup>st</sup> century will have to give increased recognition to technological, cultural and societal change and design regulations and regulatory policy consistent with consumer demands. Standards must become sufficiently flexible to accommodate use of dairy and other ingredients derived from modern technology.

It should be noted that “traditional views” are found both among regulators and food manufacturers. Food manufacturers subject to compositional standards must ask the following question:

**“Are compositional standards really an impediment to product development and innovation or is it the acceptance of the traditional views about standards combined with a deference to perceived authority that is really the issue?”**

In our view, an appropriate regulatory strategy for the dairy value chain would be to retain regulatory provisions that contribute to product quality and safety and product recognition, without restricting technological, ingredient and product innovation. This requires thinking outside of the standardized food box.

Compositional standards for food represent an ancient form of food regulation, established prior to specific regulations respecting the use of food additives, nutrient substances (i.e. vitamins and minerals) and other ingredients. In general, prescriptive standards are not conducive to product development and innovation.

Although we note that the development of many food standards, especially compositional standards, pre-dated the development of current regulations pertaining to use of food additives, ingredient listing and nutrition labelling, the use of standards can be incorporated into designing outcome-based regulations if done in parallel to modern regulatory thinking.

After some 30 years of dealing largely with identity and compositional standards, the Codex Alimentarius Commission concluded that enough work had been devoted to commodity

standardization. In the early 1990s, this internationally pre-eminent food standardization body “shifted gears” in favour of “horizontal activities” including food labelling, food additives and contaminants, food hygiene, nutrition and food import and export. This decision was approved by the entire membership of the Commission that includes in excess of 170 countries.

Compositional, prescriptive, regulatory standards often become non-contemporary and simply do not reflect technological change and societal realities. For example, the federal standard for “jam” requires that the product contain 66% soluble solids (sugar) so that the product is stable (will not spoil) at room temperature. Without the presence of the mandatory 66% sugar, the product cannot be called “Jam”. Manufacturers must resort to calling nutritionally different products (e.g. containing less sugar) a “(naming the fruit) spread”.

The jam standard was promulgated in Canada prior to the widespread availability of refrigeration. Now that refrigeration is universally available in Canada, such a standard is not only technologically out of phase but also inconsistent with the demands of many Canadians who want products containing more fruit and less sugar.

Now that mandatory nutrition labelling is a reality in the Canadian marketplace as of December, 2005, the consumer will have the ability to judge and purchase products based not only on declared ingredients but also on nutritional profile. Thus, the presence of ingredients such as carbohydrates and saturated fat will become much more obvious, facilitating consumer choice.

While standardized foods must generally be labelled with the common name prescribed by regulation, the CFIA has recognized that there are instances where it is possible to qualify the common name of a standardized food.

Section 4.2.2 of the *Guide to Food Labelling and Advertising* states the following:

*A **modified common name** of a standardized food **may not** be used to describe a food that does not meet that standard **unless** the following conditions are met.*

*It must always be clear to consumers that the food so described does not meet the standard.*

*The consumer is told, in all respects, on the label and in advertisements, the provisions(s) which the food does not meet within the standard. This information must always be in evidence in a clear and prominent manner as part of the common name on labels and in advertisements (e.g. flavoured shortening, coloured sugar).*

Readers should note that although the *Guide to Food Labelling and Advertising* is widely interpreted by industry as regulatory policy, the Guide in fact has no regulatory (legal) status. Enforcement activity based on the Guide is therefore subject to challenge.

In 1999, the Codex Alimentarius Commission published a *Codex Standard for the Use of Dairy Terms*. At the outset, this labelling standard recognizes that the name of a food shall be declared in

accordance with the general principle of labelling found in Section 4.1 of the *Codex Standard for the Labelling of Prepackaged Foods*.

Section 4.3.3 of the *Codex Standard for the Use of Dairy Terms* recognizes that the names of dairy products may be qualified under certain circumstances. This section is as follows:

*Products that are modified through the addition and/or withdrawal of milk constituents may be named with the name of the relevant milk product in association with a clear description of the modification to which the milk product has been subjected provided that the essential product characteristics are maintained and that the limits of such compositional modifications shall be detailed in the standards concerned as appropriate.*

Although adherence to Codex standards and guidelines is not mandatory unless adopted in domestic regulation, it is clear that at both the domestic and international (Codex) levels, authorities recognize that compositional standards must start to incorporate a degree of flexibility to retain relevance in the 21<sup>st</sup> century.

Innovative manufacturers in the jam industry have designed new higher fruit, lower sugar products to meet consumer demands related to the consumption of lower carbohydrate products. While the product may not be called “jam”, the consumer has readily accepted these products recognizing the nutritional benefits and the fact that the product must be refrigerated after opening. In this case the standard for “jam” has not been changed; it has been the manufacturer being able to meet consumer demand and expectations by moving the product into a “non-standardized” category.

In the dairy sector, there are thousands of pages of prescriptive regulations. However, is it really the regulations that are the impediment to progress or rather the inability to reinterpret requirements in a modern context using mechanisms such as the principle for qualifying the common name as found in the *CFIA Guide to Labelling and Advertising*.

