

Enhancing Risk Analysis:

*A more systematic and consistent
approach*



Introduction

The CFIA's mandate is to administer and enforce legislation designed to safeguard food, protect the health of animals and plants, contribute to consumer protection, and contribute to market access for Canada's food, plants and animals. The CFIA designs and delivers programs around food safety, and plant and animal health, and conducts oversight activities to determine whether regulated products and parties are compliant with regulatory requirements, as well as any relevant domestic and international standards and obligations. These activities range from verifying that regulated parties have systems in place to produce safe food and that plants and animals entering and leaving Canada are free from pests and disease, to ensuring that the information on food labels is accurate and not misleading to Canadian consumers.

The CFIA is currently pursuing a comprehensive transformation agenda that will change the way it delivers these mandated responsibilities.

The transformation agenda involves modernizing the CFIA's current approach to regulating activities around food, and plant and animal health, and includes making changes to the legislation it enforces – through the *Safe Food for Canadians Act* and the *Agricultural Growth Act* – the programs it delivers, and the way it inspects regulated parties. These changes are helping the Agency to foster continuous improvement as well as meet the growing challenges posed by a complex and evolving operating environment.

The ways in which food, animals and plants are produced and distributed have undergone fundamental changes in recent decades. This has been driven in part by advances in technology as well as increased global trade. Consumer demands and expectations are also changing, from a desire for access to fresh fruit and vegetables year-round as well as exotic fruits, plants and pets to more meaningful information about the safety and quality of the food they are consuming. To keep pace with the changes occurring, governments are adjusting as well – adopting flexible, more outcome-based approaches to regulations that focus on prevention and robust risk-management.

This discussion paper provides an overview of the CFIA's transformation agenda and the proposed systematic application of risk analysis to guide the CFIA's regulatory oversight activities. The paper is also designed to help establish a common understanding of terminology and principles that underpin CFIA's risk analysis activities, and provides an opportunity to solicit feedback from stakeholders.

What is Agency Transformation?

The CFIA's transformation agenda involves modernizing the Agency's approach to regulating activities around its mandated responsibilities. The changes are focused around the four pillars of the Safe Food for Canadians Action Plan: stronger safety rules; more effective inspections; enhancing transparency with consumers and regulated parties; and commitment to service. These four pillars are also reflected in the changes proposed in the *Agricultural Growth Bill* which was tabled in Parliament in December 2013 and has been moving through the legislative process since that time. The long-term result associated with the CFIA's transformation is envisioned as an outcome-based system that is more squarely focussed on prevention while at the same time leveraging inspection resources for maximum value.

The work involved in the transformation agenda includes a series of interrelated and complementary initiatives. The CFIA's legislative framework for food is being enhanced with the replacement of 13 regulations with a single set of food inspection regulations under the *Safe Food for Canadians Act*. These regulations will provide common requirements across all food commodities. The CFIA is also developing a set of complementary regulations regarding disclosure of information, administrative monetary penalties, appeals and redress to enhance transparency for all stakeholders, and introducing regulations for food safety and licensing requirements for importers. It is expected that the *Agricultural Growth Act* will modernize nine statutes that regulate Canada's agriculture sector. Some of the key improvements include stronger intellectual property rights for plant varieties, which will enhance farmers' access to new varieties, and making farmer payment programs simpler, faster and more flexible. In conjunction with legislative changes, the CFIA is also modernizing its systems for risk analysis, inspection and oversight activities.

How is CFIA changing its approach to oversight?

Increased international trade, global supply chains, and advances in science and technology have created new realities for regulated parties and the CFIA. As part of its transformation to adapt to changes in the operating environment, the CFIA is modernizing its approach to oversight that includes

Oversight: The collective activities that the CFIA undertakes as part of its regulatory responsibilities. These activities include product and facility inspections, auditing preventative control systems, surveillance, product sampling and testing, and other forms of supervision and verification to confirm that risks related to food, and plant and animal health are being effectively managed or eliminated.

Oversight activities take place in a variety of areas along the production chain. For example, before and after the product is at market, before and at place of import, and prior to export.

a range of activities such as front-line inspection, surveillance, systems auditing, and sampling and testing. With the development of the Integrated Agency Inspection Model (iAIM), the CFIA will be moving away from its current system that uses different approaches to oversight for each commodity. In its place, the CFIA will be implementing a single risk-based approach that will be applied consistently across all commodities.

