

[Discussion Paper]

Notice of Multi-Year Regulatory Modernization and Plan for Consultation

Introduction:

In the fall of 2011, the Canadian Food Inspection Agency (CFIA) began a systematic review of its regulatory frameworks for food safety, plant health and animal health. Over the coming months, the CFIA plans to engage with Canadians, industry stakeholders and other government departments, including federal partners, through a series of discussions and electronic consultations to discuss its regulatory modernization strategy.

The CFIA recognizes the importance of supporting Canadians' access to safe, reliable and wholesome agricultural products, while at the same time creating and maintaining a regulatory environment that supports competitiveness and innovation in the Canadian agricultural sector. With its broad mandate for food safety, animal health and plant health, the CFIA recognizes the need for and the importance of setting priorities for the review of the 13 federal statutes and 38 sets of related regulations for which it is responsible. A list of relevant statutes and regulations can be found in the annex. Through its initial consultations, the CFIA plans to develop short, medium and long term plans for regulatory reviews.

This document is intended to provide a basis for discussion between the CFIA and Canadians, including the industry it regulates. Through this discussion, the CFIA will develop an agenda for regulatory modernization that is strategic, balanced and achievable and meets the needs of stakeholders.

Objective:

Through a structured and comprehensive review, the CFIA will strengthen its regulatory frameworks to reduce overlap and redundancy, address gaps, weaknesses and inconsistencies while providing clarity and flexibility to assist regulated parties in fulfilling their obligations. Canadians and regulated parties will continue to be supported by an effective, efficient and accountable regulatory system that is both science and risk based.

Modernized regulatory frameworks will improve consistency and reduce complexity in regulation, and will enhance the ability of the CFIA and regulated parties to contribute to the safety of the food supply, and the protection of the animal and plant resource bases.

Effective regulation contributes to the health and safety of Canadians, the protection of the animal and plant resource bases and the environment and to a well functioning economy. This regulatory reform initiative offers an opportunity to better align regulatory frameworks with the strategic objectives of the Agency and the government's

priorities related to economic prosperity and border security, reduce unnecessary burden on stakeholders, reflect changes in science and technology, support innovation, and ensure that Canadians and the resources they rely on are protected.

Our Operating Environment:

Since the CFIA was created in 1997, the environment in which it operates has evolved and become increasingly complex. Global supply chains have fundamentally changed the way agricultural products are produced, processed, packaged, distributed and sold, which presents new challenges in food safety and the protection of plant and animal health. Governments need to keep pace by providing a modern suite of tools, including legislative and regulatory frameworks and other instruments, to respond to existing and emerging challenges/threats and opportunities and to enable industry to adapt to the new environment, while ensuring appropriate regulatory safeguards are in place.

Consumer demands are changing as consumers seek more choices and information on food safety, labelling of food and agricultural products, production methods, animal and plant resource base sustainability, the humane treatment of animals as well as the safety, quality and effectiveness of agricultural inputs.

Globalization and industry restructuring have resulted in increased production and trade of new and innovative products. In the past two decades, global trade in agriculture and agri-food products has increased significantly. This growth has been driven by population and income growth in emerging economies and by consumer demands for more and cheaper food choices.

Canadian farms and food processors are consolidating to remain competitive in this environment. The food processing industry has become increasingly sophisticated—resulting in significant increases in production speed, volume and diversity. Larger companies are dominating the food landscape and have greater capacity to monitor and manage risk. Small and medium-sized businesses continue to develop niche markets. Both seek opportunities for innovative products. Similar trends are also being observed in the agricultural input industry, with continued consolidation of fertilizer, pesticide and seed companies.

Industry consolidation and large-scale food production coupled with changes in science and technology present additional challenges. The emergence of new pathogens, the re-emergence of familiar pathogens and development of more rapid and sensitive laboratory testing methods have become our reality. Risks are no longer confined within our borders, and the Agency must face the challenge and focus its resources where the risk is greatest and where there is the greatest net benefit to Canadians.

Need for Regulatory Reform:

The volume and complexity of the CFIA's legislative and regulatory base contribute to the challenge of keeping it up to date and relevant. The CFIA derives its mandate from authorities and enforcement powers spread across 13 acts (5 of which are food safety-related) and 38 sets of regulations.