In terms of developing a mind-set that would favour innovation, the dairy industry should think of milk and milk components as ingredients that can form the basis for a wide range of unstandardized value-added foods and beverages that can be positioned in the market to compete with non-dairy unstandardized foods.

This is not to say that traditional standardized dairy products should not be a part of the product continuum.

### **Incorporation by Reference**

Incorporation of standards and best practices by reference can be a useful tool in designing outcome-based regulations where the standards (or best practices) that exist within other legislation/regulation or have been established by an accredited standards-writing organization are deemed to be appropriate for the product or issue being regulated. Canada has a well developed system for accreditation of standards-writing organizations who employ recognized principles and practices for setting of standards.

We would argue that compositional standards for dairy products have advanced to the point where no further refinement and no additional standards are necessary. A single set of identity and compositional standards, including provisions for addition of vitamins and minerals and food additives should exist within the Canadian federal regulatory framework. This would be readily available to be incorporated by reference into other federal and into provincial regulation.

We would also argue that best practices used in dairy production, storage, handling and transportation and processing have advanced to the point that these also need reside only in one place in the federal regulatory framework.

### **Federal Regulation Affecting Dairy Products**

Federal regulation affecting dairy products is detailed, comprehensive and pursuant to more than one statute. We conducted a comparative analysis of the requirements under the *Food and Drugs Act and Regulations* and the *Dairy Product Regulations, Canada Agricultural Products Act*. The comparison is summarized in table format in Appendix B.

It is important to note that the federal regulatory framework is made more complex by the fact that the two statutes are subject to different constitutional heads of power. The Food and Drugs Act is part of criminal law, while the CAP Act is part of the trade and commerce power.

The original intention of developing the Dairy Product Regulations pursuant to the CAP Act was principally to provide requirements relating to federal registration of dairy processing facilities. These regulations actually reference the Food and Drug Act and Regulations for definitions of food and food additives. These regulations also define food additives, sweetening agents or vitamins as permitted by the Food and Drug Regulations.

The original intention of incorporating provisions respecting dairy products in the Food and Drug Regulations was to ensure uniform national application with respect to safety and composition. However, the ability to enforce compositional standards was compromised in 1977 by a Supreme Court of Canada decision. ("*Labatt Lite Decision*")

A major review of the Dairy Product Regulations has been underway since 1997. The ninth draft of revised regulations dated January 2003 would incorporate further reference to the Food and Drug Regulations, specifically the terms "dairy product", "milk ingredients" and "modified milk ingredients". Draft 9 has incorporated additional compositional standards for cultured products, including yoghurt. This would appear to render the compositional standards found in the National Dairy Regulation and Code, redundant.

## **Proposed Federal Policy on Addition of Vitamins and Minerals to Foods**

Federal government (Health Canada) policy on voluntary (discretionary) fortification of foods with vitamins and minerals has been under review for many years. The latest proposed policy was published for public consultation in April, 2005. The policy excludes fluid milk products from eligibility for voluntary fortification and therefore does not really offer opportunity to modify standardized products. Similar treatment has been applied to standardized foods in other food groups. This is being challenged by other food industry sub-sectors.

However, the policy would appear to offer opportunity for voluntary fortification of unstandardized foods, including dairy-based foods since this will be permitted within the scope of proposed regulation that is currently in the drafting stages. The policy document states that:

*“Eligible Foods: All foods are eligible to be fortified at the discretion of manufacturers except: flours, breads, pasta (dry, fresh, frozen, single ingredient), rice, milks, butter, suet, lard, varietal cheeses, sugar and sugar syrups, maple syrup, honey, artificial sweeteners, salt, herbs, spices, dry seasonings, vinegar, flavouring preparations, leavening agents, alcoholic beverages, fresh produce, fresh unprocessed meat, poultry and fish, eggs, nuts, legumes, simulated and extended meat and poultry products, coffee beans, leaf tea, infant foods, formulated liquid diets, breakfast cereals, meal replacements and nutritional supplements.”*

The foods that are exempted are considered by Health Canada to be standardized and staple foods that are pervasive in the food supply. Because these foods are pervasive Health Canada has deemed it to be impossible to establish a safe level of addition that could be permitted for many nutrients. Some of the exempted foods (flour, pasta, milk) are already fortified under other regulatory provisions that are mandatory.

At the time of writing, Health Canada’s target date for publication of draft regulations is before end of calendar 2005.

Readers should note that the proposed federal policy and regulation will permit the continued sale of fortified vegetable-based and plant-based beverages and vegetable and/or milk protein based products that resemble cheese currently permitted under interim marketing authorizations. However, in some provinces, such products may be prohibited.

Provisions of Bill C-27 before the House of Commons, as amended in Committee, would also prohibit some of these products despite Health Canada’s assessment that such products offer consumers alternate sources of important nutrients associated with dairy products. This is consistent with a long-standing Health Canada policy that substitute products should have a similar nutritional profile to the product for which it serves as a substitute, regardless of the reason for consumer preference (allergens, other metabolic, philosophical, religious).