While the CFIA has always incorporated risk into its approach to oversight, the modernized approach will provide regulated parties with increased predictability and consistency regarding how the CFIA will be conducting its oversight activities for their regulated activities. The CFIA will continue to verify compliance of regulated parties. However, the type, frequency, and intensity of the CFIA's oversight activities will be proportional to the risks that need to be managed.

The CFIA will provide a base-level of oversight for all regulated parties. The revised approach will allow the CFIA to identify those players who warrant additional oversight. The implementation of this approach will enable the CFIA and regulated parties to more readily adapt to emerging trends, and will also allow the CFIA to focus its resources on parties and commodities that present greater risk to human, plant and animal health.

Why use a risk-based approach for oversight?

The CFIA is building on its experiences to strengthen its current approach to oversight in order to promote compliance and use resources effectively to provide value for Canadians. Based on science and risk, and aligned with international standards, the strengthened approach provides a set of common activities and standard processes for oversight that help promote compliance among regulated parties by providing greater predictability and transparency. The revised approach is expected to benefit the CFIA, consumers and regulated parties alike.

In order to better allocate human, technical and financial resources in monitoring regulated parties in Canada, the CFIA is moving away from more traditional inspection approaches oriented around commodity-specific factors. Moving to a proactive, systematic risk-based approach for

Risk is defined as the expression of the likelihood of occurrence and consequence associated with the occurrence of an event. It is composed of the hazard (the harm that something can cause) combined with the rate and likelihood of exposure (the extent to which people are subjected to the hazard).

The CFIA assesses risks related to food safety, plant and animal health. Industry is responsible to have systems in place to manage the risks.

its oversight activities will see the CFIA apply its oversight capacity to areas of highest risk and allow it to more efficiently and effectively fulfill its mandate. This approach will offer a structured and transparent approach to allocating resources across all sectors so that CFIA's oversight activities are proportional to the risks being managed for all commodities regulated by the CFIA. A flexible inspection workforce and human resources regime will be key pieces in achieving full implementation of the modernized approach.

Consumers will benefit from this approach as well. The CFIA will be concentrating oversight efforts on the areas of highest risk to food safety, plant and animal health, resulting in greater confidence that the safety outcomes for food, plants and animals are being met. Also, the CFIA will be using Canadians tax dollars in the most effective way possible.

Changes in consumer demands are constantly evolving, and new technologies are rapidly becoming available. Businesses would like to be able to adapt accordingly. The use of a risk-based system also offers increased flexibility for businesses to make changes to their production methods, while continuing to keep food, plants and animals safe for Canadians. Using a standardized and consistent approach across all commodities will help facilitate the CFIA being less intrusive in some areas of lower risk. For these low risk areas this may mean that instead of being subject to facility inspections, the CFIA's oversight activities may shift to a systems audit or random product sampling, activities that are less intrusive to the industry but that will continue to protect the health and safety of Canadians.

Additionally, a systematic, transparent approach helps continue to instill confidence among trading partners in the CFIA's regulatory system and contributes to foreign market access. In moving forward with an enhanced risk-based approach, Canada is joining other leading countries that are using risk-informed systems, and sets a standard for the regulators in the international community looking to implement a similar approach in years to come.

Risk Analysis

International standard setting bodies such as the Codex Alimentarius Commission (Codex), the World Organization for Animal Health (OIE), and the International Plant Protection Convention (IPPC) describe risk analysis as a process consisting of three separate but integrated components: risk assessment (the determination of the degree of risk involved), risk management (establishing if and what measures are required to mitigate the risk) and risk communications (communicating with stakeholders throughout the process)¹. A graphical

¹ Codex Working Principles for Risk Analysis for Food Safety for Application by Governments; OIE – Terrestrial Animal Health Code, Chapter 2.1; and IPPC – ISPM 2 – International Standards for Phytosanitary Measures

representation of risk analysis, based on the guidelines of the above mentioned international bodies, is shown in Figure 1.

The CFIA has developed the "*Risk Analysis Framework to Address Animal Health, Plant Health and Food Safety Risks within the Canadian Food Inspection Agency.*" This framework is consistent with international guidance and supports the Government of Canada's request for government organizations to establish systematic and holistic approaches to manage risks as part of an *Integrated Risk Management Framework.*

Historically, risk analysis activities have been applied both formally and informally in the development of inspection systems across all disciplines within the CFIA. These systems were designed to meet CFIA's objectives – safe food, consumer protection, the protection of plants, and the health of animals in Canada. As noted earlier, the CFIA is now moving towards a more consistent and structured approach to overall risk analysis.



