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REGULATORY ROADMAP FOR HEALTH PRODUCTS AND FOOD

ROADMAP

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ROADMAP

PREFACE

Evolving our regulatory tools and environment is a key priority for health products and food to ensure we have the regulatory system needed to best protect the health and safety of Canadians. The objective of the *Regulatory Roadmap for Health Products and Food* (Roadmap) is to provide a vision of the transformation from where we are, to where we are going, and how we are going to get there. The Roadmap builds upon earlier initiatives such as Blueprint for Renewal and the Progressive Licensing Project. It provides overarching concepts, the details of which will be developed and shared as the work progresses, resulting in a series of regulatory proposals for consideration by the Governor in Council (represented by the Treasury Board Ministers).

Throughout the process of transformation, a key commitment within the Roadmap strategy is to work openly, transparently and meaningfully with Canadians, stakeholders and international partners in the development, improvement and implementation of the plan for modernization.

INTRODUCTION

The *Regulatory Roadmap for Health Products and Food* is a strategy to produce a sustainable regulatory future that meets the objectives of protecting the Canadian public from the sale and advertising of unsafe food and health products, and supporting the safest consumption of food and use of health products.

The Roadmap provides the vision to transform nearly a dozen current frameworks for food and health products that are of various ages and regulatory approaches into an efficient, transparent, and aligned regulatory system that contributes directly to the safety of Canadians and the benefits they gain from food and health products. As a strategy, it will also be cognizant of the previous work accomplished by the Department, which recognized that there is a progression in the knowledge about a health product or food over its full life-cycle. This increase in knowledge reduces the uncertainty associated with the benefits and harms of a product and can lead to improved health outcomes for Canadians. As a consequence, it is logical to regulate in a manner that reflects the full life-cycle.

The Roadmap also recognizes, just as the strategies of other international regulators have increasingly recognized, that international partnering has to occur to regulate food and health products in a sustainable way, given the international nature of the food and health product industries and their increasingly complicated supply chains. No one domestic regulator can maintain safety oversight alone. The Roadmap lays out what Canada can gain in a shared global approach, and what it can contribute. In addition the Roadmap will align with current Government of Canada initiatives to find ways to reduce and prevent regulatory barriers - Regulatory Cooperation Council (RCC) and the Red Tape Reduction Commission (RTRC). Further promoting Health Canada's cooperation internationally will continue to be a priority, and a factor in developing the regulatory agenda going forward.

The Roadmap also acknowledges that Canadians, now more than ever, want transparency – meaningful transparency. Key to promoting meaningful transparency (beyond just access to information online) is taking leadership, being honest, taking action to engage stakeholders and the public, showcasing sources, and providing good (not only new or pre-packaged) information. The ability of the regulator to gain and disseminate information will be complemented by the obligations placed on regulated parties.

With this vision and guiding principles, the Roadmap lays out the way to move from the old frameworks to the new regulatory system. This will require the sequencing of a number of amending initiatives, some staged in the near future and others implemented in the longer term. While aiming for the eventual comprehensive amendment of all regulatory frameworks for food and health products under the *Food and Drugs Act*, early emphasis will be placed upon amendments that will deliver:

- the clearest value to Canadians and the health care and food safety systems; and
- the greatest efficiency by cutting through unsustainable administrative requirements or approaches and replacing them with ones drawing upon international partnering, best practices and new technological advantages to contribute directly to the safety of food and health products.

Building upon these early initiatives, the resetting of the frameworks will be accomplished through a series of more comprehensive amendments over the next years.

The benefit of making the transformation from the old frameworks to a modernized, efficient regulatory system is for all Canadians to have:

- safe foods and beneficial health products;
- clear, accurate and understandable information about food and health products; and
- rapid regulatory response when problems occur.

The benefit to those in the food and health products industries is to have:

- operational sustainability;
- international alignment; and
- the enabling of innovation and excellence in science to improve health outcomes.

The Roadmap is structured into three parts:

Where we are: provides an understanding of the existing regulatory frameworks (for food and health products, including pharmaceuticals, natural health products, biologics, veterinary drugs, medical devices) that are to be transformed.

Where we are going: provides the objectives and an outline of the new regulatory system for implementation.

How we will get there: guides discussion on the planning and sequencing of amendments over the next years, both short and long term, to best achieve modernization.