Most regulatory changes undertaken by the CFIA have addressed specific issues and as such have been one-offs. Because of this and despite common objectives, CFIA-administered regulations have generally evolved along separate pathways which have resulted in distinct commodity-specific provisions. Substantial changes are needed to consolidate and align where appropriate, and to develop regulations that are responsive to current and future threats and opportunities. This will require the CFIA to systematically review all the regulations that it administers to ensure that the necessary level of protection for Canadians is maintained and to enable industry to adapt as its practices evolve.

Throughout regulatory modernization, food safety and protection of the animal and plant resource bases will remain paramount.

The agriculture and agri-food sectors are highly competitive domestically and internationally and a growing number of countries are seeking to participate in global trade. Regulatory frameworks must therefore be considerate of the needs of industry to remain competitive in this environment through innovation and adaptation. Current regulatory frameworks tend to be prescriptive and are often reactive and inflexible. Through regulatory review, we propose to elaborate a regulatory system that **fosters consumer choice and enables improved business opportunities by building flexible regulatory frameworks that are anticipatory and proactive in mitigating risks, facilitate innovation and support competitiveness**, while maintaining the Agency's primary focus on safeguarding the food supply and the animal and plant resource bases.

Updated authorities are also required to address new business practices, such as the use of electronic commerce and new industry technologies such as plant molecular farming and new methods of production. These changes require consideration of new risk profiles for all commodities to identify where preventative measures are required to protect consumers and maintain the integrity of the regulatory system.

Many of Canada's trading partners have updated the regulatory frameworks and tools they rely on to deliver inspection services in a more flexible, risk-based and innovative manner. For example, in early 2011, the US launched a review of all of its regulations with a view to avoiding excessive, redundant and inconsistent regulation. Canada needs to adopt a similar approach within its legislative and regulatory framework to ensure that it provides the power and flexibility to respond appropriately to existing and emerging risks.

Internationally, there is also an evolution to outcomes-based approaches to regulation that include specification of expected performance and results rather than prescriptive standards. The United States, Australia, New Zealand and the European Union have begun to move in this direction.

Regulatory renewal would be consistent with Canada's World Trade Organization obligations and would be science-based, be applied only to the extent necessary to protect human, animal and plant health, and not be unnecessarily trade-restrictive.

Around the world, **the importance of regulatory frameworks being participatory and transparent**, to be responsive to issues and challenges and the needs of regulated parties, by being inclusive in the development of regulations, has never been greater. By being open and inclusive in the design and development of regulations, we want regulated parties to have a clear understanding of rules and their relevance. Through a more collaborative process, the contribution of industry in shaping regulations in a way that facilitates their application will lead to greater effectiveness of the regulatory system.

Appropriate approaches to prevent and to respond to risks will be developed in consultation with stakeholders, considering many factors. The nature of the risk and the public benefit from any regulation designed to address the risk must be clear and must be weighed against the cost of compliance to ensure an appropriate balance. Regulation also requires flexibility to permit all regulated parties, regardless of size, to achieve compliance. As such, the capacity of small businesses will be considered in the review of the frameworks. **The appropriateness of a regulatory framework in response to risk should be evident and, as such, regulations need to be clear in meeting their intended policy objective and commensurate with the risks they are intended to mitigate. In addition, finding an appropriate balance between the costs of implementation and compliance and the benefits of regulatory intervention is an integral part of the regulatory development.**

Industry movement toward consolidation and vertical integration means that the Canadian agricultural landscape has changed, with many businesses operating multiple establishments in different commodities across the country. **It is therefore reasonable for these industries to be able to apply a common and consistent strategy and risk management principles regardless of commodity. Similar risks warrant similar oversight and response.** As we review regulations, we must be cognizant of the risks associated with different commodities and seek to apply common approaches that are effective in addressing risks, and enable consumer and stakeholder understanding of the approach and rationale. For example, the control of *Listeria monocytogenes* (Lm) in a smoked fish product should not differ from the Lm control for processed meat products, which fall under a different regulatory framework.

