A New Regulatory Framework for Federal Food Inspection:

THE CANADIAN FOOD INSPECTION AGENCY'S FOOD SAFETY REGULATORY FORUM

Discussion Document

Canadian Food Inspection Agency | Agence canadienne d'inspection des aliments

Canada

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Preface

Canada has one of the best food safety systems in the world, but continuous improvement is needed to ensure that Canadians maintain access to safe food. The *Safe Food for Canadians Act* (SFCA), which received Royal Assent in November 2012, establishes a modern and robust legislative framework for the safety of food commodities sold to Canadians and provides for ongoing reviews of the federal food safety system in Canada.

The SFCA is the foundational element of the Safe Food for Canadians Action Plan -- a comprehensive set of activities to improve Canada's food safety system and better manage risk to protect Canadian families. The Plan represents an ambitious transformation agenda in four strategic focus areas:

- Stronger food safety rules (legislative and regulatory modernization efforts), which includes the SFCA and proposed regulations,
- More effective inspection (inspection modernization, training for inspectors and enhancing science capacity),
- Renewed commitment to service (statement of rights and services, service standards and user fees and compliance promotion), and
- More information for consumers (transparency and labelling review)

While no food safety system can guarantee a completely risk-free environment, the Safe Food for Canadians Action Plan will contribute to consistent food safety approaches in Canada. We encourage you to find out more about the Safe Food for Canadians Action Plan at www.inspection.gc.ca.

To strengthen food safety rules, a new regulatory regime must be crafted as the SFCA replaces three CFIA inspection statutes – the *Canada Agricultural Products Act* (CAPA), the *Fish Inspection Act* (FIA), the *Meat Inspection Act* (MIA), and the food-related provisions of the *Consumer Packaging and Labelling Act* (CPLA). The intent is that regulations made under these statutes will be consolidated into the proposed regulations. It is expected these regulations will be in place and the Act in force at the beginning of 2015.

The regulations also represent an important step in the implementation of the CFIA *Improved Food Inspection Model* which was developed and widely consulted on during 2012 and 2013. Key features of the model, including licensing of food commodity importers and those who prepare food commodities

for inter-provincial trade and the introduction of preventive control plans, represent transformational changes on which further consultation will be undertaken here in the context of developing the proposed federal food inspection regulations.

Once the SFCA is in force, two federal legislative regimes will apply to food in Canada instead of five – the *Food and Drugs Act* (FDA) and regulations, which apply to all food sold in Canada, and the SFCA and regulations, which include requirements that apply to food that is imported, exported, or prepared for trade across provincial borders. Both Health Canada and the Canadian Food Inspection Agency (CFIA) are modernizing their respective regulatory frameworks and are committed to working together and with stakeholders in the regulatory development processes.

This paper sets out elements of a proposed regulatory framework under the SFCA and marks the first consultation step in the regulatory transformation process. It highlights particular proposals and introduces new approaches in order to stimulate debate, generate ideas, and provide a starting point for discussions.

The Government is seeking feedback on all aspects of the proposed regulatory framework, including the overall approach and specific elements. We invite all food industry stakeholders and Canadians to make their views known on these and other issues related to the proposed regulatory framework so that the future regulations for this essential sector of our economy works as well as it can to protect all Canadians.

Consultation Process

This consultation document launches a process that is intended to lead to new regulations made under the SFCA. This consultation period will run from now until November 30, 2013. Unless submitting parties advise the CFIA that they don't want their comments posted, written comments received may be made available on the CFIA website.

Over the coming months, a series of consultation opportunities, such as webinars (web-based seminars) and face-to-face meetings, between CFIA and stakeholders will be organized. Associations are urged to take this document and gather feedback from their members on the proposed regulatory framework. CFIA will be available to answer questions and hear feedback.

Work on the proposed regulations will continue to progress, taking all the comments and feedback into account. In spring 2014, a Notice of intent will be released that will contain a discussion draft of the proposed new regulations. Further consultations will be undertaken at that time. Final publication of

the regulations in Canada Gazette Part II is expected at the end of 2014 with a target for coming into force at the beginning of 2015.

Introduction

Recent decades have seen significant changes in the global food environment. An increasingly global marketplace for food commodities, including agricultural products, means that there are increased opportunities for the introduction and spread of contaminants, including pathogens and new diseases in Canada. With advances in science and technology have come new and innovative food commodities and processes as well as increased capacity to detect food safety risks, at the same time that the ageing of the Canadian population is changing the food risk environment. Global commerce has also led to new business models and consolidation in the food and agricultural industries that have effectively changed the makeup of the parties regulated by the CFIA. The CFIA document entitled *The Improved Food Inspection Model: The Case for Change* more fully describes the changing global food safety environment.

In response to these developments governments around the world are rethinking their approaches to food safety and consumer protection, including renewing legislative frameworks, applying systems approaches to inspection and better leveraging oversight resources. At the same time, the food industry is pioneering new approaches to traceability and third party certification systems, investing in innovative approaches to making food safer and taking a greater role in managing some areas of trade.

Canada requires a food safety system capable of continuous improvement that evolves with new food safety practices, technology, and other developments in industry to deliver the best possible protection for Canadians from food safety risks. The vision of the proposed regulatory framework is a system that:

- confirms industry responsibility for safe food commodities and requires globally-recognized HACCP-based approaches best designed to deliver safe food commodities;
- provides industry with flexibility and the potential opportunity for innovation in terms of food safety approaches within facilities;
- enables a more risk-based approach to inspection of food commodities and establishments regulated under the SFCA that pose the greatest risk for consumers;
- enables regulated parties and CFIA to rapidly mitigate emerging food safety risks;
- reflects international standards;
- facilitates alignment with provincial/territorial governments and international trading partners, in particular, the United States, thereby supporting market access;

- moves away from prescriptive to outcome-based regulations, where appropriate;
- enables the CFIA to apply consistent regulatory requirements and inspection approaches across all federally regulated food commodities; and,
- addresses non-food safety requirements in a more consistent and efficient manner.

The following are elements of the proposed regulatory framework under the SFCA. The scope of this review largely applies to food that is imported, exported, or prepared for trade across provincial borders. Release of this document represents the start of a broad discussion with all stakeholders, including domestic producers, processors, exporters, importers and consumers, as well as with provincial and territorial regulatory partners, and foreign governments. Final positions have not been taken by the CFIA and additional elements of the proposed regulatory framework are still to be developed. As such, engagement is essential in shaping the future regulations and CFIA welcomes feedback on the proposed regulatory approaches.

CFIA Food Regulations – Today and Tomorrow

CFIA is responsible for the enforcement of the CAPA, FIA, MIA, and the food-related provisions of the CPLA and the FDA. These Acts are supported by fourteen regulations:

- *Dairy Products Regulations*
- *Egg Regulations*
- *Processed Egg Regulations*
- *Processed Products Regulations*
- *Fresh Fruit & Vegetable Regulations*
- *Honey Regulations*
- *Maple Products Regulations*
- *Licensing and Arbitration Regulations*
- *Organic Products Regulations, 2009* (OPR)
- *Livestock & Poultry Carcass Grading Regulations*
- *Meat Inspection Regulations, 1990* (MIR)
- *Fish Inspection Regulations* (FIR)
- *Consumer Packaging and Labelling Regulations* (CPLR)
- *Food and Drug Regulations* (FDR)

While current regulations have served Canadians well, the SFCA presents an opportunity to modernize and consolidate the regulations under CAPA, FIA, MIA, and the food-related provisions of the CPLR to ensure that they are more comprehensive, consistent and reduce duplication and gaps, where possible. The provisions in the FDR, under the FDA, will not change as a result of this exercise.

The proposed regulatory framework will create food inspection regulations with consistent, internationally recognized requirements for all food commodities imported or traded inter-provincially. It builds on the policy direction articulated in the *Improved Food Inspection Model* on which consultations were concluded in May 2013.

International standards such as *Codex Alimentarius* and the legislative schemes of other countries, such as Australia and the United States, were also considered to ensure optimal alignment with Canada's key trading partners. CFIA also looked to its own examples of best practices, such as the *Food Safety Enhancement Program Manual* and *CFIA's General Principles of Food Hygiene, Composition and Labelling* to identify requirements that should be applied more generally to all food commodities.

The proposed food inspection regulations will be supported by a suite of new guidance documents, including "model systems", which will provide examples of how outcomes could be achieved. The majority of these "model systems" will be drawn from existing CFIA programs and manuals, proven to be effective at addressing hazards, but re-written and presented in more accessible formats for industry. In addition, CFIA is considering new approaches to assist industry to achieve regulatory compliance. Readers are encouraged to review a CFIA discussion document on this issue entitled *Compliance Promotion: Formalizing an Approach to Stakeholder Compliance*.

Contents of the Proposed Regulatory Framework

The proposed regulations will have a number of horizontal requirements that will apply to all federally regulated food commodities traded inter-provincially and internationally such as, licensing, preventive controls, traceability, record-keeping, and a review mechanism. Certain commodity specific food safety requirements will be maintained (e.g. slaughter), as well as other commodity specific and consumer protection provisions (e.g., standards of identity, grades, inspection marks, labelling and packaging). It is expected that exemptions authorized by the Minister of Agriculture and Agri-Food (Minister) to address shortages and for market testing of new food commodities will be maintained in the proposed regulations.

In addition, the SFCA provides new authorities for disclosure of personal information and confidential business information. It provides new regulation making authorities under the *Canadian Food Inspection Agency Act* (CFIA Act) for the recall of products. In addition, consideration is being given to amending the *Agriculture and Agri-Food Administrative Monetary Penalties Regulations* (AAAMPR) to make it possible for CFIA to use this enforcement tool in relation to food commodities.

This document surveys these major components of the proposed regulatory framework and seeks feedback on specific questions. Policy and program design considerations that impact the proposed regulatory framework are also presented in some cases.

Horizontal Requirements

Licensing

Ensuring industry commitment to food safety is important in enabling effective oversight of the safety of food consumed by Canadians. Licences assist in identifying who is preparing food commodities destined for inter-provincial trade or importing food commodities into Canada, where these regulated parties are located and what activities they are conducting in relation to a food commodity. Licensing would be an additional tool in the food safety regime. It allows the Minister to authorize a regulated party to conduct an activity and, where relevant, to attach specific conditions to the activities.