Figure 1. Risk Analysis Framework.

Risk Assessment

Building on past experience ...

Risk assessment is the process of identifying and characterizing hazards to determine the probability of an event and the severity of its impacts. The process involves taking into account information from various sources to determine the specific risks posed to the health of humans, plants and animals. Risk assessments provide a characterization of the risk, but do not provide any decisions on the acceptability of level of risk, or the activities or actions intended to mitigate the risks.

For plants and animals, the intent of the risk assessment is to examine the potential for the introduction or spread of pests or diseases into or from the Canadian environment. For example, the purpose of the pest risk assessment is to determine if a commodity (plants, soil, wood) could be carrying pests, diseases or weeds that could establish in Canada and cause losses affecting farmers or foresters, or cause environmental change. This assessment looks at factors such as the potential pest or disease, the volume and source of material that is potentially infected or infested, and the availability of susceptible hosts at ports of entry.

For the purposes of food safety, risk assessment involves the:

- Identification and characterization of the specific chemical and biological hazards inherent to the food commodity (including the potential presence of allergens);
- Evaluation of the nature of the adverse effects; and
- Assessment of the degree of exposure to the food commodity, and characterizing the attendant risk to the health of consumers.

Integrating these components provides an estimation of the likelihood that the adverse effects will occur in a given population.

There are two distinct – but related – areas where the food safety risks are assessed. The first being a health risk assessment conducted by Health Canada concerning identified hazards or risks in food, both proactively and in response to specific requests or situations². This involves determining if the presence of a certain substance or microorganism in food (e.g., chemical contaminant, natural toxin, allergen, unapproved food additive, microorganism etc.) poses a health risk to consumers. Health Canada conducts health risk assessments on its own initiative and at the request of other government departments and agencies, including the CFIA.

² For more information on health risk assessments please visit Health Canada's website at http://www.hc-sc.gc.ca/fn-an/securit/chem-chim/food_risk-risq_alim-eng.php

The second area where food safety risks are assessed is in the context of food establishments producing or preparing a certain food. This risk assessment takes into account the food safety risk assessment conducted by Health Canada as well as other factors related to the establishment itself which may impact the ultimate safety of the product, such as preventative control plans the industry has in place. It is industry's responsibility to produce safe food; the CFIA verifies that the industry has the appropriate systems in place to achieve this goal.

... to enhance future approaches.

As part of the modernized risk-based approach, the CFIA is developing a Risk Assessment (RA) model for food establishments that will provide a standard and consistent tool to inform the CFIA's decisions for oversight for licensed establishments initially. The development of this model is a multi-year initiative on which the CFIA has only recently embarked. The CFIA RA model has been developed for meat, poultry and dairy establishments as a starting point. However, the intent is to eventually expand its use across-the-board to other food license holders (e.g. Importers, Fresh Fruit and Vegetables, Fish), as well as to non-food license holders (i.e. plant and animal).

The CFIA RA model for food establishments takes into account several sources of information that can be grouped into three categories: initial risk factors, mitigation factors, and compliance factors, in order to evaluate the risk associated with the food-producing establishment.

- Initial risks – risks that are inherent to a specific food commodity, operation or manufacturing process. The volume and scope of production is considered in the initial risk as an indicator of potential for exposure. This part of the model will also look at the potential end use of the commodity, for example nursing homes or hospitals to evaluate potential impacts on a specific area of the population.
- Mitigation factors – measures or strategies that are applied by the regulated party in order to further reduce the risk posed by a specific hazard, and ultimately reduce the likelihood of the occurrence of a food safety issue. The implementation of robust preventative control plans will be evaluated here.
- Compliance factors – historical and real data collected by CFIA inspection staff on the establishment's performance at implementing its preventive control plan, its mitigation factors, and the establishment's compliance with regulatory requirements. This data may include using information from Establishment Track Records and Compliance History.

The CFIA RA model combines information collected from these three categories to provide an overall risk assessment result which will be used to inform the CFIA's oversight activities for each regulated establishment (Figure 2). The risk assessment should not provide any decisions

on the acceptability of the risk level or identify activities or actions to reduce the risk.