## **Alignment of Current Provincial Regulation With Federal Regulation**

In comparing provincial regulation of dairy products and processing with regulation that applies at the federal level, we were struck by the inconsistencies within and among provinces. There is a wide variation in the design, scope and composition of statutes and regulation affecting the dairy industry at the provincial level. The provincial frameworks vary from being as simple as one statute and one regulation pursuant to that statute affecting the entire dairy value chain (British Columbia, Manitoba) to the other extreme, where as many as four statutes are in place and in excess of 20 regulatory instruments (Nova Scotia) for the entire dairy value chain. Although the regulatory provisions that directly govern product composition, labelling and marketing are relatively few in number in most provinces, additional regulatory provisions do affect the operation of dairy processing facilities.

We also noted the limited extent to which provincial regulation has become transparently aligned with federal regulation, notwithstanding fairly recent reviews and amendments in some provinces. This is also noteworthy, given the years of effort invested by the dairy value chain (industry) and provincial departments and agencies to develop the National Dairy Regulation and Code as a model.

From our perspective as consultants, we had anticipated a greater degree of visible alignment, based on the progress report of July 2000 posted on the Canadian Food Inspection System website.

The lack of alignment is demonstrated by considerable variation among provinces in requirements related to package sizes, for example. There is also variation in product labelling requirements and to some extent, product composition requirements. When considered together within the context of a national market, these variations would appear to remain as impediments to interprovincial trade and to be inconsistent with the Agreement on Internal Trade.

### **Typical Provisions of Provincial Regulation Affecting Processors and Processed Products**

Most provincial regulations affecting the dairy industry contain detailed provisions governing primary production of milk and cream. These typically include design, construction and operation of dairy barns, milking facilities and on-farm milk storage and handling facilities. Broadly speaking, these provisions are included to promote dairy animal health and the sanitation of facilities and equipment with which milk and cream have the potential to come into contact. Similar provisions are found within sections of the National Dairy Regulation and Code.

Most provincial dairy regulations also include detailed provisions regarding the design, construction and operation of dairy processing facilities that include the following:

- licensing of processing facilities and persons employed in processing
- establishment and collection of license fees
- health and personal hygiene of persons engaged handling and processing of milk
- training of dairy processor employees
- professional qualifications and training of personnel employed in dairy processing

- classes of licenses required for bulk milk graders, pasteurizer operators, producers of milk, processors of milk licensing of persons employed in processing
- procedural and analytical methods for inspection, testing and grading of milk and cream
- seizure of adulterated and non-compliant products
- establishment and application of monetary penalties for infractions
- mandatory pasteurization of all milk sold
- primary processing of milk and cream
- operation of facilities engaged in the further processing of milk
- methods for manufacturing and pasteurizing
- blending of milk fat with any other fat or oil
- composition of dairy products
- standard package sizes and dimensions for dairy products
- grades and standards of milk, cream and dairy products
- labelling of dairy products
- imitation milk products (prohibitions and exemptions)
- establishment and collection of fees (levies) to be used for promotion of dairy products
- standards for milk and cream, including permissible levels of specified micro-organisms
- sampling and testing procedures
- grading of cream and milk
- construction, layout and operation of dairy processing facilities
- construction and operation of pasteurization equipment within dairy processing facilities

### **Imitation and Substitute Dairy Products**

When one examines all provincial regulations as we have done in this project, it is clear that provincial legislation and regulations have been shaped to some extent by objectives to protect the market share enjoyed by traditional dairy products. This is reflected in legislation and regulations in the majority of provinces dealing with “imitation” and “substitute” dairy products. These provisions are typically prohibitions with specified exemptions for products such as margarine, butter-margarine blends, coffee whiteners and dessert toppings.

In one province (Nova Scotia, please refer to Appendix I), processors require a license to manufacture such products and the regulations list the brand names of imitation dairy products that are permitted for manufacture and sale. As another example, in Prince Edward Island (please refer to Appendix G), the Dairy Industry Act requires a quantitative declaration on the product label of the percentage of each kind of oil or fat present in the product. The implication is that a product falling in these categories that is completely compliant with federal food labelling requirements could not be legally sold in the provincial market. This is, to our knowledge, unique among all categories of pre-packaged foods and beverages intended for retail sale.

## **Incorporation by Reference - Selected Examples in Provincial Regulation**

Rather than replicate all provisions of other standards and regulations that the drafters of provincial statutes and regulations found to be of value, some have incorporated these standards by reference (Please refer to discussion on incorporation by reference in Section II above). For example, the Dairy Industry Regulation in Alberta has referenced the 3-A Standards for hygiene published by the International Association of Milk, Food and Environmental Sanitarians “as amended or replaced from time to time”. This is a noteworthy incorporation by reference also found in other provincial regulations (British Columbia) since the standard was developed by organizations that are not, to the best of our knowledge, formally accredited as standards-writing organizations in Canada.