Building on the *Improved Food Inspection Model*, the new licensing regime will help enhance the CFIA's surveillance schemes and food safety inspection activities. Furthermore, this new regime will contribute to improved risk-based inspection oversight which will be used to streamline inspection priorities, and improve emergency management.

Licensing and registration requirements currently exist under CAPA, FIA and MIA. The definition of food commodity in the SFCA is broader than the definition of "agricultural product" under CAPA, "fish" under FIA and "meat product" under MIA. The proposed regulations would, therefore, extend licensing requirements to encompass all regulated parties who import food commodities or prepare them for inter-provincial trade. This means that some regulated parties that prepare food commodities destined for inter-provincial trade that are not currently regulated under CAPA (e.g., cookies, cake mixes) would now be required to have a licence under the SFCA. Also, all importers of food commodities would now be required to be licensed. The CFIA is proposing to no longer register establishments as licence holders would be subject to requirements related to the establishment where the food commodity is being prepared.

Voluntary licence applications would be permitted by regulated parties not subject to licensing requirements under the proposed regulations (e.g., regulated parties solely trading food commodities within a province). If a licence were to be issued, the licence holder would be subject to all requirements of the SFCA and its regulations.

In the context of the consultations in relation to the *Improved Food Inspection Model*, it had been proposed that all licence holders should have an address in Canada. This approach has raised some concerns in relation to companies that import food commodities into Canada but are not located in Canada. CFIA is considering conditions under which non-resident importers might be permitted.

Proposal:

- A licensing requirement is being proposed for any regulated party who imports food commodities or prepares food commodities for inter-provincial trade. The licence would be valid for two years. Licence holders would be required to apply for the renewal of their licence prior to expiry, including payment of applicable fees.
- Regulated parties would have the option of applying for a licence per establishment or per activity (for example, import, prepare, etc.) or a single licence which would cover all of their operations in multiple establishments and/or multiple activities. Of note is that if a single licence is issued for multiple establishments or activities one must be aware that the suspension or cancellation of the licence would affect all of the establishments and/or activities subject to the licence.
- There may be special cases where the requirement to have a licence may not apply (e.g. food imported for industrial uses) or where special conditions may be applied to licence holder given the nature of the business (e.g. food brought into compliance after entry into Canada).
- The Minister may refuse to issue or renew a licence if the applicant does not meet the requirements of the SFCA and its regulations, has provided false and misleading information, or has outstanding unpaid fees.

Question 1: The Government is seeking comments on the proposal to move away from the registration of establishments and instead require a licence for those responsible for the preparation of food.

Question 2: In certain cases, modified licence requirements for specific activities and products may be warranted. Please describe any cases that justify these modified requirements.

Question 3: Currently, some programs allow for importers that do not have a Canadian address (Non-Resident Importer). What are your views on whether non-resident importers should be permitted for licensing? How might the regime accommodate non-resident importers?

Export Licences

Food commodities exported from Canada are exempt from the requirements of the FDA, provided that (a) the package is marked for "Export" or "Exportation" and (b) a certificate that the package and its contents do not contravene any known requirements of the law of the importing country has been issued. Any additional requirements that are set under the new SFCA will not impact that exemption.

Those who export food commodities from Canada need to meet the requirements of the country of import. Some importing countries require that food commodities be prepared in accordance with Canadian requirements, others have specific requirements for the food commodities they allow for import, while some others have no requirements. In certain cases, importing countries may require the government of the country of origin to certify the safety or other attributes of a food commodity, before the importing country will accept the shipment.

The SFCA provides the authority to the Minister to certify food commodities for export. It also allows for the licensing of regulated parties who export food commodities or prepare them for export. The *Improved Food Inspection Model* proposed that all exporters should be licensed and have preventive control plans in place to meet importing country requirements. As CFIA now considers making the export licence a legal requirement, additional issues have been raised such as the benefit derived from licensing all exporters relative to the costs this would entail.

There are many possible approaches to regulating the export of food commodities and the Government is seeking input on these possible approaches. These range from approaches that require full oversight of exports, to those that respond only to the demands of Canadian exporters and the importers of their food commodities, to no oversight. Licensing of exporters who are required to adhere to Canadian requirements or who require an export certificate to access markets could allow for a more efficient approach to providing assurance to trading partners that food meets their requirements. In choosing among these approaches, there are a number of factors that must be taken into account, including:

- Cost to the exporter (e.g., administrative burden, time delay, fees)

- Benefit to the exporter (e.g., value of access to markets)
- Cost to Canada (e.g., cost of the inspection system to the Government of Canada – and hence the Canadian taxpayer, cost of inability to access markets)
- Benefits to Canada (e.g., value of access to markets)

Regardless of whether or not exporters are licensed, exported food commodities will need to meet some basic Canadian labelling requirements (e.g., common name, net quantity and lot code). Such requirements are necessary for adequate identification and traceability of food commodities being exported.

Question 4: Should exporters or those who prepare food commodities for export be required to hold a licence issued by the Minister? Why or why not?

Question 5: What requirements should a licensed exporter need to meet?

Question 6: Should those who need the Minister to certify their food commodities for export be required to hold a licence, or should the Minister handle these requests on an ad hoc basis? What would be the value of a licence in this scenario?

Licence Application

A licence application must be made to the Minister. The proposed regulations would require that an approved application form be used and be accompanied by the applicable fee that would be prescribed in the *Canadian Food Inspection Agency Fees Notice*.

The information contained in the licence application would be used by the Minister to issue a licence. It will also assist the CFIA to assess the risks associated with the food commodity and/or processes. Some of the information that could be required as part of the application may include; contact and legal information (name, physical location, address/contact info where records will be available, etc.), activity related information (type of activity, size of business, number of employees, etc.), and commodity related information (commodity type, volume of production, countries from which products are typically imported, consumers to whom products are typically sold etc.). Licence holders would also be required to attest that they have a preventive control plan in place that is suitable to their operation.

The Government is also considering requesting as part of the application a Canada Revenue Agency's Business Number, if available. This number is increasingly being accepted as a common client identifier for businesses to simplify their dealings with federal, provincial and municipal governments. While in the short-term it will provide an extra measure of assurance for CFIA, in the future it holds potential for seamless integration, improved identity management, on-line transactions and improved electronic service for Canadians.

Suspension and Cancellation of a Licence

Under the SFCA, the Minister has the authority to suspend or cancel a licence. The proposed regulations would include grounds for the suspension and cancellation of a licence.

Proposed Grounds:

The Minister may suspend a licence if:

- The licence holder has not complied with the conditions of the licence or any provision of the Act or Regulations
- The licence holder has unpaid fees
- It is reasonable to believe that public health may be endangered if the licence holder continues to conduct the authorized activity

The Minister may cancel a licence if:

- The licence was issued on the basis of false or misleading information, or false or falsified documents submitted in or with the application;
- The reason for the suspension cannot be resolved within 90 days following the day on which the licence was suspended. When the reason for suspension cannot be resolved within 90 days, a longer time period may be granted upon request of the licence holder;
- The licence holder has continued to conduct the authorized activity while their licence is under suspension.

Question 7: What are your views on the grounds for the suspension or cancellation of a licence?

Question 8: The Government is considering imposing a 2 year period after a licence cancellation, during which a regulated party would be unable to apply for a licence. Do you agree with this? Please explain your response.

Preventive Control Plan

A preventive control plan (PCP) is a written document that sets out how food safety and other regulatory requirements (e.g. labelling, product composition, etc.) will be achieved. PCPs are recognized internationally as the best way to demonstrate that food safety risks and hazards are controlled or eliminated because they focus on prevention and systems-based examination of operations by regulated parties. PCPs will address not only food safety requirements but will also address other requirements such as net quantity and grades.

The proposed regulatory framework for food proposes to reduce, where appropriate, the current prescriptive commodity-specific requirements, by moving to a system of requirements that articulates the expected outcomes as it relates to food commodities.

Proposed outcome-based regulatory requirements are included in Annex 1. They are based on HACCP principles, consistent with international standards such as *Codex Alimentarius* and were guided by the *Improved Food Inspection Model* with respect to scope, language and element requirements. The regulations of key trading partners, such as Australia, New Zealand, the United States, the European Union, were also considered in developing this proposal.

Depending on the licence holder's operation and activity, they will have to address some or all of the following regulatory requirements:

1. Processes and products
2. Sanitation and pest control
3. Hygiene and competencies
4. Equipment design and maintenance
5. Physical structure and maintenance
6. Receiving, transportation and storage
7. Recalls, complaints and record-keeping

It should be noted that importers, at a minimum, must address the regulatory requirements for Process and products (1) and Recalls, complaints and record-keeping (7). In addition, importers who are involved in handling or repackaging of food must address all of the above regulatory requirements (1-7) that apply to their activities.

The *Improved Food Inspection Model* identifies certain operations not subject to licensing. Such operations include, for example, transporters of food commodities as well as facilities that store food commodities but that are not involved in importing, exporting or preparing food commodities. Although it is recognized that such important operations in the food chain may not necessarily require a PCP of their own, such operations will need to be included in the PCP of the licence holder in order to address hazards and risks that are likely to occur during transportation and storage, which can impact the safety and compliance of their food commodities.

PCPs can be adapted to the risks and complexity of operations but must address the applicable regulatory requirements. It is the responsibility of the regulated party to ensure that effective controls and precautions are in place to address potential hazards and risks associated with their food commodities and processes, as well as to consider what they would do in the event that something went wrong.

The proposed regulations contribute to enhanced food safety and regulatory compliance by requiring that all licence holders develop, implement and maintain a PCP. Consequently, licence holders must demonstrate in their PCP how they achieved compliance with regulatory requirements and that they have appropriate systems to mitigate risks posed by their operation. Hence, licence-holders should describe how they control their operations, including how they monitor, verify and correct problems, and respond to unforeseen food safety and non-compliance situations.

Proposal:

- Anyone who imports or prepares food commodities destined for inter-provincial trade is required to develop, document, implement, and maintain a PCP adequate to their activities.

The PCP would involve a systematic examination of operations to identify potential food safety hazards, which may reasonably be expected to occur in the preparation of food commodities, along with their corresponding controls. Furthermore, hazards that may lead to non-compliance with regulatory requirements but that are not food safety in nature must also be considered and controlled. The PCP would also outline monitoring and verification procedures, corrective actions, management review (review procedures by the licence holder), record keeping and traceability procedures. Hazard Analysis and Critical Control Point (HACCP) is the internationally accepted system adopted by the joint WHO/FAO *Codex Alimentarius* Commission. Some sectors have already implemented PCPs, based on HACCP principles, to demonstrate how they achieve compliance [for example, voluntary Food Safety

Enhancement Program (FSEP), Quality Management Program (QMP)] and would be able to transition to the new model with little adjustment.