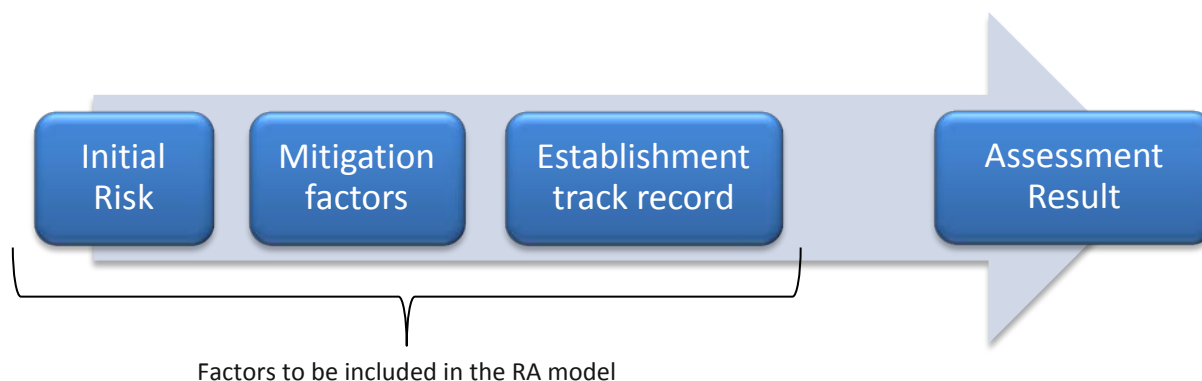


Figure 2: CFIA's Risk Assessment Model for food establishments

As a means to assess the effectiveness of the model, validation projects are being undertaken at establishments in the meat, poultry and dairy commodity sectors in selected locations in Quebec and Ontario. After the model testing phase a report will be generated to determine next steps. This report will identify any lessons learned during the validation phase so that they may be incorporated in the longer term approach and the model can be further refined. The validation projects being conducted will help the Agency demonstrate that the model is robust and will enable its broader application across commodity sectors.

Risk assessment is a scientific process which should not be influenced by social, economic or political considerations; these latter aspects of risk analysis are addressed through the risk management process, a critical element in the risk analysis continuum.

Risk Management

Risk management refers to coordinated activities put in place to minimize or reduce an identified, unacceptable level, of risk. In keeping with internationally accepted approaches, risk management is described as a distinct, but complimentary, step to risk assessment. Decisions taken to manage unacceptable levels of risk are based on the risk assessment and are proportionate to the risk. Risk-informed decisions take into account, where appropriate, other factors relevant for protection of human, animal and plant health and for the promotion of fair trade practices³. This includes the option of not taking any action.

Part of the CFIA's mandate is to develop programs that contribute to other activities around consumer protection and market access for Canada's food, animals and plants. Therefore, consideration is given to factors beyond risk assessment results when making decisions

³ Codex Working Principles for Risk Analysis for Food Safety for Application by Governments; OIE – Terrestrial Animal Health Code, Chapter 2.1; and IPPC – ISPM 2 – International Standards for Phytosanitary Measures

regarding risk management (some examples depicted in Figure 3). It should be noted that the factors shown in Figure 3 are not exhaustive but illustrate the factors that inform CFIA's decisions on oversight.