In addition, use of the language “as replaced or amended from time to time” means that any changes whatsoever to the 3-A Standard must be implemented in Canadian provinces that have referenced the standard in regulation, even if the changes are not acceptable to the Canadian dairy industry. This is an example where regulatory authority is sub-delegated to an organization that is entirely outside of, and at arm’s length from, the provincial and federal governments of Canada. There are examples in the Canadian food and beverage sector where such sub-delegation has resulted in unforeseen changes in regulatory requirements that have been prohibitively costly and/or impossible to comply with, notwithstanding use of modern manufacturing technology, facilities and good manufacturing practices.

Some, but not all provincial regulations, incorporate by reference, provisions of the federal Food and Drugs Act and Regulations. However, where this has been done, it is typically only a portion of the Food Regulations that are intended for reference, such as permitting use of food additives that are listed in the Food Regulations (Division 16 - Food Additives) specifically for use in dairy products. Notwithstanding the presence of compositional standards within the federal Food and Drug Regulations and Dairy Product Regulations (pursuant to the Canada Agricultural Products Act), most provincial regulations also include compositional standards and product definitions that do not necessarily align with the federal standards and definitions.

In particular, while the existing federal regulations have no compositional standards for yoghurt, Manitoba, Québec, New Brunswick and Nova Scotia each have standards for yoghurt in their respective provincial regulations. These provincial standards are not harmonized with each other or in all cases with the model standard found in the National Dairy Regulation and Code. Similarly, there are standards for eggnog (Manitoba, Appendix M), “calorie-reduced butter” (Québec, Appendix K) and some cheese varieties (Swiss cheese - New Brunswick, Appendix J) found in provincial regulations that are either not found in or are different from existing federal regulations.

We would observe that in the absence of a single set of compositional standards at the federal

regulatory level, it is not currently possible for provincial regulations to incorporate compositional standards by reference to reflect all that are being sold in these markets. There is clearly a need for a single set of federal compositional standards that lends itself to incorporation by reference in the interest of modernizing, harmonizing and abbreviating provincial regulations affecting dairy processing and products. This issue has been addressed in the drafting of the National Dairy Regulation and Code and in the development of Draft 9 of the proposed revised Dairy Product Regulations.

### **Delegation and Sub-delegation of Regulatory Powers**

The delegation and sub-delegation (further delegation) of regulatory powers adds to the complexity and the administrative burden of provincial regulations affecting the dairy industry in Canada, including dairy processors.

In the federal regulatory environment, the power to make new regulations or amend existing regulations is typically vested through legislation with the Minister (elected member of government chosen by the Prime Minister to serve in Cabinet) responsible for the regulatory department or agency. For example, the federal Minister of Health is the Minister responsible for the administration of the Food and Drugs Act and Regulations. The Minister's regulatory authority to apply and interpret the Food and Drug Regulations is sub-delegated to officers (non-elected public servants) of Health Canada

Compliance and enforcement responsibility for foods has been transferred through statutory authority (legislation) to the Canadian Food Inspection Agency. CFIA is accountable to the government of Canada through its President and the Minister of Agriculture and Agri-Food.

The power to amend the Food and Drug Regulations is part of the responsibilities of a number of Ministers who are members of the Special Committee of Council that must approve all regulatory amendments. The regulatory amendment process is clearly prescribed and in part in the public domain (Canada Gazette publication and consultation stage following Cabinet approval). In summary, at the federal government level, Ministerial regulatory authority is extensively sub-delegated to non-elected public servants and diffused among members of Cabinet (Ministers). Except in rare instances, regulatory powers are not sub-delegated to organizations outside of federal departments and agencies.

Some noteworthy examples of sub-delegation are included in the provincial regulatory summaries found in appendices G through P. In most cases some regulatory powers are delegated to commissions and supply management agencies. In Newfoundland and Labrador, regulatory powers under the Milk Scheme and the Natural Products Marketing Act have been delegated to the Dairy Farmers of Newfoundland and Labrador. The implication is that dairy products and dairy processing establishments are regulated by dairy producers. This does not exist in any other provincial jurisdiction for any food and beverage product outside of the dairy industry.

## **Agreement on Internal Trade**

The federal/provincial/territorial Agreement on Internal Trade (1994) was intended to facilitate interprovincial trade within a single national market, in part by removing regulatory provisions that present barriers to such trade. In drafting and executing the agreement, the federal and provincial governments acknowledged the importance of internal trade to a healthy and growing economy.

Specifically, Article 100: Objective of the AIT states:

*“It is the objective of the Parties to reduce and eliminate, to the extent possible, barriers to the free movement of persons, goods, services and investments within Canada and to establish an open, efficient and stable domestic market. All Parties recognize and agree that enhancing trade and mobility within Canada would contribute to the attainment of this goal.”*

This is reflected in provisions found in Chapter Four (General Rules) and Chapter Nine (Agriculture and Food Goods).

Article 401 sets out requirements for Reciprocal non-discrimination. Article 401.1 states:

*“Subject to Article 404, each Party shall accord to goods of any other Party, treatment no less favourable than the best treatment it accords to:*

- (a) its own like, directly competitive or substitutable goods;*
- (b) directly competitive or substitutable goods of any other Party or non-Party.*

Provisions of Chapter Four apply to Chapter Nine. In addition, Annex 903.1, Memorandum of Understanding on Procedures for the Elimination or Reduction of Interprovincial Barriers to Trade in Agricultural and Food Products, called for the identification and elimination of technical barriers to trade arising from differing product and grade standards.