To facilitate the transition to an outcome-based approach, the Agency will provide guidance material to regulated parties with options or model designs, and the performance measures that will help them achieve the desired outcomes. A model system for compliance is a non-binding model that provides guidance to a regulated party to meet a specified outcome. Model systems set out practices and procedures for premises and equipment that, when implemented, would facilitate compliance.

The proposed outcome-based approach provides regulated parties with flexibility to introduce new technologies, processes, and procedures that could enhance safety and/or reduce costs, rather than having regulations prescribe specific methods and processes. Likewise, it allows the CFIA to better adjust its oversight to changes in science, technology, and the risk environment. In addition, it holds promise in greater collaboration with regimes in other jurisdictions which require similar outcomes, both within Canada and abroad. CFIA has prepared a policy document entitled *"Foundation of an Outcome-Based Approach"* to guide the use of this approach.

Question 9: Are the proposed outcome-based regulatory requirements in Annex 1 sufficiently clear for industry to understand what outcomes they will need to achieve and their regulatory responsibility?

Question 10: Is there anything missing in the requirements that should be addressed to ensure food safety?

Question 11: Industry is responsible for safe food and meeting regulatory requirements. The CFIA will be developing a suite of guidance documents. How could CFIA assist industry in meeting these outcomes through guidance documents, or other tools/methods?

Question 12: To address potential unforeseen emerging issues that would not be covered by a standard hazard analysis process but may have an impact on public safety, should PCPs also include a requirement for regulated parties to routinely consider how to make their food safety approaches resilient in the face of new emerging threats?

Food Safety Prohibitions

Additional food safety requirements which outline some prohibited practices are addressed in sections 4 to 19 of the *Safe Food for Canadians Act* (SFCA). The proposed regulations will include additional prohibitions that currently exist in the regulations under CAPA, FIA, and MIA and are fundamental to ensuring the safety of food products.

Proposed requirements:

- A person must not import, export, or send or convey a food commodity from one province to another unless the food commodity, including its components and ingredients,

  (a) is not contaminated;
  (b) is edible;
  (c) is prepared under sanitary conditions; and
  (d) meets all other requirements of the *Food and Drugs Act and the Food* and *Drug Regulations.*

- A person must not mix a contaminated food commodity with another food commodity that is not contaminated for the purpose of bringing the finished product into compliance with the requirements without further processing.

Systems Equivalence

Under the proposed regulations, all importers will be required to have a licence and a preventive control plan demonstrating that the food commodities they import meet Canadian requirements. This is a substantial new requirement that seeks to assure that domestically produced and imported food commodities are held to the same food safety standards.

Equivalence or comparability means that the foreign country's system does not have to be the same as Canada's food inspection system, but is based on the ability of an exporting country's system or a sanitary measure to achieve the same outcome or provides for the same appropriate level of protection as Canada's system or sanitary measure.

Equivalency agreements, or recognition of foreign food safety systems, may provide additional "assurance" that food commodities imported into Canada meet regulatory requirements. While system recognition would not eliminate the need for licences, it could reduce the burden on importers who import from countries that have been deemed equivalent and facilitate oversight of imports.

Based on risk and available resources, the CFIA may choose to perform onsite foreign system audits to review the food safety requirements imposed by a foreign country on their domestic manufacturers. The CFIA is developing a policy to guide the application and determination of foreign system recognition and equivalency agreements.

Question 13: What criteria could be used as a basis for foreign system recognition? What benefits or risks exist with such recognition that need to be taken into account in regulations or program design?

Question 14: The current regulations for egg, dairy and meat products require that imports can only be from countries with equivalent food safety systems. Given the proposed requirement on importers to have a licence and a PCP, are equivalency provisions still needed for these commodities? Please explain.

Traceability

Rapid identification of the origin and movement of a food commodity is essential for protecting consumers during a food safety incident. This process requires that accurate information about the food commodity be available to regulated parties and the CFIA in a timely and accessible manner.

While many regulated parties in the food sector have implemented voluntary traceability systems, others do not have the necessary record-keeping practices to facilitate timely food safety investigations, recalls or withdrawals. The resulting information gaps within the food supply chain may lead to a less efficient response to a food safety incident.

The international standard for traceability established by *Codex Alimentarius* calls for tracking of food commodities *forward* to the immediate customer and trace materials / food commodities *backwards t*o the immediate supplier ("One step forward, one step backwards").

The proposed regulations would, at a minimum, apply the *Codex* standard to every stage of the food supply chain, from production to retail. Although many regulated parties have already implemented a traceability system that meets the Codex standard, all regulated parties are encouraged to adopt this practice now, in advance of the legal requirement to do so, to align with the proposed regulations. Retailers may be covered by the proposed traceability regulations but would not be required to trace food commodities sold to the final consumer.

Proposal:

- Anyone who imports, exports or prepares food commodities would be required to maintain specified traceability records to facilitate the tracing of the physical flow of food commodities to the immediate customer (except when food commodities are only sold to the final consumer) and tracing the physical flow of food commodities backwards to the immediate supplier.
- These records would need to be provided to an inspector on request, in a format defined by the CFIA, within 24 hours. If provided in an electronic format, the records would need to be un-encrypted and provided in a format that could be imported and manipulated by standard commercial software.

Question 15: What are your thoughts on the proposed traceability requirements?

Record-keeping

Accurate and up-to-date records are crucial for the ability to respond to a food safety incident in a timely manner.

Proposal:

- Specified records shall be prepared, kept, maintained and provided, in English or French, and be available in Canada for a period of three years.

Question 16: What are your comments on the proposed record keeping requirements? Should the requirement be limited to record availability?

Recall

The CFIA Act provides authority to order a recall. The SFCA amends the CFIA Act to include a new regulation making authority respecting the recall of products. Hence, new regulations will be proposed under the CFIA Act for the recall of products, which may include requirements to notify customers and suppliers.

Seizure and Detention, and Held Tags

Currently, under CAPA, FIA, MIA and CPLA, inspectors have the authority to seize (take legal control of a thing) and detain (maintain legal control over a seized thing) anything that is believed to be in contravention of the Act or regulations. This authority also exists in the SFCA.

Proposal:

- A notice of seizure and detention would need to be delivered to the owner of the thing seized, or the person having possession, care or control of it at the time of its seizure, and would need to include the following:
    - the detention tag identification number;
    - the quantity of seized thing, if applicable;
    - a description of the thing seized;
    - the reason for the seizure and detention;
    - the date of the seizure and detention;
    - the name of the owner or person having possession, care or control of the seized thing, and contact information, in block letters;
    - the location of the seized thing
    - the name and contact information of the inspector.
- Unless authorized by an inspector, no person other than an inspector would be able to alter, deface or remove a detention tag from something that had been seized or detained.
- To maintain the integrity of the food commodity during the period of detention, the owner of the thing seized, or person having possession care or control of it at the time of seizure, would need to ensure that the seized food commodities are stored under conditions appropriate to the preservation of the food commodity.

- An inspector who releases a thing seized would need to provide a notice of release to the person to whom a copy of the notice of seizure and detention was delivered.

In addition to the authority to seize and detain, the SFCA also provides authority to the inspector to order the owner or the person having possession, care or control not to move an item or to restrict its movement for any time that may be necessary.

Proposal:

- An inspector who orders not to move an item or to restrict its movement pursuant to the inspection authority in the SFCA may attach to the item a tag, upon which would be clearly written:
    - the word "held";
    - a held tag identification number;
    - a brief description of the item held;
    - the date of the order;
    - the name and contact information of the inspector, and
    - the signature of the inspector.
- Unless authorized by an inspector, no person other than the inspector would be able to alter, deface or remove a "held" tag attached by an inspector.
- Where an inspector is satisfied that it is no longer necessary to hold the item and where a held tag has been attached to the item, a release would be delivered to the owner or person having possession, care or control of the item at the time of the order.

International and Inter-provincial Trade

The proposed regulations would require everyone importing or preparing food for inter-provincial trade to be licensed and comply with all the requirements of the Act and regulations, including labelling, packaging and standards requirements. Imported food commodities would need to be accompanied by all required import documentation and meet regulatory requirements.

Some regulated parties currently import food commodities that are not compliant with Canadian requirements, but subsequently bring them into compliance prior to being offered for sale. This practice is particularly used to correct a non-compliance related to product labelling and often on

products for smaller market segments. Other food commodities, such as spices, are imported into Canada for further processing before sale to Canadians.

It is proposed that such food commodities would not be subject to regulatory requirements at the time of import if they are clearly labelled with, for example, "For further processing only, "Not for human consumption", "Not for sale in Canada".

Currently in CAPA, FIA, and MIA, there are a number of situations where regulations do not apply to the import, export, or inter-provincial trade of a food commodity, including those solely for personal use (sometimes with commodity specific limits to amounts); items carried on any vessel, train, motor vehicle, aircraft or other means of transportation for use as food commodity for the crew or passengers; imported from the United States into the Akwesasne Reserve for use by an Akwesasne resident; part of an immigrant's or an emigrant's effects; being sent or conveyed from one federal penitentiary to another; to be used solely for scientific analysis, a trade show [national or international exhibition] or business-to-business market analysis, or food commodities not intended for human consumption.

Question 17: Do you think the situations outlined above where regulations would not apply to the import, export, or inter-provincial trade of a food commodity should be maintained? Are there any other situations you can envision where the regulations should not apply?

Question 18: Sometimes food commodities are imported into Canada solely for export to a third country, or "trans-shipped" through Canada, and are not offered for sale in Canada. In these cases, should these shipments be exempt from the application of the Act and the Regulations? Why or why not?

Ministerial Exemptions

The SFCA provides for regulation making authority permitting the Minister to exempt, with or without conditions, any food commodity from specific requirements of the Act and regulations, only if the Minister is of the opinion that no risk of injury to human health will result.

In the current regulatory regime, ministerial exemptions are granted for two main purposes: to alleviate shortage of fresh and/or processed fruits and vegetables; and to allow test marketing of certain food commodities, provided food safety requirements are met.