As the government moves to streamline and simplify regulations, the responsibilities of all participants in the regulatory system in achieving the specified outcomes will be clarified. Traditionally, governments have used prescriptive regulation to hold industry

accountable by outlining obligations, providing oversight and enforcing compliance. Such regulation has tended to be reactive. Through regulatory modernization, the opportunity exists to redesign regulations so they focus on prevention, provide for appropriate intervention to address identified risks, and are flexible and measurable. **Shifting to outcome-based and transparent regulations** aims to establish clear expectations regarding risk management outcomes to be achieved. Such regulations will **provide flexibility for the regulated industry to demonstrate how it is achieving the desired outcome**. Development of regulation should provide an opportunity for regulated parties to build a greater understanding as to why regulation is needed, the expected outcomes, and their rights with respect to interaction with the regulator.

However, a shift to outcome-based regulation may present challenges for those enterprises that lack the capacity to develop systems and process controls that would easily permit their transition from prescriptive to outcome-based regulation. Some parties may prefer prescriptive direction. As such, it will be important to strike a balance that continues to support regulated parties and where appropriate to provide additional guidance on the achievement of outcomes such as through provision of model control requirements in complement to an outcome-based regulatory framework.

Where possible, the CFIA will also shift to implementing systems-based approaches to provide oversight of industry procedures, so that resources are focussed on verifying compliance based on overall risk. The CFIA will look to build upon principles such as hazard analysis of critical control points (HACCP), which is currently mandatory in federally-registered meat and fish processing facilities. Agriculture and agri-food safety issues will continue to be met with a prompt, risk-based response to protect the health and safety of Canadians. Regulatory renewal will provide an enabling framework to support the development of modern and consistent inspection approaches that apply to all commodities.

Having regulations with outcomes that are measurable and provide for the appropriate level of government oversight will support the maintenance of confidence in the regulatory system. Being able to demonstrate that there are effective controls in the system helps to sustain market access for all regulated industries.

In the review of the regulatory frameworks, the CFIA will, whenever possible, **seek to align with international standards and the frameworks of major trading partners and provinces**, while providing the foundation for determining equivalence or comparability but also recognizing conditions that require a made-in-Canada approach.

Guiding Principles

Regulatory modernization at CFIA will therefore be guided by the overarching principles reflected above, and will set the stage for a more coherent and consistent approach for the next generation of regulatory frameworks:

- Balance protection of public safety while maintaining confidence in the food inspection framework;

- Enabling an environment of improved business opportunity, and consumer choice by facilitating innovation and competitiveness;
- Clear policy objectives established in consultation with partners – including industry, consumers, small business, other departments and provinces;
- Appropriate balance between administrative cost and benefits derived from regulatory intervention;
- Consistent, integrated, outcomes-based, transparent regulation with performance measurement to maintain effectiveness;
- Enabling framework for modern and consistent inspection approaches; and,
- To the extent possible, harmonization with international standards and the frameworks of major trading partners and provinces.

Considerations:

Regulatory review is consistent with the recommendation of the Organization for Economic Cooperation and Development, that member countries take effective measures to ensure the quality and transparency of government regulations. While the CFIA embarks on a systematic review of its regulatory frameworks, there are other Government of Canada initiatives being considered at this time that may impact CFIA regulatory requirements and help shape our path forward. These include the Food and Consumer Safety Action Plan, Red Tape Reduction, the Border Security Initiative and the Regulatory Co-operation Council with the United States.

The Cabinet Directive on Streamlining Regulation applies to all departments and agencies involved in the federal regulatory process. Government officials are responsible for abiding by the Directive at all stages of the regulatory lifecycle: development, implementation, evaluation, and review. While reviewing its regulations, the CFIA will strive to develop a performance-based regulatory system designed to achieve public policy objectives in health, safety and security, respecting the environment and the social and economic well being of Canadians.

As the CFIA moves through its regulatory review, its approach to service standards and user fees associated with regulations will be examined. CFIA user fees have changed very little since 1997 and work has begun to bring fees into alignment with operational costs of delivering services. The process used to determine individual fees was finalized in the Fall 2010, and can be found at:
<http://www.inspection.gc.ca/english/agen/manges/polrec/polrece.shtml>.

Where there are private benefits, the CFIA can improve its accountability to regulated parties by ensuring that fees are aligned with the costs of providing the service, linked to service standards and applied consistently across sectors.

Criteria:

Recognizing that not all of our regulations can be reviewed at once, the CFIA has established criteria to help guide the path forward. In anticipation of the launch of its review of regulatory frameworks, an internal review was undertaken to examine the regulations for which it is responsible, and a proposed plan forward was established. The following criteria have been considered to assist in establishing priorities and appropriate timing for a systematic review, which will take place over the short (1 to 3 year), medium (3 to 5 year) and long (5 to 10 year) terms:

Are there risks from outdated requirements?