*“As a beginning, with regard to technical barriers, and recognizing that the proliferation of different technical standards and norms can constitute significant impediments to trade, Ministers agree to work towards the adoption of common national standards within the next five years. National technical standards acceptable to provincial governments will be negotiated taking into account both domestic and international considerations. This would remove technical barriers to interprovincial trade in the agri-food industry.”*

Subsequent to the signing and pursuant to this MOU, the Federal-Provincial Agriculture Trade Policy Committee (FPATPC) identified four areas of technical barriers to be addressed. These are: horticultural products in bulk containers; margarine colouring restrictions and other margarine standards; standards regarding dairy blends and imitation dairy products; and fluid

milk standards and distribution. Responsibility for dealing with technical barriers with policy implications resides with the Federal-Provincial-Territorial Agri-Food Inspection Committee (FPTAFIC). FPTAFIC recommended (2001):

“that provincial and territorial legislation and regulations relating to dairy product analogs be repealed; that provinces defer to federal labelling regulatory processes with respect to all products that imitate or resemble dairy products; and that the priority issues of dairy terminology, consumer information, labelling and fraud be adequately addressed federally.”

The Council of the Federation created by provincial and territorial premiers in December of 2003, agreed in its Internal Trade Work Plan of 2004, agreed to recommit to honour all obligations under the AIT.

However, our examination of provincial dairy regulations indicates that the intent of the Agreement on Internal Trade has not been universally respected by provinces and reflected in amendments to provincial dairy statutes and regulation. There are numerous examples where existing dairy regulations present barriers to internal trade. The most obvious impediments are prohibitions against and/or permit requirements for interprovincial trade in unprocessed milk and cream and in some cases, processed milk and cream. Less obvious but very substantial if fully enforced are:

- restrictions on package sizes
- dairy product labelling requirements
- compositional standards, including those that exist at the provincial level for yoghurt
- regulations regarding dairy blends (milk fat with other edible oils) and imitation dairy products, including quantitative ingredient declaration

In recent years, there have been several challenges of provincial regulatory barriers to interprovincial trade, particularly in relation to dairy product analogues and dairy blends. In one case, a panel appointed to hear a dispute respecting Ontario regulation of dairy analogues and dairy blends brought jointly by the governments of Alberta, British Columbia, Manitoba and Saskatchewan, recommended that Ontario repeal the Edible Oil Products Act (enacted in 2005). The panel also drew attention of all AIT parties to their obligation of transparency contained in Articles 406 and 907.

In 2002, a panel examined a complaint by Co-operative Dairy Limited (Farmers' Dairy) regarding New Brunswick's fluid milk distribution licensing requirements. The panel found that the NB Natural Products Act and the manner in which it was administered by the New Brunswick Farm Products Commission, in denying a fluid milk distribution license to Farmers' Dairy were inconsistent with the AIT, impaired internal trade and were injurious to Farmers' Dairy.

In an earlier case, Nova Scotia challenged amendments to PEI regulation, citing inconsistencies with the AIT and resultant barriers to trade. The panel ruled that PEI's amendments to the Dairy Industry Act Regulations were inconsistent with the AIT.

Most recently, the government of Alberta, supported by governments of Manitoba and Saskatchewan, challenged the Québec regulatory prohibition concerning manufacture and sale of margarine that has the same colour as butter. It was widely reported in Canadian media in late June, 2005, that the panel found in favour of Alberta. However, a formal report of the panel was not yet released at time of writing of this report.

In our view, the Agreement on Internal Trade, being intact and having the full support of the federal, provincial and territorial governments, remains a significant opportunity for harmonization of regulation affecting dairy processing and products and the removal of barriers to interprovincial trade in dairy products.

### **Implications of Regulation for Dairy Processing Industry**

Based on our broad experience in regulatory matters throughout the Canadian food and beverage sector, we would expect any experienced manager entering the dairy processing sub-sector from another food industry sub-sector to have considerable difficulty in comprehending the totality of regulatory requirements affecting dairy products and processing. As noted in several sections of this report, there are provisions and principles affecting dairy products and processing that are unheard of in other Canadian food industry sub-sectors with the possible exception of the meat industry.

In examining the implications of existing federal and provincial regulations for dairy products and processing, we think it important to note the aspects of the business environment that are sought by all food and beverage processors as critical success factors for competitiveness and profitability. These are:

- Opportunity to locate processing facilities to competitive advantage anywhere in Canada
- Ability to mandate single plants to supply specified products to the entire Canadian and North American markets
- Predictable access to all markets across Canada through a single national requirement for product formulation and labelling
- Access to state-of-the-art technology
- Secure, ample and predictable supply of raw materials, including additives and ingredients used in other jurisdictions
- Ability to innovate and formulate new products to meet changing consumer demands and compete with substitutable products
- Ability to attract qualified employees in a mobile work force

As a consequence of existing regulations affecting dairy products and processing, all of these success factors are not available to dairy processors in all provinces, as they are to processors in other food industry sub-sectors.