Currently, the procedures, submission requirements, consultation policies and time frames differ between the different regimes, as do the scope of the exemption (either only permitted to the applicant or to the industry as a whole, or by geographic area).

In the proposed regulations, the approach will be to incorporate the current ministerial exemptions to alleviate shortage and for test marketing. A common and transparent process will be developed for administering these exemptions, which will apply to all food commodities regulated under the SFCA.

Review Mechanism (Under the CFIA Act)

A modern food safety and consumer protection system should balance stronger rules in legislation and regulations with opportunities for appeal and redress. The CFIA made a commitment to implement an internal review mechanism to address issues that are raised by regulated parties and others. A Complaints and Appeals Office (CAO) has been established already for regulated parties, stakeholders, and members of the public to register complaints related to quality of service, administrative errors and certain other types of decisions with which they disagree.

The SFCA, when fully in force, will amend the CFIA Act to permit the Minister to designate review officers who will conduct reviews of certain decisions made under the authority of an Act that the CFIA enforces and/or administers. Currently, there is no specific authority for a review officer to modify a decision made by an inspector or other CFIA official in the course of carrying out his or her responsibilities under legislation enforced by the Agency. The ability of a review officer to vary, cancel or confirm prescribed decisions will require regulations to be made setting out the parameters of the process before the authority may be exercised. Without this authority, the CAO's role in relation to complaints respecting decisions is limited to that of making recommendations.

Therefore as part of the proposed regulatory framework, a regulation would be made under the CFIA Act that will define the parameters of the decisions that are reviewable and a process for review. The intent is that the types of decisions that are reviewable would be similar for all statutes.

The proposed regulations would include:

- Who can make a request for review of a decision,
- The manner in which a review officer must conduct the review,

- The manner in which a requester may make an application for review,
- The time in which an application must be made, and
- Which decisions are reviewable. Areas currently being considered under the SFCA are:
    - Suspension or cancellation of a licence
    - Restriction of movement of an item
    - Start or stop an activity or prohibiting or limiting access
    - Seizure and detention
    - Removal or destruction of unlawful imports.

Question 19: What additional decisions, if any, would you like to see as reviewable, and why?

Question 20: What would be an appropriate time-frame within which an application may be made?

An administrative policy would provide greater detail on the procedures and best practices with regards to how a review would be conducted.

Commodity-Specific Safety Requirements

Food Safety Requirements for Fresh Fruits and Vegetables

Most food commodities are prepared in a manner to reduce potential food safety hazards. Fresh fruits and vegetables, however, are sold raw and often not cooked prior to being consumed. There are many sources of contamination of fresh fruits and vegetables in pre-harvest production and post-harvest processing and handling. Microbiological food safety hazards can be introduced at the farm level through irrigation systems from questionable water sources, proximity of animals to the growing and harvesting operations, food contact surfaces, personnel hygiene and soil conditions and treatments.

In recent years, the majority of global outbreaks have been associated with fresh fruits and vegetables. In 2012, CFIA conducted an analysis of this food commodity sector. It found that fresh fruits and vegetables present the fastest growing microbiological safety risk among food commodities. In addition to the potential for sickness and death, a food safety outbreak originating from a single farm

could have devastating economic consequences to the entire sector and diminish consumer confidence in fresh fruits and vegetables.

On January 4, 2013, the Food and Drug Administration in the United States released for public comment its proposed rule to establish science-based standards for growing, harvesting, packing and holding produce on domestic and foreign farms shipping to the United States. The US proposes to set standards associated with identified routes of microbial contamination of produce, including: (1) agricultural water; (2) biological soil amendments of animal origin (3) health and hygiene (4) animals in the growing area and (5) equipment, tools and buildings. The proposed produce rule covers most fruits and vegetables while they are in their raw or natural (unprocessed) state. It would not apply to raw agricultural commodities that are rarely consumed raw, those produced for personal or on-farm consumption, and (with certain documentation) those destined for commercial processing, such as canning, that will adequately reduce microorganisms of public health concern. Some farms would not be covered by the rule, or would be eligible for a partial exemption based on factors including the monetary value of their food sales and to whom they sell.

Recognizing the Canadian environment for fresh fruit and vegetable producers, the Government of Canada is considering establishing requirements for fresh fruit and vegetable producers to develop, document, implement and maintain a PCP if they export or send or convey fresh fruits and vegetables across provincial borders for sale. Producers simply selling fresh fruits and vegetables within their province would not be required to have PCPs given the size of their operations and extent of consumer exposure to their products.

In Canada, the fresh fruit and vegetable industry has proactively developed and is voluntarily maintaining a CFIA recognized and internationally benchmarked food safety program (CanadaGAP). The Government is considering establishing legal requirements for primary producers of fresh fruits and vegetables which would be very similar to the elements of CanadaGAP.

Proposal:

- Establish requirements for fresh fruit and vegetable producers that send or convey fresh fruits and vegetables from one province to another or export. (See Annex 2).
- Impose the PCP requirements on fresh fruit and vegetable producers who send or convey from one province to another or export fresh fruits and vegetables intended to be sold directly to market.

Question 21: Do you support a requirement for fresh fruit and vegetable producers to develop, document, implement and maintain a PCP if they send or convey directly to market in other provinces or other countries?

Slaughter

Operators of establishments that slaughter animals intended for food have unique facilities and carry out specialized activities that are not performed in other food establishments. Presently there are multiple inspection systems for slaughter facilities (i.e., by species) reflecting the different industry handling practices. The CFIA conducts ante- and post-mortem inspection activities to support animal health, humane treatment, food safety and quality and market access objectives.

As with all other regulatory provisions, existing regulatory requirements related to slaughter will need to be brought under the SFCA. At an international level, a number of Canada's major trading partners are examining changes to how oversight of animal slaughter facilities is carried out. Moving forward, the CFIA will look to modernizing its approach to ante- and post-mortem inspection activities consistent with the concepts found in the *Improved Food Inspection Model*.

Consumer Protection and Labelling

The food label is one of the most important and direct means of communicating product information between buyers and sellers. It is one of the primary means by which consumers differentiate between individual foods and brands to make informed purchasing choices.

Labelling provisions exist in the FDR, MIR, FIR, CPLR and the regulations under CAPA. Some of these provisions apply to all food commodities (e.g. common name, net quantity). Other provisions are commodity-specific (e.g. percentage of milk fat declaration on certain dairy products).

The CFIA *Food Labelling Modernization* Initiative aims to develop a modern and innovative food labelling system. Improvements to the food labelling system based on the results of this initiative, including any changes to the labelling requirements, will happen over time. A discussion document on *Food Labelling Modernization* is available.

In the interim, the current regulatory modernization process is an opportunity to make some adjustments to the requirements including addressing any duplication between the various regulations. Below is the proposed approach to these issues that is being considered in the short term.

Horizontal Labelling Requirements

There is duplication and inconsistency across the existing labelling related regulations that CFIA enforces. The labelling requirements in the FDR are outside the scope of this proposed regulatory framework and will not change as part of this exercise. Therefore, it is recommended that where there is duplication with the FDR, reference to the FDR will be made in the proposed regulations, where appropriate, rather than having two different requirements.

Question 22: What are your thoughts on the proposed approach to referencing the FDR where appropriate?

Commodity Specific Consumer Protection Requirements

Existing regulations contain numerous commodity specific requirements, such as compositional standards, grades, inspection marks, labelling and packaging (including container sizes). The provisions vary significantly between regulations and can be challenging to apply, particularly for regulated parties that deal with multiple food commodities.

The approach for the proposed regulatory framework will involve a detailed review of the existing provisions and consideration of whether requirements should apply to all food commodities or be commodity-specific if they are still justified. This has resulted in three proposed groupings:

1) Where the requirements should apply to all food commodities, the CFIA will replace the multiplicity of commodity-specific requirements with a single requirement that will apply to all food commodities. This is proposed for the following:

    - Font size and legibility
    - Positioning on labels
    - Inspection marks
    - Language requirements (French and English)

2) Where commodity-specific requirements are justified, no substantive changes will be made to requirements. However, provisions of similar purpose will be grouped together. This approach would allow for a general consolidation of requirements without causing major disruptions to regulated parties. This is proposed for the following:

   - Grade standards
   - Standards of Identity
   - Container sizes

   The CFIA is reviewing whether some of these commodity-specific requirements would be appropriate for incorporation by reference. Pursuant to the SFCA, the Governor in Council will have the explicit authority to seek the incorporation by reference of documents into regulations under the SFCA. Documents appropriately incorporated by reference have the force of law. There is also authority for the Government to make modifications to its own incorporated documents as opposed to requiring regulatory amendments. This helps to reduce regulatory delays, cuts red tape and makes the food safety regulatory system more efficient and flexible. Although changes to incorporated documents do not go through the full regulatory process, the public and stakeholders will be consulted on changes made to any Government document incorporated by reference. The CFIA, jointly with Health Canada, is in the process of developing a policy on incorporation by reference on which there will be consultation with stakeholders in the future.

3) Where the requirements are no longer justified, consideration is being given to not including them in the proposed regulations in order to reduce unnecessary regulatory burden.

   Annex 3 contains examples of the commodity specific requirements discussed above and demonstrates how this approach could be applied.

Question 23: Do you support the use of incorporation by reference for the grade standards, standards of identity, container sizes? Under what conditions/controls should IBR be used or not used? Question 24: Do you support the proposed approach to the commodity-specific requirements?

Standards of Identity

Standards of identity (also referred to as compositional standards) list permitted ingredients or specific requirements for a named food commodity. There are over 250 standards in the FDR and in MIR, FIR and regulations under CAPA, sometimes creating duplication or inconsistency. The existence of two standards for the same food commodity can present challenges.

The proposed regulations will address the duplication and differences between regulations by conducting a provision by provision analysis to determine which standards should be kept and, when it is appropriate, which FDR standard should be referenced. Each standard will be evaluated to determine the approach to be applied.

Question 25: Do you have any comments that CFIA and Health Canada should take into account as we work to consider the best approach regarding existing standards?

Country of Origin Labelling

In Canada, there are requirements for certain food commodities to be labelled with the country of origin (e.g., certain imported meat, dairy products, honey, maple products, and poultry). Regulated parties may also make voluntary claims to highlight the origins of a food commodity. Country of origin labelling does not provide information on the safety of a food commodity.