PART I – WHERE WE ARE

The current frameworks for the federal regulation of food and health products have been brought into force under the *Food and Drugs Act* (Act) at various times over the course of more than fifty years. The oldest frameworks are located in the *Food and Drug Regulations*, which are by far the largest set of regulations under the Act. The regulations are summarized with further detail in Appendix A.

The *Food and Drug Regulations* are divided into Parts that govern foods and some of the major health products: prescription and non-prescription pharmaceuticals, biologic drugs, radiopharmaceuticals, and drugs for veterinary use.

The newer frameworks have been written as stand-alone codes and provide governance for specific product lines:

Medical Devices Regulations

Natural Health Products Regulations

Safety of Cells, Tissues and Organs for Human Transplantation Regulations

Processing and Distribution of Semen for Assisted Conception Regulations

(Proposed Blood Regulations are under development)

Only a few elements of this large and varied cluster of frameworks under the *Food and Drugs Act* apply to all products comprehensively. **Part A** of the *Food and Drug Regulations* is the main example, containing provisions relevant to the conduct of inspections under the Act and very general labelling and packaging provisions that cover all products.

Part B of the *Food and Drug Regulations* is comprised of 28 Divisions that cover various aspects of regulating food products. The primary mode of regulation throughout these Divisions is the direct prohibition of activities that could render a food unsafe, such as selling substances for use as an additive, or selling food that has an inappropriate level of additives, fortifying agents, contaminants or drug residues. In this model, the sale of substances or foods is typically permitted only within values or limits set out in provisions, tables and schedules within the regulations, which must be maintained through regulatory amendment as new scientific developments require or new products or uses of them become ready for the market. Mixed in with these food safety rules are provisions that serve a fundamentally different purpose: to set out standards for foods as a measure of trade and to prevent consumer deception.

Precise specifications are set out to define products such as specific stews, cheeses and beverages, which must be followed if the food is to be sold as such. Additionally, a few requirements have a distinct public health purpose in the prevention of disease states, for example, the addition of Vitamin D to milk (to prevent Rickets) or iodine to salt (for the prevention of thyroid problems). There are few exceptions to the generally prescriptive model used in Part B for food safety and food standards. One example is a scheme created for novel foods that requires a manufacturer to provide scientific information and receive a notification prior to selling on the market.

Part C contains 9 Divisions that cover various aspects of regulating drugs. These Divisions contain a mixture of provisions that directly prohibit activities that can render drugs unsafe, and licensing requirements in which pre-market applications are required to be made and a licence issued before a drug can be sold for investigational reasons in a clinical trial or in the more general market. Licensing is required not only for the sale or advertising of drug products, but also for establishments in which drugs are manufactured and distributed. The general organization of the Divisions under Part C is to regulate disparate products such as prescription and non-prescription pharmaceuticals, biologics, and drugs for veterinary use together under the same provisions. The two major frameworks for the premarket review of drugs are presently organized around whether a drug is new or not, rather than by product type. Divisions 3 and 4 are an exception to this, containing unique provisions for radiopharmaceuticals and biologic products. Many of the provisions for biologics, especially for vaccines, are prescriptive in the same manner as the older food standards and have become in some cases scientifically dated.

In general, the provisions of Part C are designed for the pre-market regulation of drugs, with few requirements and powers in the post-market stage of the life-cycle.

Part D contains 4 Divisions that cover vitamins, mineral nutrients and amino acids in foods and minerals in drugs. The provisions in these Divisions are similar in kind to the prohibition structure within Part B so that sale is only permitted within levels and under conditions specified in the regulations.

Part E contains only one Division and covers cyclamate and saccharine sweeteners in food and drugs.

Parts G and J cover controlled and restricted drugs, which are now governed under the *Controlled Drugs and Substances Act* rather than the *Food and Drugs Act*.

The **Medical Devices Regulations** are a comprehensive framework. They are designed for the most part to provide for a pre-market licensing scheme for medical devices. Licensing is required to sell and advertise medical devices and for establishments that import or distribute them, so that quality management systems are in place. As a more modern framework, these regulations allow for the classification of medical devices based upon risk, so that devices of the least risk (bandages) do not need to seek a licence prior to entering the market, while those of the highest risk (pacemakers) must file the considerable scientific evidence needed to demonstrate that the device meets the safety and effectiveness requirements. Four categories of medical devices are identified through classification rules. Regulatory oversight is adjusted according to the level of risk.