As well intentioned as compositional standards for dairy products have been in the past and remain today in terms of product quality, integrity and identity (consumer recognition), they do not reflect the reality of competition at retail and foodservice levels from multi-ingredient unstandardized products. The formulation of competing products such as soy-based beverages and edible oil products is at the discretion of the manufacturer, so long as the products are compliant with the Food and Drugs Act and Regulations. Put in other terms, products that compete with dairy products, do not face comparable restrictions to innovation, formulations, labelling, distribution and marketing.

### **Regional Markets Versus a National Market - Plant Mandating and Infrastructure Use**

Given its population of approximately 31 million, Canada is often seen by investors (existing and potential) in agri-food processing as a small market relative to the United States, Japan and the EU. The U.S. market alone is approximately 9 times as large as that of Canada. Each of the states of New York, Florida and California has a market at least as large as Canada when measured in terms of population. As a consequence, U.S. based food processors and Canadian-based processors who are able to move products into U.S. markets are able to structure their businesses to accommodate larger combined demand.

The majority of shipments from Canadian dairy processing facilities are to nearby domestic (Canadian) markets. This is in part as a consequence of the substantial freight costs for movement of fluid milk products. However, it is also in part as a consequence of regulatory impediments to interprovincial trade that still reside within provincial regulations. These various regulatory barriers to internal trade have the effect of dividing Canada into many provincial markets for dairy products, rather than a national market of 31 million consumers. Such impediments preclude mandating individual dairy processing plants for larger interprovincial markets. In other food industry sub-sectors, product mandating is key to achieving economies of scale in manufacturing.

### **Product Development and Product Formulation for Product Attributes and Lower Costs**

Food and beverage manufacturers in other sub-sectors have considerable discretion in developing new products and in formulating these products to deliver product attributes such as flavour, texture, smell, colour, nutritional profile and cost of manufacturing. This facilitates quick response to market changes and to cost of ingredients, including for products that compete with standardized dairy products.

Modern dairy processing technology available around the world permits the fractionation (separation of components) into a range of food ingredients that have been collectively described

as “modified milk ingredients”. This term has, in fact, been adopted in Division 1 of the federal Food and Drug Regulations for food labelling purposes, recognizing that modified milk ingredients are used in the manufacture of a wide range of foods, including nutritious portable snacks, processed meats and prepared desserts. We note that Draft 9 of the proposed revised Dairy Product Regulations has incorporated this definition and includes the addition of modified milk ingredients in some compositional standards (eggnog, yoghurt, buttermilk, sour cream, cultured cream, cheese, fresh cheese, whey cheese, cream cheese and others). This would facilitate the use of domestically produced and imported modified milk ingredients for a number of purposes at the discretion of the manufacturer.

In comparison (please refer to Appendix D), the most recent (April 13, 2005) draft of the Dairy Product Regulations brought forward by the Dairy Farmers of Canada, if adopted and brought into force, would eliminate the definition of modified milk ingredients (as proposed in Draft 9) and not permit use of modified milk ingredients in any standardized product. This would deny dairy processors an opportunity to continue to compete more effectively in the marketplace through lower cost formulation and potentially enhanced product attributes.

In response to the proposal of the Dairy Farmers of Canada to eliminate the definition of “modified milk ingredients” and to prohibit the use of this product in standardized dairy products, the dairy processing industry has notified the Minister of Agriculture that such action would be very detrimental. In particular, the dairy processing industry has acquired the necessary expertise to develop its by-products through research, development and technological innovation. The processors also point out that technologies for the processing and concentration of Canadian dairy ingredients allow for an increase in cheese manufacturing capabilities. The processors have concluded that the regulatory proposals of the Dairy Farmers of Canada would send the dairy processing sector back half a century in terms of technological development and overall competitiveness.

### **Investment Climate Uncertainty**

The interpretation of regulation and the potential for unanticipated changes in regulation present uncertainties for all food and beverage processing industries who invest and operate in Canada. Business decisions pertaining to investment in processing capacity and new product development are usually made in the belief that the investors have a reasonably complete and correct understanding of current regulatory requirements.

As outlined in this report and as identified in the appendices, there are anomalies and conflicts within and among provincial and federal regulations affecting dairy processing and products. As a result, it is difficult to achieve a reasonably complete and correct understanding of the totality of regulatory provisions and requirements in the dairy processing sector as opposed to other sub-sectors of the food industry. This, coupled with the sub-delegation of regulatory powers, contributes to a climate of uncertainty for dairy processors.

In some provinces, producer controlled organizations hold licensing and inspection powers relating to processing facilities and authority over which producers ship to which processing facilities. These sub-delegations of Ministerial regulatory authority, coupled with prohibitions against importation of milk and cream, render processing facilities vulnerable to unforeseen interruptions in ingredient (unprocessed milk and cream) supply that cannot be addressed by actively competing with other processors (domestic and international) for such ingredients.