Requirements for country of origin labelling vary between regulations, including which food commodity labels must include the country of origin (e.g., pre-packaged vs. bulk); circumstances when the country of origin is required to be included on the label (e.g., in all cases, only if imported, if packed for export, if domestically produced); and, how it must be declared (e.g., wording, language, location, type size).

Requirements for country of origin labelling may ultimately be addressed through the *Food Labelling Modernization* initiative. In the interim, requirements regarding country of origin labelling will be carried as is into the proposed regulatory framework, while the *Food Labelling Modernization* initiative works to consult stakeholders. The existing requirements will be consolidated and grouped, in an appropriate fashion, so that any duplication in the wording would be resolved.

Complementary Regulations

Disclosure of Information

Although the CFIA currently provides information regarding the outcomes of its enforcement actions and decisions to the public in the context of its transparency initiative, the SFCA provides the Minister with a new authority for the disclosure of personal information (PI) and confidential business information (CBI) to the public. Circumstances where CFIA is considering disclosing PI and CBI include:

- Food safety investigations,
- Food recalls,
- Licence suspensions or cancellations,
- Notice of violations, warning and penalties issued under AAAMPS, and
- Order the removal of unlawful imports.

Question 26: What are your views on the proposed disclosures? Would more compliance and enforcement information be of interest?

Administrative Monetary Penalties

The *Agriculture and Agri-Food Administrative Monetary Penalties Act* (AAAMPA) provides an alternative enforcement tool to prosecution and supplements existing enforcement measures. It allows for the issuance of an administrative monetary penalty (AMP) for the contravention of any specified provision of an agri-food act or its regulations (including the SFCA, when it will come into force) that is designated as a violation under the *Agriculture and Agri-Food Administrative Monetary Penalties Regulations* (AAAMPR). The AAAMPR establishes the penalty amounts based on the type of violation and the classification of the violation (minor, serious, or very serious). These amounts may be adjusted in light of harm, history and intent, but may not exceed the maximum penalty amounts established in the AAAMPA. To date, CFIA has not used AMPs in the context of its food safety enforcement measures. However, the CFIA is in the process of developing a regulatory proposal to amend the AAAMPR to include violations under the MIA and its regulations.

AMPs are an important element of a modern enforcement and inspection regime and allow alternate actions to be taken to help ensure compliance with requirements. CFIA could use its compliance and enforcement policy and guidelines to respond to the non-compliance and would take action by using tools as described in the *Improved Food Inspection Model* that provide for a range of possible responses. If a person having been issued an AMP wishes to appeal it, they may request a review of the facts by the Minister or by the Canada Agricultural Review Tribunal.

The SFCA will amend, upon coming into force, AAAMPA to provide the opportunity to issue AMPs to persons who contravene the SFCA and its regulations.

Examples of provisions that could be included are under an AMP scheme:

- Conducting certain activities not in accordance with the regulations or without a licence
- Failure to assist an inspector
- Failure to produce documents, information or samples

The process of allowing AMPs to be issued for violations of the proposed regulations will begin after the content of the proposed food regulations is finalized.

Question 27: What are your comments in regard to the use of AMPs for contraventions under the SFCA and its regulations?

Requirements for Fresh Fruit and Vegetable Dealers

Fair trading practices within the fresh fruit and vegetable industry are particularly important due to the perishable nature of the food commodity. Currently under the *Licensing and Arbitration Regulations* (LARs) fresh fruit and vegetable dealers are required to have a licence from the CFIA. An exemption from the LARs' licensing requirement applies for members of the Fruit and Vegetable Dispute Resolution Corporation (DRC). The purpose of licensing under the LARs or membership with the DRC is to ensure that fresh fruit and vegetable dealers are financially sound and have acceptable business histories (e.g., making payments). The LARs are an anomaly among CFIA regulations and do not contain any food safety or consumer protection components.

The Canadian fresh fruit and vegetable industry has recommended to the Government of Canada, under the auspices of the Canada-US Regulatory Cooperation Council, that the current licensing regime

under the LARs be replaced by a system whereby conditions for orderly trade are established and enforced by a non-government body. The Canadian fresh fruit and vegetable industry believes that such an approach would improve financial protection for industry; more effectively address unscrupulous trade behaviours and better align with the system in the United States

The CFIA agrees that this role should reside with industry. As such, it is proposed to replace the LARs with a requirement for fresh fruit and vegetable dealers to be members of a non-government body with a mandate to facilitate orderly trade in the industry.

The DRC was established to harmonize orderly trade conditions across North America and provide members with a contract and payment dispute settlement service. Over 80% of the Canadian fresh fruit and vegetable dealers are members of the DRC. As such, consideration could be given to whether the DRC should be the entity selected as the appropriate non-government body with whom membership would be required.

Question 28: Do you support the proposed approach of industry providing arbitration of fair trade practices for fresh fruit and vegetable dealers?

Question 29: Under what conditions should an entity be selected to carry on this function?

Question 30: Do you support the identification of the DRC as the entity for this function?

Organic Products Regulations, 2009

The *Organic Products Regulations, 2009* (OPR) provide the authority to certify organic products and the packaging and labelling of organic products, and were promulgated in 2009 following extensive industry engagement. They incorporate by reference industry-developed Canadian Standards (CAN/CGSB 32.310 and 32.311) and provide for the designation of conformity verification bodies and accreditation certification bodies who provide organic certification. The OPR have also been the basis for a number of equivalency arrangements with foreign countries regarding the trade of organic products.

The OPR do not currently cover aquaculture given that aquaculture products did not meet the definition of "agricultural products" under CAPA when they were first developed. Now that the regulations are moving under the SFCA that applies to all food commodities, consideration can be

given to including an aquaculture standard in the regulations. Additionally, at the time the OPR were first developed, aquaculture products did not have a technical standard within the Canadian General Standards Board (CGSB) Organic Standards.

The Department of Fisheries and Oceans Canada sponsored a technical working group to develop an Organic Standard for Aquaculture through the CGSB process. The CGSB Aquaculture Organic Standard is now published. Given that the SFCA provides the authority to regulate aquaculture products, the new regulations represent an opportunity to include them.

It is proposed that existing organic products requirements be extended to aquaculture products.

Question 31: What are your comments on the proposed approach to extend the requirements for organic products to aquaculture products?

Support for Small Businesses

The proposed regulatory framework encompasses all food commodities and introduces new requirements for licensing and PCPs.

Although PCPs are adaptable to the size and complexity of the operations, they will represent a new requirement for many businesses that have not previously been subject to the licensing or registration schemes under CAPA, FIA and MIA. This may be a particular challenge for small businesses.

The CFIA is proposing the following to help small businesses not previously subject to licensing or registration requirements under CAPA, FIA and MIA adapt:

- Clear guidance documents, including `model systems`
- Sample PCP for small businesses

Question 32: What other accommodations could be made, in regulation or in program design, to support small businesses?

Review & Report

Regular reviews of the effectiveness of regulations and legislation are an important feature of modern regulatory systems.

The Safe Food for Canadian Act (SFCA) requires the review of provisions and operation of the Act five years after coming into force, and every five years thereafter, including an assessment of the resources allocated to its administration and enforcement.

The CFIA is considering a regular review of the proposed food regulations at the same time as the review of the SFCA. This would provide a comprehensive assessment of the legislative framework and contribute to an overall assessment of system performance.

Question 33: Do you support the approach to conduct reviews of regulations on a regular 5 year cycle?

Conclusion

The coming years will be a time of change, challenge, and opportunity as Canada moves forward in the development of the proposed regulations that will strengthen protection of Canada's food supply. While the current regime works well, it reflects outdated regulated frameworks and does not achieve the full integration of inspection approaches envisioned when the CFIA was created. The regulatory system that is both science and risk-based will continue to be effective and efficient. Success will be built through careful planning and engagement of CFIA staff and stakeholders, including other federal departments, provinces, and industry.

The success of this undertaking will depend on the participation of all food stakeholders in the development of the new regime and new approaches. This document represents an invitation to provide candid feedback and perspectives as we develop the draft of proposed food regulations.

Next Steps

Written comments regarding any element of this paper are invited and should be forwarded by November 30, 2013 to:

Food Regulatory Modernization
Canadian Food Inspection Agency
1400 Merivale Road, T1-4-327
Ottawa, Ontario
K1A 0Y9

Comments can also be emailed to cfia-Modernisation-acia@inspection.gc.ca

Annex 1: Proposed Regulatory Requirements (Outcome- Based)

1 - Processes and Products Requirements

1.1 Process Control

1.1.1 Incoming ingredients/materials, live animal for slaughter and packaging materials

- Incoming ingredients, live animal for slaughter, raw materials and packaging materials, including rework materials used to make a food commodity shall be managed to prevent contamination of the food commodity and labelling inaccuracies.

1.1.2 Product formulations and specifications

- For each food commodity being manufactured, there shall be a written formula as well as specifications for each finished food commodity.
- All factors in the product formulation that may be critical to the product's composition, nutritional profile, labelling and safety shall be identified and managed.
- Only food additives, nutrients, and chemicals permitted for use in the food commodity as prescribed in these regulations and the FDR shall be used.
- Foods for which grades and standards are prescribed in these regulations shall contain only the ingredients prescribed in these regulations and the FDR.
- Food commodities shall be formulated and labelled to comply with applicable Canadian legislation.
- Conditions under which rework may be safely used shall be identified.

1.1.3 Process Design and Control

- Each process is designed to produce safe food that is accurately labelled and meets all regulatory requirements including composition. This shall be demonstrated / validated using scientific methods
- Each process is documented with a written description which shall include a description of the processing steps, associated control measures and critical limits and be specific for each equipment, food commodity, container size and type.

- All critical processing factors identified in the written documentation shall be managed to meet the safety, compositional integrity and labelling requirements
- The written documentation shall be updated whenever changes are made to the system

1.2 Product Control Requirements

1.2.1 Packaging Control

- Handling and use of packaging materials during processing is managed.
- Packaging materials suitable for the intended purpose shall be used.
- Contaminated, damaged or defective packaging materials shall not be used

1.2.2 Product Coding and Labelling Control

- Each food commodity shall be marked with a code mark on the label or container
- The code mark shall be applied in a legible and permanent manner.
- The exact meaning of the code shall be available to the inspector
- Application of codes shall not compromise the integrity of the container
- Cases / shipping containers shall be coded in a manner that represents the container codes within
- Labels shall match the food commodity

1.2.3 Finished Product Evaluation

- Finished products shall be evaluated to confirm compliance with prescribed safety, compositional and labelling requirements.