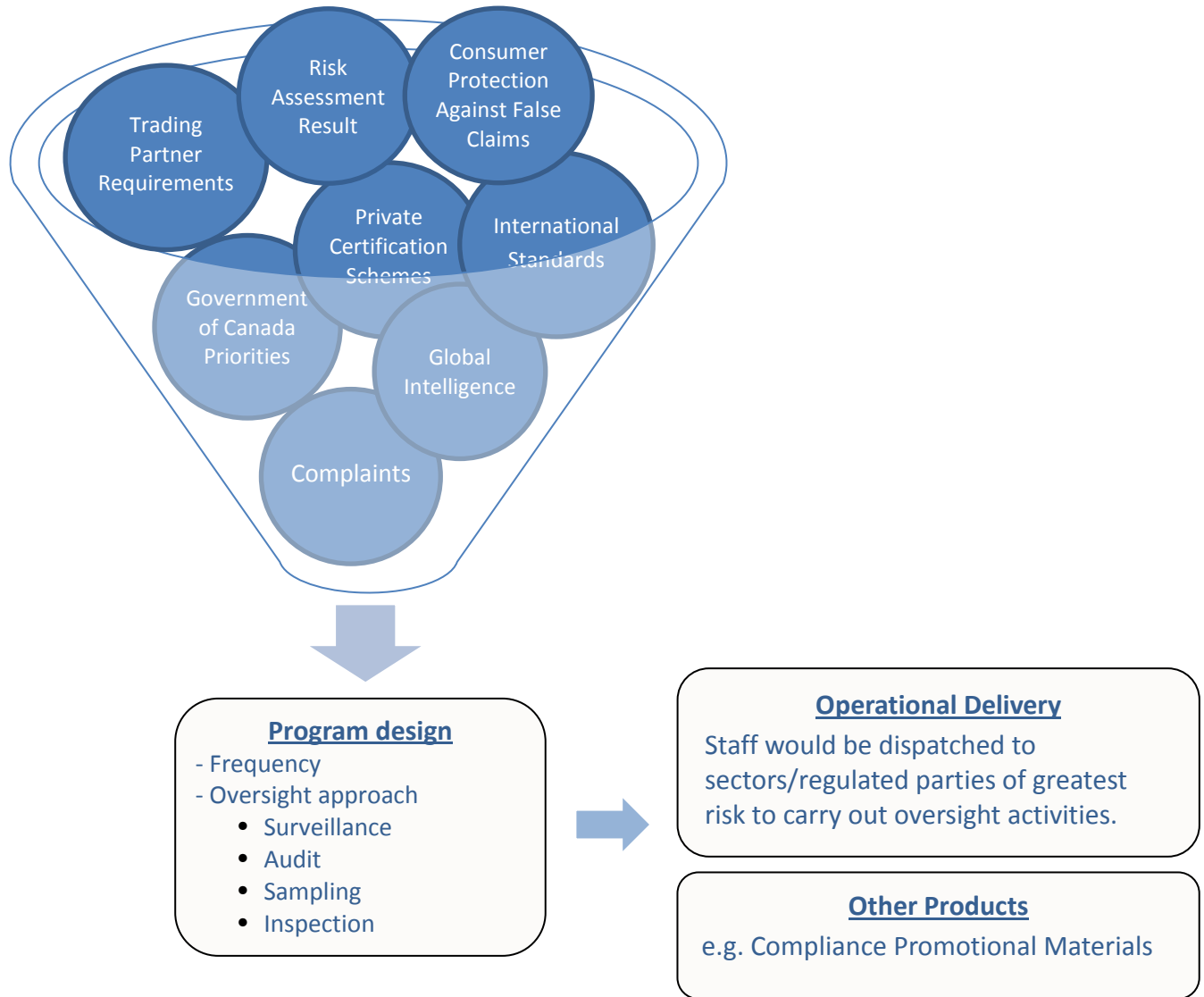


Figure 3. Examples of factors taken into account to inform the appropriate regulatory oversight.

Prior to determining the type, frequency, and intensity of the CFIA oversight activities, the CFIA considers not only the risk assessment conclusion, but other risk management considerations, such as:

- *Consumer protection against false claims*

Health Canada sets the guidelines for food labelling for health and safety purposes (e.g. nutritional labelling, allergen labelling etc.). The CFIA has responsibilities for verifying that regulated parties are compliant with requirements for labelling, including voluntary claims (e.g. Organic, Kosher, Product of Canada, etc.). Fraud, misleading claims, and other non-compliant activities related to labelling and consumer protection can have negative impacts for consumers. Therefore, considerations regarding these factors will be taken into account when the CFIA develops its oversight approach for an establishment choosing to use voluntary claims.

- *Requirements of trading partners*

The CFIA provides certification of foreign market requirements for regulated parties in Canada wishing to export their products to other countries. For example, some countries require the presence of a CFIA inspector in the food establishment on a daily basis. For plants to be exported the CFIA needs to issue a Phytosanitary Certificate indicating the shipment have been appropriately treated for plant pest. Animal exports require similar documentation. Requirements for exporting to another country will be taken into account when determining oversight for a regulated party that wishes to export to that market.

- *Complaints*

The CFIA collects and responds to complaints received from industry and consumers regarding regulated parties and products. This information may impact the CFIA's approach to oversight for implicated establishments.