Are there opportunities that can be realized through a review?

Would a review support other government priorities?

Has the regulated industry indicated readiness for changes to the framework?

When was the framework last reviewed?

Providing easily understood descriptions of regulatory intentions, the desired outcomes, the guiding principles and the processes to be used in achieving these outcomes would allow stakeholders to focus on how they can apply innovation to improving regulatory performances in ways that support business competitiveness, environmental performance, and corporate social responsibility.

Moving Forward:

The CFIA will work with its federal partners to promote consistency and coherence in regulatory modernization initiatives and where appropriate, to coordinate stakeholder engagement to minimize duplication and overlap.

Based on our assessment of the elements above, regulatory renewal initiatives for each of the CFIA's business lines (Food, Animal and Plant) are being proposed in the short, medium and long term as follows.

Short term:

- Meat Inspection Renewal
- Feed Regulatory Renewal
- Agriculture Inputs Renewal (Fertilizers and Seeds*)
- Food Regulations following Legislation adjustments¹
- Animal Traceability Regulations

¹ In the Speech from the Throne (March 3, 2010) the Government signalled its intention to reintroduce legislation to protect Canadian families from unsafe food. Such legislative change would necessitate the review of all food safety regulations concurrently and would alter this proposed schedule.

* Seeds anticipates a number of individual regulatory amendments, with a full review of the framework anticipated in the longer term.

Medium term:

- Plant Breeders' Rights Renewal
- Agrifood Regulatory Renewal (see footnote)
- Plant Protection Regulatory Renewal

Long term:

- Fish Inspection Regulations Renewal (see footnote)
- Health of Animals Regulations Renewal
- Seed Regulatory Renewal

While this proposed consultation will include a discussion of the above priorities, the CFIA has been engaged with some industry sectors regarding the need for modernization. As a result of these discussions, the CFIA has already initiated work on Feed and Fertilizer regulatory review. This early work will be informed by the continued development of the comprehensive regulatory review plan and the feedback from stakeholder views in response to this paper.

Next Steps:

Over the coming months, the CFIA will engage with stakeholders through various fora, including value chain round tables, to validate its path forward on reviewing regulatory frameworks. Stakeholders will also be encouraged to undertake analysis to identify areas for change in anticipation of the frameworks which fall in the medium and long term time frames for review. Umbrella groups and industry associations can begin to engage on issues of interest and reflect on opportunities that can be explored through regulatory review.

Over the winter months, the CFIA will:

- Engage a broad range of stakeholders to discuss CFIA's goals and objectives for regulatory modernization;
- Further clarify and validate the short, medium and long term priorities for the framework reviews; and,
- Publish results of consultations.

Once the priorities have been validated, broader engagement and consultation will be undertaken on each of the specific areas of priority for regulatory review. As the intention is to shift to broad based reviews of frameworks, it is important to recognize that there is, and will remain, opportunity to make necessary individual regulatory changes outside of the proposed time frames for regulatory modernization. For example, as the Government moves forward with implementing results from initiatives such as the Red Tape Reduction Commission and the Canada/U.S. Perimeter Security and Economic Competitiveness initiative, some targeted regulatory changes may be required. Where feasible, these changes will be aligned with the overall framework

reviews. A list of the Beyond the Border and Regulatory Co-operation Council initiatives that are being led by the CFIA are contained in Annex 2.

Involving you early:

The CFIA wishes to encourage stakeholders to actively participate in this regulatory review process. We welcome feedback on the priorities the Agency has proposed

- Consider the key questions we have used in our scan of the regulatory frameworks. Are there additional questions that should influence prioritization?
- Are the proposed guiding principles relevant and appropriate to you as a stakeholder?
- Are you satisfied with the priorities?
- How can the industry and government work together to approach the issues?
- What would be the most effective way to continue to engage you in regulatory review?
- How would you characterize the level of consensus in your industry regarding the nature of issues and gaps in the relevant regulatory framework and the type of changes necessary to achieve a modern framework?

Please provide your perspective in the context of these questions on the priorities proposed and explain any changes you might suggest to the priorities using the questions to guide your rationale.