2 - Sanitation and Pest Control Requirements

2.1 Sanitation Program

- Equipment including food contact and non-food contact surfaces, utensils and premises, shall be maintained in a clean and sanitary condition

2.2 Detergents, Sanitizers and Chemicals

- Managed by personnel with competencies appropriate to the activity and in accordance with manufacturers' instructions.

- Stored in identified containers and locations.

2.3 Pest Control Program

- Entry of pests into the facility shall be prevented and there shall be a system in place to detect and eliminate pests
- No animals, other than those intended for slaughter for food, shall be allowed entry into an establishment.
- Assistance animals shall be permitted only in non-processing areas.

3 - Hygiene and Competencies Requirements

3.1 Clothing and Footwear

- Every person who enters or is in any area of an establishment where a food commodity is prepared shall:
  - wear protective clothing, footwear and coverings fit for purpose;
  - take measures to prevent their body, anything from their body, and anything they are wearing from contaminating food or surfaces likely to come into contact with food.

3.2 Hygienic Practices and Behaviour

- Every person engaged in the preparation of a food product shall:
  - maintain personal cleanliness and take measures to prevent contamination of food;
  - refrain from behaviours which could result in contamination of food;
  - wash their hands at any time when personal cleanliness may affect food safety;
  - avoid unnecessary contact with ready-to-eat food;
  - sanitize their hands where direct food contact is unavoidable.

3.3 Health

- No person who is suffering from or is a known carrier of a communicable disease which is transmissible through food or who has an open or infected lesion shall work in any area of a food establishment where there is a danger of contaminating a food product, or a surface with which a food product comes into contact.
- Any person in a food establishment who has or appears to have symptoms of a disease or illness that could be transmitted through a food product shall report the symptoms, disease or illness to the licence holder.

- Upon being notified of a disease or illness the licence holder shall determine whether the person must undergo a medical examination or be excluded from certain areas of the food establishment.

3.4 Competency

- Persons undertaking or supervising food handling operations, maintenance and calibration or responsible for PCPs shall have competencies in food safety, manufacturing and food hygiene matters

4 - Equipment Design and Maintenance Requirements

4.1 General Equipment

- Equipment, including food and non-food contact surfaces, instruments and utensils, including single service, shall be designed, constructed, installed and validated to function consistently as intended, to permit effective cleaning, maintenance and sanitation and to prevent contamination of food or food packaging materials.
- Equipment, instruments and utensils shall be made of materials that do not contaminate or damage the food or food packaging materials, when used as intended, and are capable of withstanding repeated cleaning, and, as applicable, sanitizing and disinfection.
- Equipment, instruments and utensils including containers used to handle inedible or contaminated materials shall be identified and shall not be used to handle food products.
- Equipment shall be fitted, where necessary, with the appropriate control device(s).

4.2 Maintenance and Calibration of Equipment

- Equipment and instruments shall be maintained and calibrated to perform consistently as intended.

5 - Physical Structure and Maintenance Requirements

5.1 Building Exterior Requirements- Outside Property and Building

- Buildings and areas surrounding the establishment shall:
    - not be in such proximity to any source of pollution or any place that harbours insects, rodents or other vermin or any similar thing that is likely to contaminate food commodities.
    - be situated on land that:
        - is free of debris and refuse,

        - permits good drainage, and prevents standing or pooled water, and
        - has surfaces that are hard, smooth and impervious to moisture.
    - be designed, constructed and maintained in a manner to prevent conditions which may result in the contamination of a food commodity or packaging material.

5.2 Building Interior Requirements: Design, Construction and Maintenance

- Building interior, including storages and interior structures, shall be designed, constructed and maintained in a manner to prevent conditions which may result in the contamination of a food commodity or packaging material.

5.2.1 Floors, Walls, Ceilings

- Floors, walls, and ceilings shall be constructed of material that is suitable for the production conditions and are durable, impervious to moisture, smooth, cleanable.
- Floors shall be designed to prevent standing or pooled water.

5.2.2 Windows and Doors

- Windows and doors shall be designed and constructed to :
    - prevent contamination of food,
    - limit direct access to processing areas, and
    - prevent the entry of pests.

5.2.3 Process Flow Separation

- Separation of activities or incompatible operations shall be provided by physical or other effective means where cross contamination may result.
- Establishments shall be designed and constructed to provide space for equipment to facilitate maintenance and hygienic operations by means of a controlled flow in the process from the arrival of the raw material at the establishment to the finished product.

5.2.4 Lighting

- Natural or artificial lighting, of an intensity suitable to the operation shall be provided.
- Lighting shall not be such that the resulting colour is misleading.

- Lighting fixtures shall be protected to ensure that food is not contaminated in the event of breakage.

5.2.5 Air Quality and Ventilation

- Natural or mechanical ventilation shall provide sufficient air exchange to prevent unacceptable accumulations of steam, condensation or dust and to remove contaminated air.
- Ventilation systems shall be designed and constructed so that air does not flow from contaminated areas to clean areas.
- If air is used in direct contact with food or packaging materials it shall be hygienically sourced and treated.

5.2.6 Sanitary Facilities

5.2.6.1 Employee facilities

- Employee facilities including hand washing stations, lavatories, lunch and change rooms shall be designed, constructed, maintained and suitably located to permit effective employee hygiene and to prevent contamination.
- Facilities for handwashing shall be provided with hot and cold running water, materials for cleaning hands and means for hygienic drying.

5.2.6.2 Cleaning and Sanitizing Facilities

- Cleaning and sanitizing facilities shall be designed, constructed, maintained and located to prevent contamination.

5.2.7 Other Facilities

5.2.7.1 Facilities for animal holding and slaughter

- Receiving and holding facilities for animal for slaughter shall allow the segregation of animals as necessary to achieve safe and humane conditions.
- Slaughter establishment shall be equipped with facilities for:
    - restraining animals for slaughter for detailed inspection,
    - conveying injured or disabled animals for slaughter in a humane manner, and

- slaughtering animals that have been identified as condemned.

5.2.7.2 Facilities for receiving and storing returned or recalled products

- Facilities for receiving and storing returned or recalled products shall permit segregation, appropriate storage conditions and areas for re-inspection.

5.2.7.3 Facilities for CFIA staff

- Where CFIA staff have a continuous presence in an establishment there shall be access to showers, dressing rooms, lavatories and lockers and an office suitably equipped for use by CFIA inspection staff.

- If grading or inspection is required by CFIA staff the establishment shall provide suitable facilities .

5.3 Water/Ice/Steam

- The quality and safety of water, ice and steam in direct contact with food or food contact surfaces is controlled to prevent contamination.

- Water shall be potable or clean and shall be suitable for the process being undertaken.

- Water, ice and steam shall be sampled, tested and analyzed to confirm their safety for the intended purpose.

- Hot and cold potable water, ice and steam supply shall be protected against contamination and supply shall be adequate to meet operational requirements.

- There shall be no cross-connections between potable and non-potable water supplies and means must be provided prevent back-flow or back-siphonage.

- Water and ice storage facilities shall be adequately designed constructed and maintained to prevent contamination.

- Water and steam including re-circulated water, when treated, shall be treated, monitored and maintained as appropriate for the intended purpose. Treatment chemicals, where used, shall be safe and used at concentrations as per the manufacturer's recommendations.

- Ice used as an ingredient or in direct contact with food shall be made from potable water.

- Water other than potable or clean water may be used for fire protection, boilers or auxiliary services where there is no connection between the system for that water and the system for potable / clean water.

5.4 Waste Management Treatment and Disposal Requirements

- Sewage, effluent and waste storage, treatment and disposal systems:
    - Receptacles for the storage of waste and inedible material, prior to removal from the establishment, shall meet operational needs and shall be identified.
    - Waste shall not be allowed to accumulate in food handling, food storage, and other working areas and the adjoining environment except so far as is unavoidable for the proper functioning of the business.
    - Food processing waste and inedible materials shall be segregated and labelled "inedible-not for human consumption" so as not to be mistaken for food destined for human consumption.

6 - Receiving, Transportation and Storage Requirements

- Food commodities and packaging materials shall be transported, received and stored under conditions that prevent damage, spoilage and contamination.
- Carriers used to transport food commodities or packaging materials shall be designed, constructed, maintained, cleaned and utilized in a manner to prevent food contamination.
- Food commodities requiring temperature and humidity controls shall be received, stored and transported in a manner to prevent abuse that could result in deterioration affecting food safety and quality.
- A licence holder shall not permit a food commodity, food packaging material or any other substance into their establishment unless:
    - it is received into an area separate from the processing area.
    - it meets the requirements of these regulations and the Food and Drug Regulations.
    - in the case of a returned or recalled food commodity, it is clearly identified and isolated in a designated area for disposition.
- Food intended to be used as rework shall be clearly identified and stored in a designated area.
- A stock rotation system shall be implemented to prevent deterioration and spoilage food commodities and packaging materials.

7 - Recalls, Complaints, and Record-Keeping Requirements

7.1 Recall

Every licence holder shall

- develop, implement and maintain written procedures for the recall of food products.
- develop and maintain any product distribution records that are necessary to facilitate the location of products in the event of a product recall.
- review the product recall procedures and shall conduct a product recall simulation at least once a year.
- make available to the inspector, in a readily accessible format and location, a copy of the product recall procedures, the results of the product recall simulations for the previous year and the product distribution records for at least one year after the expiry date on the label or container or if there is no expiry date, for at least two years after the date of sale.

7.2 Complaints

Every licence holder shall prepare written procedures and maintain records for receiving, investigating and responding to to food safety and product misrepresentation complaints.

7.3 Record-Keeping

All records associated with the preventive control plan shall:

- be legible, permanent and accurately reflect the actual event, condition or activity.
- have errors or changes identified in a manner such that the original record is clear.
- have each entry made by the responsible person at the time that the specific event occurred.
- once completed, be signed and dated by the responsible person and be reviewed at an appropriate frequency to provide an early indication of potentially serious deficiencies.
- in the case of critical records, be signed by a qualified designated individual prior to distribution of product, (e.g., records related to the adequacy of the thermal process and the achievement of a hermetic seal).

- be retained for at least one year after the expiry date on the label or container or if there is no expiry date, for at least two years after the date of sale.
- be available upon request.