The **Natural Health Products Regulations** also provide a comprehensive framework that primarily sets out a pre-market licensing scheme for natural health products. The definition of “natural health product” includes a variety of products, ranging from vitamin supplements in capsule form to products that are delivered in food format such as teas. They also include traditional products such as herbal products and Traditional Chinese and Aryurvedic medicine. Pre-market applications are required to be filed and a licence issued before any natural health product can be sold. Licences for establishments that manufacture, import, or distribute natural health products are required and are based upon the attestation by the company that good manufacturing practices are being followed.

The **Safety of Cells, Tissues and Organs for Human Transplantation Regulations** provide for a scheme that addresses the risk of disease transmission through specified cells, tissues and organs used in transplantation. The primary oversight is to require the registration of transplantation establishments and the observance of safety-related requirements such as keeping adequate documentation, conducting donor suitability assessments, and properly testing and labelling products.

The **Processing and Distribution of Semen for Assisted Conception Regulations** provide a scheme that is designed to address the risk of disease transmission through semen used in assisted conception. The scheme requires notification by those who process or import semen and the observance of safety-related requirements for screening, labelling, record keeping and tracing.

PART II – WHERE WE ARE GOING

GOALS:

A modernized system of the federal regulation of food and health products that maintains the protections against the sale and advertising of unsafe food and health products.

A science-based regulatory system in which the benefits, harms and uncertainties associated with foods and health products are made meaningfully transparent to the Canadian public.

A regulatory system that is efficient, sustainable and responsive to the evolution in science, patient and consumer behaviour as well as practices in healthcare.

DESIGNING TO MEET THE GOALS:

To meet these goals in a sustainable and transparent way, the following objectives have been identified through considerable stakeholder engagement to shape the future regulatory system:

Keep it consumer- and patient-centred:

- Align the product life-cycle approach with the health care system and food safety system in Canada to achieve positive health outcomes for Canadians.

Keep it focused on the best evidence:

- Ensure that the new regulatory structure:
 - » manages benefits, harms and uncertainties by considering the nature, intended use and exposure of the product;
 - » maintains appropriate regulatory oversight;
 - » promotes meaningful transparency;
 - » enables Health Canada to implement best international regulatory practices by learning from and collaborating with our counterparts; and
 - » better integrates with the activities of our domestic partners
- Encourage and make best use of evolutions in science
- Ensure the sustainability of the regulatory framework while adopting sufficient flexibility and foresight to accommodate future challenges

KEY THEMES:

To explore and expand further, the following key themes will help guide the regulatory agenda – meaningful transparency, international collaboration, sustainability and benefits/harms/uncertainties.

Transparency

The era of the internet, with such ready access to information from a multitude of sources, has provided the public with the capability to search for and find information that they feel is important to the management of their health and well-being. In this day and age the regulator needs to provide current, accurate and unbiased information to enhance and build its role as a trusted source of information. The current regulatory system pre-dated the internet and the information revolution, and was not designed to manage an open and transparent interchange of information. As a result, most of the existing provisions were designed to support printed material traditionally seen on a product label. Canadians also want to better understand the decision-making process undertaken by the regulator. Health Canada must provide greater and more meaningful transparency by enabling easier access to information, as well as providing information in a format that is easy to understand and provides value to the end user – whether the Canadian public, patient or health care provider, domestic or international partner, or regulated party. New abilities available to the regulator supported by new obligations placed on the regulated parties will enable more meaningful and more open information exchange under the new regulatory system.

International Collaboration

Canadian regulators and scientists are highly respected worldwide and have contributed greatly towards the goal of greater international collaboration. Participation with international partners, through intergovernmental exchanges or through forums such as the World Health Organization (WHO) and the Joint FAO/WHO Expert Committee on Food Additives (JECFA), the International Conference on Harmonization (ICH) and the Global Harmonization Task Force (GHTF) to name a few, has resulted in the creation and adoption of standards and processes, such as the use of the Common Technical Document (CTD and eCTD). This important collaborative work brings efficiencies to the regulatory system, while enhancing the high level of oversight for the foods and health products that Canadians consume and use. The use of Mutual Recognition Agreements (MRAs) and Memoranda of Understanding (MOUs) have already resulted in the

sharing of the global regulatory workload. Implementation of the Roadmap will build upon these successes, converging in an even greater level of cooperation. Regulatory amendments will be designed to allow for greater information sharing, common registries, common application filings, joint reviews and other work sharing arrangements, where appropriate and when it is in the best interests of Canadians. Many of these concepts are already used or being piloted, and the circumstances to promote even greater global collaboration are ideal.