### **III Recommendations for Modernization and Rationalization of Existing Federal and Provincial Regulatory Framework**

The authors acknowledge that there have been various initiatives undertaken by dairy value chain participants and government agencies to modernize and align dairy statutes and regulations in Canada. As this report is being written, some initiatives are, in fact, ongoing under the auspices and with involvement of the Canadian Food Inspection Agency, Health Canada, provincial regulators, Dairy Farmers of Canada and the Dairy Processors Association of Canada.

Our analysis of all existing statutes and regulations (please refer to summary tables and comments in Appendices B through Q), coupled with our experience in dealing with regulation in other food and consumer product sub-sectors, leads us to a number of recommendations to DPAC/ATLC and other dairy sector stakeholders in industry and government.

There are several underlying objectives and strategies for these recommendations. The objectives are:

- remove conflicts and redundancies between and among various regulations and guidance documents at the federal level
- create a federal regulatory framework for dairy processing and dairy products that can be easily and consistently referenced by provincial and territorial governments in their respective dairy industry and other regulations pertaining to foods
- ensure that this federal regulatory framework preserves the compositional integrity and quality of standardized dairy products while facilitating development of non-standardized dairy-based products and the development and use of ingredients derived from processing and further processing of milk and cream
- remove conflicts and anomalies from provincial regulations so that the regulatory obligations of dairy processors are clear and predictable and so that the powers of regulators and their use are also clear and predictable
- remove barriers to interprovincial trade that reside within provincial dairy regulations, thereby creating a national market for dairy products in which to compete more effectively with non-dairy food and beverage products

The strategies for realizing these objectives are:

- capture the benefits of the sector's efforts to create the National Dairy Regulation and Codes by completing the Code as a best practices guidance document for production, storage, handling and transportation, testing and analytical methods, and processing

- clearly delineate regulatory provisions intended for primary production, storage and handling from those intended for processing and products
- execute joint and concurrent revisions to the federal Food and Drug Regulations and the Dairy Product Regulations
- encourage the adoption and incorporation by reference within provincial regulations, the National Dairy Regulation and Code, the federal Food and Drug Act and Regulations and the federal Dairy Product Regulations (as amended as outlined below)

**Our recommendations are outlined below.**

## **1. Proposed Amendments to the National Dairy Regulation and Code**

Having carefully considered all the work that has been invested in creating the National Dairy Regulation and Code, we recommend that the Code be edited and modified so as to complete it as the definitive reference for best practices in the dairy industry. This would entail:

- **Removal of the word “Regulations” from the title of the “*National Dairy Regulation and Codes*” as this is a non-regulatory document. Thus the title becomes the “*National Dairy Code*”.**
- **removal of all compositional standards from the Code**
- **retaining and editing of existing text to create one chapter or division for each of primary production and on-farm storage, farm-to-processor handling and transportation, good manufacturing practices for processing,**

These steps would result in the National Dairy Code becoming a comprehensive guidance document for best practices within the entire dairy value chain that will contribute to the outcomes of consistently high levels of quality and safety of dairy foods.

## **2. Proposed Amendments to the Food and Drug Regulations**

The existing Food and Drug Regulations are frequently amended for various reasons, including the positive listing of food additives permitted for use in Canada. The existing Food and Drugs Act and Regulations contain many provisions that support current and long term interests of the dairy value chain. In fact, Part I, Sections 4 to 7 contain the basic provisions that are intended to ensure food safety, good sanitation in food manufacturing and distribution, adherence to food standards and truthfulness in labelling and advertising. Moreover, the Act is criminal law, empowering federal regulators to conduct compliance and enforcement down to the local (municipal) level in matters relating to health and safety, labelling and advertising.

In addition, Part B, Division 16, tables IV through XV of the Food and Drug Regulations identify food additives permitted for use in Canada, the purposes for which they may be used and conditions for their use (limits and good manufacturing practices). Part D of the Food and Drug Regulations also contain tables which specify products to which vitamins, minerals and amino acids may be added. In the case of fluid milk products, the addition of Vitamin A and Vitamin D is mandatory.

However, the compositional standards for dairy products contained within Part B, Division 8 of the Food and Drug Regulations do not include all those found in Draft 9 of the *Dairy Product Regulations*. The standards found in Draft 9 of the *Dairy Product Regulations* are the result of several years of consultation and are thus more current and complete than those found in the *Food and Drug Regulations*.