Annex 2: Proposed Regulatory Requirements (Outcome-Based) for Primary Production of Fresh Produce

Fresh Produce includes fresh fruit and vegetables, edible fungi, nuts, fresh herbs, sprouts and edible flowers that grown in the field (with or without cover) or in protected facilities (e.g., hydroponic systems, greenhouses, mushrooms, sprouts).

1 - Processes and Products Requirements

1.1 Primary Production Control

1.1.1 Agricultural Inputs and Packaging Material

- Agricultural inputs and packaging material used in the primary production of fresh produce shall be managed to prevent contamination of fresh produce and labelling inaccuracies.

1.1.2 Primary Production Design and Control

- Primary production shall be designed to result in the production of safe produce that is accurately labelled and meets all regulatory requirements, including grade standards. This shall be demonstrated / validated using scientific methods.
- The steps involved in primary production shall be documented with a written description which shall include:
  - a description of all the steps and agricultural inputs involved;
  - associated control measures and critical limits; and
  - be specific for each equipment and commodity produced.
- All critical factors identified in the written documentation shall be managed to meet safety and labelling requirements.
- The written documentation shall be updated whenever changes are made to the system.

1.1.2.1 Growing

- Fresh produce shall be grown in a manner to prevent contamination.
- Agricultural inputs shall be managed to prevent contamination of the fresh produce and the growing environment.

1.1.2.2 *Harvesting*

- Harvest shall be timed to prevent contamination of fresh produce.
- Fresh produce shall be harvested in a manner to prevent contamination.

1.1.2.3 *Packing, including field-packing*

- Only food additives and chemicals permitted for use in the fresh produce as prescribed in the FDR shall be used.
- Fresh produce shall meet the grades and standards as prescribed in these regulations.
- Fresh produce shall be packaged and labelled in a manner to prevent contamination and labelling inaccuracies.

1.2 Product Control Requirements

1.2.1 Packaging Control

- Handling and use of packaging materials is managed.
- Packaging materials suitable for the intended purpose shall be used.
- Contaminated, damaged or defective packaging materials shall not be used.

1.2.2 Product Coding and Labelling Control

- Packaging material shall be marked with a code mark.
- The code mark shall be applied in a legible and permanent manner.
- The exact meaning of the code shall be available to the inspector.
- Application of codes shall not compromise the integrity of the packaging material.
- Cases/shipping containers shall be coded in a manner that represents the code mark on the packaging material within.
- Labels shall match the fresh produce.

1.2.3 Finished Product Evaluation

- Finished products shall be evaluated to confirm compliance with prescribed safety and labelling requirements.

2 - Sanitation and Pest Control Requirements

2.1 Sanitation Program

- Equipment including food contact and non-food contact surfaces, utensils and premises, shall be maintained in a clean and sanitary condition.

2.2 Detergent, Sanitizer and Chemical

- Shall be managed by personnel with competencies appropriate to the activity and in accordance with manufacturers' instructions.
- Shall be stored in identified containers and locations.

2.3 Pest Control Program

- Entry of pests into indoor production facilities shall be prevented and there shall be a system in place to detect and eliminate pests.
- No animals are allowed in indoor production facilities.
- Assistance animals are only permitted in non-production areas.

3 - Hygiene and Competencies Requirements

3.1 Clothing and Footwear

- Every person who enters in the production and preparation site of fresh produce shall:
    - wear protective clothing, footwear and coverings fit for purpose.
    - take measures to prevent their body, anything from their body, and anything they are wearing from contaminating fresh produce or surfaces likely to come into contact with fresh produce.

3.2 Hygienic Practices and Behaviour

- Every person who enters production and preparation sites of fresh produce shall:
    - maintain personal cleanliness and take measures to prevent contamination of fresh produce;
    - refrain from behaviours which could result in contamination of fresh produce;
    - wash their hands at any time when personal cleanliness may affect the safety of fresh produce;

- avoid unnecessary contact with fresh produce;
- sanitize their hands where direct contact with fresh produce is unavoidable.

3.3 Health

- No person who is suffering from or is a known carrier of a communicable disease which is transmissible through food or who has an open or infected lesion shall work in any area of a food establishment where there is a danger of contaminating the fresh produce, or a surface with which the fresh produce comes into contact.
- Any person in a primary production or packing site who has or appears to have symptoms of a disease or illness that could be transmitted through a food product shall report the symptoms, disease or illness to the to the licence holder.
- Upon being notified of a disease or illness the licence holder shall determine whether the person must undergo a medical examination or be excluded from certain areas of primary production and packing.

3.4 Competency

- Persons undertaking or supervising the primary production of fresh produce, maintenance and calibration of equipment or responsible for the preventive control plan, shall have competencies in food safety, hygiene and production practices.

4 - Equipment Design and Maintenance Requirements

4.1 General Equipment (including instrumentation and portable equipment)

- Equipment, including food and non-food contact surfaces, instruments and utensils, including single service, shall be designed, constructed, installed and validated to function consistently as intended, to permit effective cleaning, maintenance and sanitation and to prevent contamination of fresh produce or its packaging materials.
- Equipment, instruments and utensils shall be made of materials that do not contaminate or damage the fresh produce or its packaging materials, when used as intended, and are capable of withstanding repeated cleaning, sanitizing and disinfection.
- Equipment, instruments and utensils including containers used to handle inedible or contaminated materials shall be identified and shall not be used to handle fresh produce.
- Equipment shall be fitted, where necessary, with the appropriate control device(s).

4.2 Maintenance and Calibration

- Equipment and instruments shall be maintained and calibrated to perform consistently as intended.

5 - Environment, Physical Structure and Maintenance Requirements

5.1 Environment

- Production areas shall take place on land:
    - that is not contaminated or in such proximity to any source of pollution that is likely to contaminate food commodities.
    - where domestic and wild animals are excluded to the extent possible.

5.2 Building Exterior– Outside Property and Building [indoor production]

- Buildings and areas surrounding the establishment shall:
    - not be in such proximity to any source of pollution or any place that harbours insects, rodents or other vermin or any similar thing that is likely to contaminate food commodities;
    - be situated on land that:
        - is free of debris and refuse;
        - permits good drainage, and prevents standing or pooled water; and
        - has surfaces that are hard, smooth and impervious to moisture.
    - be designed, constructed and maintained in a manner to prevent conditions which may result in the contamination of fresh produce or its packaging material.

5.3 Building Interior [indoor production]

- Building interior, including storages and interior structures, shall be designed, constructed and maintained in a manner to prevent conditions which may result in the contamination of fresh produce or its packaging material.

5.3.1 Floors, Walls, Ceilings

- Floors, walls, and ceilings shall be constructed of material that is durable, cleanable, and suitable for the production conditions in the area.
- Floors shall have drainage that prevents standing or pooled water.

5.3.2 Windows and Doors

- Windows and doors shall be designed and constructed to:
    - prevent contamination of fresh produce;
    - limit direct access to processing areas; and
    - prevent the entry of pests.

5.3.3 Process Flow Separation

- Separation of activities or incompatible operations shall be provided by physical or other effective means where cross contamination may result.
- Establishments shall be designed and constructed to provide space for equipment to facilitate maintenance and hygienic operations by means of a regulated flow in the process from the arrival of the raw material at the establishment to the finished product.

5.3.4 Lighting

- Natural or artificial lighting, of an intensity suitable to the operation shall be provided.
- Lighting shall not be such that the resulting colour is misleading.
- Lighting fixtures shall be protected to ensure that food is not contaminated in the event of breakage.

5.3.5 Air quality and ventilation

- Natural or mechanical ventilation shall provide sufficient air exchange to prevent unacceptable accumulations of condensation or dust and to remove contaminated air.
- Ventilation systems shall be designed and constructed so that air does not flow from contaminated areas to clean areas.
- If air is used in direct contact with food or packaging materials it shall be hygienically sourced and treated.

5.3.6 Sanitary Facilities [indoor and outdoor production]

5.3.6.1 Employee facilities

- Employee facilities including hand washing stations, lavatories, lunch and change rooms shall be designed, constructed, maintained and suitably located to permit effective employee hygiene and to prevent contamination.
- Facilities for hand-washing shall be provided with hot and cold running water, materials for cleaning hands and means for hygienic drying.

5.3.6.2 Cleaning and Sanitizing Facilities

- Cleaning and sanitizing facilities shall be designed, constructed, maintained and located to prevent contamination.

5.3.7 Other Facilities

5.3.7.1 Facilities for receiving and storing returned or recalled products

- Facilities for receiving and storing returned or recalled products shall permit segregation, appropriate storage conditions and areas for re-inspection.

5.3.7.2 Facilities for CFIA staff

- If grading or inspection is required by CFIA staff the establishment shall provide suitable facilities.

5.4 Water and Ice

- The safety and quality of water and ice shall be controlled to prevent contamination.
- Water and ice shall be potable or clean and shall be suitable for the process being undertaken.
- Water and ice shall be sampled, tested and analyzed to confirm their safety for the intended purpose.
- Hot and cold potable water and ice supply shall be protected against contamination and supply shall be adequate to meet operational requirements.
- There shall be no cross-connections between clean, potable, and non-potable water supplies and means must be provided to prevent back-flow or back-siphonage.
- Water delivery systems are maintained, cleaned and stored in a manner to prevent contamination.

- Water and ice storage facilities shall be adequately designed, constructed and maintained to prevent contamination.
- Water, including re-circulated water, when treated, shall be treated, monitored and maintained as appropriate for the intended purpose. Treatment chemicals, where used, shall be safe and used at concentrations as per the manufacturer's recommendations.
- Water other than potable or clean water may be used for fire protection, boilers or auxiliary services where there is no connection between the system for that water and the system for potable / clean water.

5.5 Waste Management and Disposal

- Sewage, effluent and waste storage, treatment and disposal systems:
    - Receptacles for the storage of waste and inedible material, prior to removal from the production site or establishment, shall meet operational needs and shall be identified.
    - Waste shall not be allowed to accumulate in production, handling, storage sites and other working areas and the adjoining environment except so far as is unavoidable for the proper functioning of the business.
    - Primary production waste and inedible materials shall be segregated and labelled "inedible-not for human consumption" so as not to be mistaken for food destined for human consumption.