Sustainability

Canadian regulators, in common with international partners, have access to a finite pool of resources in order to accomplish their duties. All regulators face the challenge of managing their resources in a way that sustains an appropriate level of oversight for existing products, yet is responsive to advances in science and changes in the marketplace. At a certain point, the traditional means of regulating becomes an inevitable restraint to this challenge. Reform of the regulatory system, while moving towards greater global cooperation, will provide a means for the regulator to regain and maintain sustainability and flexibility.

Benefit, Harms and Uncertainty

The regulation of food and health products is based on the principle that the product's benefit must exceed any potential harm, with a reasonable degree of certainty. *Benefit* may be loosely defined as any intended useful, positive effect obtained, whereas *harm* is any unintended effect that may cause injury or diminish human health in any way. *Benefit* and *harm* are not absolute, and regulators recognize that uncertainties exist with respect to both the benefit and harm that may result from being exposed to a food or health product. Tolerance for harm and uncertainty is inextricably linked with the benefit that a product may provide.

Clearly, no harm should be expected from foods that Canadians consume and the regulatory system for food is designed with this premise in mind. However, there are foods that may cause harm to certain populations, for example through allergic reactions. Among other things, food additives as well as false health claims for foods also have the potential to lead to harms. The potential for harm in these instances can be controlled through diligent scientific assessment, mitigations by setting consumption limits, developing standards and labelling requirements, or when necessary prohibiting the sale or use of certain substances, or the making of certain claims.

At the other end of the scale are those drugs that are well known to have toxic and harmful side effects but for which the benefit is so great, that these effects would not preclude their use. Many of the oncology drugs that have been responsible for saving and extending the lives of cancer patients fall into this category.

Sufficient evidence should in all cases be available to the regulator to allow a determination with reasonable certainty to be made based on sound scientific principles. Health Canada has and will continue to make assessments, form decisions and develop regulations based on this principle.

FOUNDED ON THE BEST SCIENCE:

Health Canada will continue to be a science-based regulator, and the regulations need to support this work. The proposed outcome of the Roadmap is to have an integrated regulatory system with discrete regulatory frameworks for food, consumer health products, natural health products, health products that are delivered through informed intermediaries (health professionals), medical devices, and health products for veterinary use.

Within this system, each framework can be understood as a complementary approach to manage the various types and levels of benefits, harms and uncertainties associated with food and health products. As such, the new system will place greater emphasis upon regulating across all product lines in a manner that pays attention to the nature of the product, its intended use, and how the consumer or patient is exposed to the product rather than placing all the focus on regulating by the type of product alone. The level of oversight, dictated by the type and amount of evidence, is rationalized not by whether the product is a manufactured food or a medical device, but rather by the level of benefit and harm the product could offer the consumer and how the chance of serious harm can be reduced or eliminated. This approach will replace the older regulatory frameworks that, because of their varied ages and designs, do not have a coordinated, proportional approach to benefit, harm and uncertainty management.

As we move forward, there is an opportunity to consider the type and amount of evidence not only within similar product lines but between different frameworks. The classification rules used to define evidentiary standards in the *Medical Devices Regulations* serve as a good example.

A modernized regulatory system will also be designed to better accommodate those products that are unique by their nature or use, such as sanitizers, disinfectants and medical gases.

The level of oversight determined by the type and amount of evidence allows for consideration of how that oversight is conducted, whether under direct control of the regulator or through the activities of a certified third party or standard setting organization.

Nature	Intended use	Exposure
fundamental characteristics of a health product or food - could include things such as composition, dosage form, size, caloric value, material of construction, design, etc.	how the product is intended to be used to achieve the desired effect - as a food, to cure treat or mitigate disease, to correct bodily function, etc.	how and to what degree a health product or food is presented to an individual or population - acute, chronic, dosage, quantity, topically, orally, etc.

While more than an integrated regulatory framework will be needed, the new system will make the most of aligning what is common between product lines and focus upon differences where necessary to meet regulatory objectives.

Commonalities:

The production of food and health products has diversified on a global scale. However, inversely, food and health products are more commonly sold together in one place. Canadian consumers are now more often able to enter a single commercial premise to buy prepared foods, consumer products such as medicated shampoos, natural health products such as vitamin supplements, medical devices such as toothbrushes, and even prescription drugs where the store includes a pharmacy. While various levels of harm can be associated with consuming any of these products, at least three regulatory expectations apply commonly:

- the product has not been rendered harmful through the way it is manufactured, imported or distributed;
- the safety-related information on the label (such as allergen information for a food or dosing and side effect information for a drug) is understandable, complete, and not misleading; and
- if something is going wrong with the product and it poses a harm, the regulator is able to intervene effectively.