We therefore recommend that:

- **the identity and compositional standards found in Division 8 of the *Food and Drug Regulations* be harmonized with the standards contained in Draft 9 of the *Dairy Product Regulations*. This would require the addition to Division 8 of the Draft 9 standards for the following products: cultured butter, whipped butter, (naming the added ingredient) butter, whipped whey butter, (naming the added ingredient) whey butter, butter oil, anhydrous butter oil, buttermilk powder, whey powder, acid-type whey powder, blended skim milk and whey powder, edible casein, edible caseinate, eggnog, yoghurt, (naming the flavour) yoghurt, yoghurt drink and cultured cream.**

### **3. Proposed Amendments to the Federal (CAP Act) Dairy Product Regulations**

Having carefully reviewed and compared the existing Dairy Product Regulations with “Draft 9” and the most recent draft tabled for discussion by Dairy Farmers of Canada, we find Draft 9 to be complete and largely suitable for referencing within provincial regulations. Draft 9 appears to have reflected many of the key attributes of the National Dairy Regulation and Codes that were developed through what we understand to have been extensive industry/government dialogue with involvement of all parties in the value chain. Specifically we propose that:

- **harmonize the provisions of the existing National Dairy Regulation and Codes dealing with microbial count limits, testing and analytical methods with those of “Draft 9”**
- **incorporate by reference, the best practices for dairy processing as found in the relevant chapter of the National Dairy Regulation and Code**
- **include the definition of “milk product” found in section B.08.001.1 of the Food and Drug Regulations.** Although Draft 9 includes a definition for “dairy product” that could be interpreted to include B.08.001.1, clarity of the text would be improved with this addition.

Implied in these recommended amendments to the Dairy Product Regulations is the recognition that as is the case today, in the future there will be many non-standardized food and beverage products that contain ingredients and food additives derived from milk and cream. Given the large number of standards that are already in existence and would remain within the federal dairy product regulations, we would question the need for additional or more detailed standards.

The complete set of dairy standards found in the *Food and Drug Regulations* would include the “health and safety” provisions, namely permitted food additives and permitted or mandatory nutrient substances (vitamins and minerals). By having a complete set of standards in the *Food and Drug Regulations*, the user of these regulations would not have to carry out a cross-referencing to determine the totality of applicable provisions. Because Health Canada retains jurisdiction for health and safety requirements of food products, the compositional or identity standard, complete with “health and safety” provisions would be a “best fit” in the *Food and Drug Regulations*. The standards would be repeated as currently drafted in Draft 9 of the *Dairy Product Regulations* with referencing of “permitted food additives”, “permitted vitamins” and possibly other health and safety provisions.

#### **4. Addition of Vitamins and Minerals to Foods**

In our view as regulatory consultants, Health Canada's proposed policy on discretionary (voluntary) fortification of foods with vitamins and minerals is generally too restrictive. That is to say that consumers may benefit from the opportunity to choose to achieve a target dietary intake of vitamins and minerals through consumption of foods that suit their taste (palate and organoleptic properties), physiologies and lifestyle. Current restrictions on addition of vitamins and minerals to foods are such that consumers with special dietary needs and objectives have the options of managing their intake through consumption of natural health products (as defined in the Natural Health Product Regulations that came into force January 1, 2004) or Foods for Special Dietary Use as defined in Part B, Division 24 of the Food and Drug Regulations.

In our view, exclusion of many staple foods, including standardized fluid milk products from discretionary fortification will deny manufacturers of dairy products the opportunity to respond to future consumer demand for fortified foods. We are therefore recommending that:

- **discretionary fortification of standardized dairy products (packaged for retail sale) be permitted subject to appropriate provisions for treating these as non-standardized foods with labelling.**

## **5. Consequential Amendments to Provincial Acts and Regulations to Achieve Alignment of Federal and Provincial Regulatory Frameworks Affecting Dairy Processing and Products**

Provincial statutes and regulations affecting the dairy value chain are of widely varying vintages (date last amended) and varying stages of review and revision. Some provincial regulations have been amended as recently as April of 2005 (Ontario) and 2004 (Nova Scotia, Alberta). Others have been in place without significant amendment since 1990 or before. However, none of the provincial regulations would escape some degree of amendment as a consequence of the provincial governments re-aligning with the proposed changes to federal regulations recommended above. To be completely aligned with changes at the federal level we have proposed above and to achieve a single national marketplace from a regulatory perspective, provincial departments and agencies would have to:

- **delete prescriptive text (specific clauses and sections) dealing with location, design, construction and operation of dairy production, storage and handling and processing facilities, to be replaced through incorporation by reference of the relevant chapters of the revised National Dairy Code**
- **adopt common definitions for “milk product” and “dairy product”, being the definitions that would be included in the revised federal Dairy Product Regulations**
- **delete all compositional standards for dairy products to be replaced through incorporation by reference of the compositional standards included in Division 8 of the Food and Drug Regulations (amended as noted above)**
- **delete prescriptive text and tables all provisions dealing with inspection, testing, analytical methods, standards and tolerances for microbial content unless such text aligns with the content of the revised National Dairy Code and the content is deemed necessary for compliance and enforcement activity falling under the purview of the provincial agency or office to whom compliance and enforcement responsibility have been delegated**

In addition, to be completely aligned with the intent of the *Agreement on Internal Trade*, provincial statutes and regulation would need to be amended to:

- **harmonize measures dealing with the manufacture, importation and sale of edible oil products through a recommitment to the measures stipulated in the Agreement on Internal Trade (Chapter Nine – Agricultural and Food Goods), particularly with reference to the adoption of recommendations concerning imitation dairy blends and butter blends (Annex 902.5, Work Programs, Section 8)**