Please provide your input to: CFIAPROGRAMS-ACIAPROGRAMMES@inspection.gc.ca by February 21, 2012 or in writing to:

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Thank you.

Annex 1

Act and Regulations

The Canadian Food Inspection Agency is responsible for the administration and enforcement of the following Acts:

Agriculture and Agri-Food Administrative Monetary Penalties Act

- Agriculture and Agri-Food Administrative Monetary Penalties Regulations

Appropriation Acts

- Rabies Indemnification Regulations

Canada Agricultural Products Act

- Dairy Products Regulations
- Egg Regulations
- Fresh Fruit and Vegetable Regulations
- Honey Regulations
- Licensing and Arbitration Regulations
- Livestock and Poultry Carcass Grading Regulations
- Organic Products Regulations
- Maple Products Regulations
- Processed Egg Regulations
- Processed Products Regulations

Canadian Food Inspection Agency Act

Consumer Packaging and Labelling Act (as it relates to food)

- Consumer Packaging and Labelling Regulations

Feeds Act

- Feeds Regulations, 1983

Fertilizers Act

- Fertilizers Regulations

Fish Inspection Act

- Fish Inspection Regulations

Food and Drugs Act (as it relates to food)

- Food and Drug Regulations

Health of Animals Act

- Compensation for Certain Birds Destroyed in British Columbia (Avian Influenza) Regulations
- Compensation for Destroyed Animals
- Export Inspection & Certification Exemption Regulations
- Hatchery Regulations
- Hatchery Exclusion Regulations
- Health of Animals Regulations
- Honeybee Prohibition Regulations, 2004
- Reportable Diseases Regulations

Meat Inspection Act

- Meat Inspection Regulations, 1990

Plant Breeders' Rights Act

- Plant Breeders' Rights Regulations

Plant Protection Act

- Eggplants and Tomatoes Production (Central Saanich) Restriction Regulations
- Golden Nematode Order
- Golden Nematode Compensation Regulations
- Introduced Forest Pest Compensation Regulations
- Phytophthora Ramorum Compensation Regulations
- Plant Protection Regulations
- Plum Pox Virus Compensation Regulations, 2004
- Potato Production and Sale (Central Saanich) Restriction Regulations
- Potato Wart Compensation Regulations, 2003

Seeds Act

- Seeds Regulations
- Weed Seeds Order, 2005

Annex 2

Joint Action Plan initiatives under the Beyond the Border (BTB) and the Regulatory Co-operation Council (RCC) (where the CFIA is leading the initiative)

BTB Initiatives:

- Better protect Canada and the United States from offshore food-safety, animal and plant health risks by conducting joint assessments and audits for plant, animal, and food-safety systems in third countries.

RCC Initiatives:

- Develop common approaches to food safety, in light of food safety modernization efforts in both countries, to jointly enhance the safety of the Canada-U.S. food supply and minimize the need for routine food safety surveillance inspection activities in each other's country (applies to products within the mandates of both the Canadian Food Inspection Agency and the U.S. Food and drug Administration).
- Enhance equivalence agreements for meat safety systems to streamline, simplify, and, where possible, reduce import and administrative procedures, while maintaining public health outcomes.
- Establish mutual reliance on jointly acceptable food safety laboratory recognition criteria, test results and methodologies to ensure that food safety laboratory testing conducted in one country is acceptable to regulators in both countries and facilitate cross-utilization of laboratory results by industry and regulators (applies to products within the mandates of both the Canadian Food Inspection Agency and the U.S. Food and drug Administration).
- Streamline the certification requirements for meat and poultry, including, where possible, the reduction or elimination of redundant certification, data elements and administrative procedures for shipments flowing between Canada and the U.S.

- Develop a perimeter approach to plant protection with a view to leverage each country's efforts to mutual advantage and, where possible, streamline certification requirements for cross-border shipments.
- Work towards a common approach to zoning of foreign animal diseases.
- Create a common meat cut nomenclature system and regulatory alignment tool to jointly maintain the system.

For additional information on initiatives, please follow this link:

http://www.borderactionplan-plandactionfrontalier.gc.ca/psec-scep/bap_report-paf_rapport-dec2011.aspx?view=d

http://www.borderactionplan-plandactionfrontalier.gc.ca/psec-scep/rcc_report-ccr_rapport-dec2011.aspx?view=d