These expectations apply evenly no matter the type of product. The various frameworks of the new system will therefore contain common strategies to effectively regulate in light of these expectations, to replace the highly varied requirements and levels of protection within the current frameworks.

Manufacturing, importing, and distributing: Given the global trends in manufacturing, importing and distributing for both foods and all types of health products, this is an aspect of regulating that will draw upon greater international cooperation. Each of the frameworks within the new Canadian system will include provisions to require a risk-based approach to quality standards and systems for manufacturing, importing and distributing for foods and health products. These quality standards and systems for manufacturing and distributing, while not exactly the same for each type of product line, are being more and more aligned internationally. The benefit of this alignment is that regulators can, given the commonality of requirements, collaborate on activities such as inspections and eliminate wasteful duplications of effort.

All those who manufacture, import and distribute foods and health products will be required to follow the appropriate quality standards and systems to minimize the chance of harm. However, a well-founded and logical approach can be taken in ensuring that these companies comply. These approaches would range from auditing only where a concern has arisen, to being required to obtain a licence prior to conducting manufacturing or distributing for products of significant benefit or harm.

Labelling and other information: Information is critical to deal with potential harms. From a regulatory point of view, while different kinds of information may be appropriate for various product types, common approaches can be taken to ensure that the benefit and safety related information on the label is understandable, complete, and not misleading. Increasing reliance upon consumer input on the quality of labelled information can apply in all frameworks. Provisions to enhance the collection of information and require label changes (e.g. where the information is unclear or incomplete) that affects the safe consumption of products is commonly envisaged across frameworks.

Effective detection of problems: The ability of the regulator to gather information and inspect facilities in order to ensure compliance and to detect problems early is critical to a quick and effective response. Regulators should have the ability to conduct reassessments under certain circumstances in order to prevent harms before they occur. This is especially important for those types of harms that may be difficult to detect in the marketplace, such as the long term effect of a food additive or drug excipient, but may be predictable through advances in science.

Effective responses to problems: Regulatory abilities to intervene when a serious harm is occurring can include the ability to require additional information about a product, issue a stop sale with respect to a product or class of products, and reassessment of the risk classification of a product to ensure that harms are appropriately dealt with. Provisions to support these abilities will be introduced in each framework.

Differences:

Foods: A new framework for foods established in its own set of regulations would introduce significant revision to the existing Part B to streamline and render more efficient and transparent the regulation of such things as food additives, contaminants, and the fortification of foods. Given the mixed provisions between safety oversight and the standardization of foods, consideration will be given to untangling the two in the standard food provisions. This would go some way to ensuring a focus upon safety-related provisions.

Any changes to the regulations must also consider and be supportive of the science and the ability of the food regulator to conduct a pre-market scientific evaluation. As an example, the safety of food additives must be well established prior to their use in food as there is no established valid scientific means, similar to adverse drug reaction reporting, to elicit safety signals once the food additive is in marketed food. Changes to the allowable levels of food additives in a certain food must be considered in the context of consumption data and new scientific information that may have been generated since the initial approval.

Health products sold through intermediaries: These products, which are largely prescription drugs or drugs used by professionals in hospitals, are generally subject to the highest levels of regulatory appraisal from a life-cycle point of view. They typically offer benefit for serious diseases or conditions and more serious levels of harm. The proposed new framework will maintain stringent evidence requirements based upon clinical trials. Additionally, recognizing that greater uncertainties may exist with such products given the complexities of the diseases they treat and the treatment environment itself, greater abilities to plan for and resolve those uncertainties will be introduced for post-market regulation without compromising existing pre-market requirements. A modernized framework for these products would build upon this work and consultations accomplished through the Progressive Licensing Project. The Project proposed that a well-designed regulatory framework should support the collection, analysis, and communication of knowledge and experience about a drug throughout its life-cycle so that it can be used wisely. Reliance on this life-cycle approach will benefit areas where uncertainties are most high, and where there is a need for post-market abilities and setting on-market obligations for new drugs. For example, the proposed new framework will include provisions for drugs for rare diseases to ensure appropriate oversight and needed international collaboration.