- *Private certification schemes*

Some regulated parties may choose to use private certification schemes for certain activities including food safety (e.g. CanadaGAP⁴). The use of private certification schemes is one of the factors currently taken into account in the RA model however there are additional considerations that may be further examined in the risk management step. For example, certain private certification schemes may have requirements that meet or exceed the regulatory standards overseen by the CFIA. In cases where there is overlap, redundancies may be eliminated by tailoring CFIA oversight in consideration of the private

⁴ CanadaGAP is a food safety certification scheme operated by a not-for profit entity for companies that produce, pack, repack and store fresh fruits and vegetables

certification attained by the establishment. This may include targeting CFIA oversight to areas not covered by the private certification scheme.

- *Government of Canada Priorities*

The Government of Canada faces a multitude of complex and interrelated issues that have wide-reaching impacts on the mandates of departments and agencies across Canada. Unexpected issues that have impacts on food safety, consumer protection, or plant and animal health can arise, creating new risks or heightening existing risks. Consequently, risk management approaches for certain establishments or entire sectors may be impacted when new or unexpected issues arise.

- *International Standards*

Canada has a strong regulatory system dedicated to safeguarding food, animals and plants that is founded on sound science and aligned with international standards. The CFIA participates in the development of international standards for food safety, animal and plant health and will continue to look to these standards to inform oversight activities.

- *Global intelligence*

The CFIA works with international organizations and trading partner countries to share information regarding issues and trends that may impact food safety, consumer protection, and plant and animal health in Canada and abroad. International trends and issues may present new or divergent risks that will need to be managed when developing oversight approaches for potentially impacted establishments in Canada.

The CFIA currently uses many of these factors in its risk-informed decision-making; however the modernized approach is designed to yield improved consistency across commodities. Using the results from the risk assessments will assist the CFIA in directing its resources to those sectors and regulated parties that represent the greatest risks for food safety, consumer protection, and human, plant and animal health. All regulated parties will be subject to a base level of CFIA oversight, however, the modernized approach will help appropriately match the frequency, level, and type of CFIA oversight activities with the level of risks that are being managed for those areas the warrant additional attention. It should be noted that the Agency's degree of oversight does not diminish; resources will be targeted to those areas of greatest concern however ultimately it is the industry that is responsible for producing safe food.

In addition to oversight activities, some other components of the risk management approach may also include compliance promotion and verification activities, incorporating industry

surveillance information, and the development of standards and guidelines. For example, the CFIA is developing a Compliance Promotion Strategy⁵ and other tools to help small and medium-sized businesses understand the regulatory requirements and ultimately improve their ability to produce safe food.

The CFIA will be developing a Risk Management Strategy that will communicate the principles and the processes that the CFIA uses to manage risks to food safety, and animal and plant health. The risk approach is still under development and other factors for consideration as part of risk management are being examined and may also be incorporated prior to finalizing the approach.

It should be noted that risk management is a continuing process that takes into account new information as it becomes available. Risk management decisions and their implementation will be regularly monitored and adjusted as necessary to ensure the continual achievement of CFIA's mandate to protect food safety, plant and animal health.

Risk Communications

The risk communications component of the risk continuum refers to the mutually beneficial exchange of information between risk assessors, risk managers and stakeholders. Enhancing risk communications, including increasing transparency, helps facilitate an exchange of information, and the CFIA is committed to being as transparent as possible.

Risk is an inherent part of food production, preparation and consumption, and Canadians expect open, timely access to information and opportunities to provide input into decisions that affect them. That is why the CFIA and industry share the responsibility for communicating those risks to consumers to help them understand potential risks and assist them in making informed decisions about food safety.

The federal government is undertaking efforts on several fronts to foster greater openness and accountability, to provide Canadians with more opportunities to learn about and participate in government, to drive innovation and economic opportunities for all Canadians and, at the same time, create a more cost effective, efficient and responsive government. This is being pursued in the context of Canada's Action Plan on Open Government⁶.

There are three streams under this broad initiative, Open Information, Open Data and Open Dialogue. Open Information is the proactive release of information on government activities on

⁵ For more information please see <http://www.inspection.gc.ca/food/action-plan/healthy-and-safe-food-regulatory-forum/presentations/compliance-promotion/eng/1369940911641/1369940962183b>

⁶ <http://www.canada.ca/en/transparency/open.html>

an ongoing basis, making it more accessible to Canadians and easier to find. Open Data encompasses projects that support the commitment to making raw data available in machine-readable formats to citizens, governments, not-for-profit and private sector organizations to leverage it in innovative and value-added ways. Open Dialogue supports projects that give Canadians an opportunity for two-way dialogue with the Government of Canada on federal policies and priorities. One example in this area is that federal regulators will be required to electronically post their forward regulatory plans so as to make the regulatory system more predictable and give Canadians and businesses early warning of upcoming changes and the opportunity to engage on regulatory plans. Regulators will also be required to post service standards and policies that clarify when stakeholders can count on receiving guidance in writing.

The CFIA's [Policy on Transparency in Regulatory Decision Making](#)⁷ is one way in which the CFIA is supporting Canada's commitment to open government. The Policy outlines the Agency's commitment to being as transparent as possible by making information available to Canadians on a proactive and ongoing basis in an effort to share knowledge and ensure accountability. The policy will help keep stakeholders better informed of all CFIA regulatory programs, services and requirements; affirm visible accountability for CFIA's regulatory programs and services; and enhance public confidence in Canada's regulatory system for food safety, animal health and plant protection. In support of the transformation agenda, the transparency policy provides the foundation for a new approach to communicating about CFIA's activities. The guiding principles the CFIA uses in its approach to transparency are:

- *Usefulness* - The CFIA will provide relevant and practical information that supports informed decision making on the part of the public and regulated parties and Information that may be used as a tool to generate compliance.
- *Clarity* - Information will be presented in clear objective language in a manner which is easily understood by the public. Rationales for regulatory decisions will be provided, detailing how and why a decision was made.
- *Timeliness* - Information will be provided early enough to preserve the value of the information.
- *Accessibility* - Information will be made available in both official languages in formats which are clear and accessible to all parties affected or interested, with no requirement of registration.
- *Accountability* – CFIA recognizes its role as a steward of a considerable amount of information, some of which is third party information. As such, this information will be

⁷ <http://www.inspection.gc.ca/about-the-cfia/accountability/transparency-in-regulatory-decision-making/eng/1363183662938/1363185978804>

treated with responsibility and integrity while simultaneously protecting the laws governing confidentiality.

Two of the Health Portfolio's key initiatives, Healthy and Safe Foods for Canadians Framework and Safe Food for Canadians Action Plan, have strong links to CFIA's approach to transparency and the open government initiative.

The CFIA is taking a phased approach to increasing its capacity on the risk communications front, starting with increasing the information available as well as expanding the technologies used to disseminate that information. Key accomplishments to date include:

- Establishment of the *Integrity and Redress Secretariat* as a one-stop area for complaints comments and complements.
- Communicating through social media and user-friendly mobile communications
- Email notification service
- Healthy Canadians Website
- Food recalls and allergy alerts online
- Easy-to-understand food recall warnings
- Multimedia products on the Role of the Meat Inspector and on Food Safety Investigations and Recalls

The next phase of CFIA's transparency agenda is strongly tied to the CFIA's modernization agenda and will be further consulted upon in the future. The CFIA's transparency policy will be reviewed and updated as CFIA's transformation advances in order to reflect the continuing push towards greater transparency and engagement.

As part of this next phase, the CFIA will continue to explore how to increase transparency in the risk assessment and risk management realm. For example, consideration is being given to how to communicate the CFIA's risk management and oversight decisions to Canadians in a meaningful way for consumers and other stakeholders. Discussions have included providing information on CFIA's website on the overall risk assessment result for each sector and the resulting decisions related to the oversight being undertaken by the CFIA. It is still early on in the development of this new approach, however, the CFIA will be engaging with stakeholders in this area and is committed to being transparent about risk management actions.

Next Steps

The CFIA is in the process of gathering feedback from stakeholders on the proposed risk-based approach, is validating the RA model and plans to eventually adapt the RA model for other

commodity types. The CFIA will be continuing work to finalize the RA model, develop its program management, and implement the enhanced approach. The CFIA will continue to engage stakeholders on the progress and outcomes as the process moves forward in the coming years.

Key Questions for Consideration

- What do you like about the proposed risk-based approach?
- What are your concerns, and how might they be addressed?

Contact

If you wish to submit a comment or other feedback, please send it:

By email: CFIA-Modernisation-ACIA@inspection.gc.ca

By mail: Strategic Partnerships Division
1400 Merivale Road, Tower 1
Floor 6, Suite 218
Ottawa, ON K1A 0Y9
Canada
Attn: Linda Webster

By fax: 613-773-5606