Medical Devices: The current framework for medical devices is respectively newer and already reflects an evidence-based approach to regulating. An analysis of the present categorization of medical devices will be undertaken and adjusted to better reflect the management of benefit, harm and uncertainty. Similar to the other frameworks, post-market abilities will also be supplemented, along with other smaller policy changes required for international alignment. More robust linkages will be made to other frameworks to reduce regulatory redundancies when dealing with combination products.

Consumer health products: It is proposed that non-prescription drugs be separated from the framework for prescription drugs. For all consumer health products, the benefit must outweigh the harm which reflects the level of oversight, and in the new framework, the type and amount of evidence will depend upon the nature of the product, its intended use and exposure. It is recognized that a greater variety in the types of evidence will exist for these products, as they range from well-established and understood products to new chemical entities. Therefore a range of regulatory models for oversight needs to be considered, including pre-market evaluation; attestation by the applicant; administrative issuance of a licence; and limited pre-market oversight with manufacturing requirements and complaint-based auditing. For these products and for all product lines, information about the benefits, harms and uncertainties would be posted transparently. As with all frameworks, a robust post-market surveillance system tailored to the levels of uncertainties will be established, and that can provide information which may result in regulatory action, including the reclassification of a product.

Natural Health Products (NHPs): The current *Natural Health Products Regulations* (NHPRs) represent a modern, well-organized structure to house regulatory requirements. The present categorization of NHPs, and evidentiary and licensing requirements could be adjusted to better manage benefits, harms and uncertainties. Consideration must be given to the range of NHPs and unique traditional and cultural approaches to their use. Again, post-market abilities could also be included, and linkages made to other frameworks to assist in classification issues. Standards of evidence could be aligned to the extent possible with the consumer health product framework, when the intended use and exposure are similar.

Health Products for Veterinary Use: A new separate regulatory framework will be proposed for veterinary drugs and primarily aimed at ensuring the safety of the food supply. This framework will be based on the premise that the degree of control exercised over various products should be proportional to the level of harm they present. For example, pre-identified/well-established products would be registered upon the manufacturer providing some basic information, while other products used on food-producing animals would require more evidence and be subject to more stringent controls.

OPERATIONAL GAINS AND EFFICIENCIES:

The success of regulatory reform is incumbent on ensuring timely operational requirements are established, such as adequate human resources, improved IT infrastructure, training programs, guidance and standard operating procedures. Concurrent planning is necessary to gain substantial efficiencies in the implementation phase and sustainability over the longer term. Greater transparency will not only provide Canadians with a greater understanding of the products they use and how they are regulated, but will reduce the need to gain that information through the burdensome process of Access to Information (ATI) requests. A critical success factor to modernizing the regulatory system is the early assessment and development of an implementation plan, which is discussed further in Part III of the Roadmap.

PART III – HOW WE WILL GET THERE:

The modernization of the regulatory system for food and health products will require staged, and coordinated amending initiatives; the details of which will be developed and shared as the work progresses, resulting in a series of regulatory proposals for consideration by the Governor in Council (represented by the Treasury Board Ministers).

The long term goal is to sufficiently amend the existing regulatory frameworks to fully modernize them and implement the science-based life-cycle model.

Early emphasis will be placed upon amendments that will deliver:

- the clearest value to Canadians and the national health care and food safety systems; and,
- the greatest efficiency by cutting through unsustainable administrative requirements or approaches and replacing them with ones drawing upon international best practices and new technological advantages to contribute directly to the safety of food and health products.

PLANNING AND EXECUTION - PHASED APPROACH:

Regulatory reform as a large and comprehensive change to the health products and food regulatory systems, its component regulations and supporting operational structure cannot be accomplished all at once. A well-planned approach separated into several phases is necessary to achieve the objectives and minimize the impact to current operations while making best use of the finite resources available to develop the requisite policy, draft the regulations and plan for implementation. Consideration must also be given to the transition required by all stakeholders, as well as any impact on the Department's ability to cost recover. The initial phase will include those regulatory packages which are well developed and support regulatory reform. Throughout the phases, particular attention will be paid to transparency, sustainability and efficiency, as well as laying in additional post-market obligations and abilities to fully support the life-cycle approach. Full and complete implementation of all phases is expected to be completed within a minimum of 5 years.

Details on timelines for proposals will be communicated on an annual basis, starting in spring 2012, as we set the priorities for the Department and will be aligned with the Government's agenda for Regulatory Reform.