6 - Receiving Transportation and Storage Requirements

- Fresh produce and packaging materials shall be transported, received and stored under conditions that prevent damage, spoilage and contamination.
- Carriers used to transport fresh produce or packaging materials shall be designed constructed, maintained, cleaned and utilized in a manner to prevent food contamination.
- Fresh produce requiring temperature and humidity controls shall be received, stored and transported in a manner to prevent abuse that could result in deterioration affecting food safety and quality.
- Fresh produce that is returned or recalled is allowed back into the primary production site or its surrounding environment if it is clearly identified and isolated in a designated area for disposition.
- A stock rotation system shall be used to prevent deterioration and spoilage of fresh produce and damage to/contamination of packaging material.

7 - Recalls, Complaints, and Record-Keeping Requirements

7.1 Recall

Every licence holder shall:

- develop, implement and maintain written procedures for the recall of food products.
- develop and maintain any product distribution records that are necessary to facilitate the location of products in the event of a product recall.
- review the product recall procedures and shall conduct a product recall simulation at least once a year.
- make available to the inspector, in a readily accessible format and location, a copy of the product recall procedures, the results of the product recall simulations for the previous year and the product distribution records for at least one year after the expiry date on the label or container or if there is no expiry date, for at least two years after the date of sale.

7.2 Complaints

Every licence holder shall prepare written procedures and maintain records for receiving, investigating and responding to food safety and product misrepresentation complaints.

7.3 Record-Keeping

All records associated with the preventive control plan shall:

- be legible, permanent and accurately reflect the actual event, condition or activity.
- have errors or changes identified in a manner such that the original record is clear.
- have each entry made by the responsible person at the time that the specific event occurred.
- once completed, be signed and dated by the responsible person and be reviewed at an appropriate frequency to provide an early indication of potentially serious deficiencies.
- in the case of critical records, be signed by a qualified designated individual prior to distribution of product, (e.g., records related to the adequacy of the thermal process and the achievement of a hermetic seal).
- be retained for at least one year after the expiry date on the label or container or if there is no expiry date, for at least two years after the date of sale.
- be available upon request.

Annex 3: Examples of varying requirements for labelling of grade names

Product	Canadian Grade Name	Equivalent Import Grade name	Minimum Type Size	Location	Language	Shape or Outline
Cartons, and trays of eggs with an overwrap	CANADA A	equivalent grade designation of the exporting country	"CANADA": 1.5 mm grade letter: 3 mm import grade name: 3 mm	Top	Both English and French	if A or B, must be shown inside the outline of a maple leaf
	CANADA B					
	CANADA C	equivalent grade designation of the exporting country	1.5 mm			
	CANADA NEST RUN					
Prepackaged Honey	Canada No. 1	No. 1	Based on the size of the Principal Display Surface (PDS) – accompanying table	Principal Display Panel (PDP)	Both English and French	N/A
	Canada No. 2	No. 2				
	Canada No. 3	No. 3				
Certain prepackaged Fresh Fruit and Vegetables	21 grade names (e.g. Canada Extra Fancy, Canada Fancy)	21 equivalent import grade names (e.g. Extra Fancy Grade, Fancy Grade)	1.6 mm	Principal Display Panel (PDP)	Both English and French	N/A
Certain prepackaged fish and seafood products	50 grade names (e.g. Choice, Standard)	Same as Canadian grade name	if 900 g or less: 3.2 mm	main panel (i.e. PDP)	Either English or French	N/A
Individually wrapped processed poultry	CANADA A	GRADE A	same proportion as illustrated in Schedule I grade letter: bold face with a height according to section 65(1) and 65(2) Must also be shown in a certain colour	immediately on or over anterior centre of breast of poultry	Both English and French	must be shown inside the outline of a maple leaf and correct colour
	CANADA C	GRADE C				
	CANADA UTILITY UTILITÉ	GRADE UTILITY UTILITÉ				
Possible New Approach	**Maintain as is in a "Grade" section or, possibly document incorporated by reference**		**Must be shown in a manner that is legible to the consumer under normal conditions.**	**On any panel except the bottom**	**In both English and French**	**Eliminate (Industry can continue to use if they wish)**

Annex 4: Glossary of Terms

This glossary of terminology is designed to standardize the language used and support consistent interpretation of terminology in the proposed regulatory framework under the SFCA.

Terminology	Definition
A	
Applicant *(Demandeur)*	Any person who applies for a licence, exemption or certificate.
C	
CanadaGAP™	CanadaGAP™ is a food safety program for companies that produce, pack and store fruits and vegetables.
Certification *(Certification)*	Written assurance from a competent authority that foods or preventive control systems conform to requirements.
Codex	*Codex Alimentarius* or *Codex Alimentarius Commission*
Coming into force	Coming into force or entry into force (also called enactment) refers to the process by which legislation, regulations, and other legal instruments come to have legal force and effect. For more information, please see this Department of Justice website: http://www.justice.gc.ca/eng/dept-min/pub/legis/rm-mr/part4/cif_orders-decret.html
Contaminant (*Contaminant*)	Any biological, physical, chemical agents or other substances that are present in food and that compromise food safety or suitability.
Contamination *(Contamination)*	The presence of any contaminant in food or food contact surfaces.
Control measure *(Mesure de contrôle)*	Any action or activity that can be used to prevent[1] or eliminate a food safety hazard or reduce it to an acceptable level. *(Hazard Analysis and Critical Control Point System and Guidelines for Its Application, Annex to CAC/RCP 1-1969 (Rev.4 – 2003), FAO/CODEX)*

[1] See “Preventive Control Program” definition.

Corrective action *(Mesure corrective)*	The steps that a regulated party takes to address non-compliance, which can include controlling affected product, conducting root cause analysis and preventing recurrence.
Cross contamination *(Contamination croisée)*	A situation that occurs when hazards that are carried by utensils, equipment, surfaces or food handlers are transferred from one food, ingredient or surface to another.
E	
Employee *(Employé)*	A person who is employed by a food operation or establishment.
Establishment *(Établissement)*	Any place, including a conveyance, where a food commodity is manufactured, prepared, stored, packaged or labelled. *(Safe Food for Canadians Act)*
Export	For the purposes of this paper, export is sending food commodities from Canada to another country.
Exporter *(Exportateur)*	Any person who sells or trades food from Canada to another country.
F	
Food Commodity *(produit alimentaire)*	(a) Any food as defined in section 2 of the *Food and Drugs Act*; (b) Any animal or plant, or any of its parts, from which food referred to in paragraph (a) may be derived; or (c) Anything prescribed to be a food commodity. *(Safe Food for Canadians Act)*
G	
Grade name *(nom de catégorie)*	A prescribed name, mark or designation of a food commodity. *(Safe Food for Canadians Act)*
I	
Import	For the purposes of this paper, import is bringing food commodities into Canada from another country.

Importer *(Importateur)*	Any person in Canada who imports food commodities into Canada.
Ingredient *(Ingrédient)*	An individual unit of food that is combined as an individual unit of food with one or more other individual units of food to form an integral unit of food that is sold as a prepackaged product. (*Food and Drug Regulations)*
Inspection mark (sceau d'inspection)	A prescribed mark, stamp, seal, product legend, word or design or any combination of those things. *(Safe Food for Canadians Act)*
Inter-provincial	For the purposes of this paper, inter-provincial means sending or conveying food commodities from one province or territory to another in Canada, crossing provincial or territorial boundaries.
L	
Label *(étiquette)*	"Label" includes a legend, word or mark that is or is to be applied or attached to or included in, or that accompanies or is to accompany, a food commodity or a package. *(Safe Food for Canadians Act)*
M	
Monitoring *(Suivi)*	The act of conducting a planned sequence of observations or measurements of control parameters to assess whether a control measure is under control. *(Codex)*
O	
Oversight *(Surveillance des parties réglementées)*	Inspection activities designed to determine whether a regulated party is complying with Acts and regulations administered or enforced by the CFIA.
P	
Package (emballage)	An inner or outer receptacle or covering used or to be used in connection with a food commodity and includes a wrapper or confining band. *(Safe Food for Canadians Act)*
Pests *(Organismes nuisibles/parasites)*	Any animal, plant, fish or insect of public health importance including, but not limited to, birds, rodents, roaches, flies and larvae that may carry pathogens that can contaminate foods.

Premises *(Lieux)*	The lands, buildings and facilities where food is prepared.
Prepare *(Conditionnement)*	In respect of a food commodity, includes to process, treat, preserve, handle, test, grade, code or slaughter it or to do any other activity in respect of it that is prescribed. *(Safe Food for Canadians Act)*
Preventive control plan (PCP) *(Plan de contrôle préventif)*	A combination of control measures[2] that, when taken as a whole, provide for a science-based approach to managing risks posed by hazards and contribute to achieving compliance to other regulatory requirements.
Primary producer *(Producteur primaire)*	A person who cultivates, grows, produces, raises, picks or harvests agricultural products or fishery products and does not alter the nature of the raw product.
R	
Ready-to-eat food (RTE) *(aliment prêt-à-manger)*	(a) do not require any further preparation or cooking before consumption, except perhaps washing/rinsing, thawing or warming for aesthetics or palatability (b) are in a form that is edible without additional preparation to achieve food safety (c) are ordinarily consumed in the same state as that in which they are sold
Regulated party *(Partie réglementée)*	A person (including an individual, corporation, partnership or organization) carrying on business in Canada who is subject to the Acts and regulations administered by the CFIA.
Regulation-making authority	"Any authority authorized to make regulations and, with reference to any particular regulation or proposed regulation, means the authority that made or proposes to make the regulation." (Excerpt from the Statutory Instruments Act)
Requirements *(Exigences)*	The criteria set down in acts or regulations administered or enforced by the CFIA.
Review mechanism	The enabling powers in legislation that will allow food producers to request the review of a CFIA decision on their product.

[2] See "Control measure" definition.

Risk *(Risque)*	A function of the probability of an adverse health effect and the severity of that effect, consequential to a hazard(s) in food. *(CODEX Procedural Manual, 20th Edition, FAO, 2011)*
Risk-based inspection *(Inspection fondée sur le risque)*	A method for using risk to prioritize and manage inspection efforts.
S	
Sell	Includes agree to sell, offer for sale, expose for sale or have in possession for sale – or distribute to one or more persons whether or not the distribution is made for consideration. *(Safe Food for Canadians Act)*
Surveillance *(Surveillance)*	The collection, analysis and interpretation of food sampling and inspection information to establish baseline data or identify trends.
V	
Verification *(Vérification)*	The application of methods, procedures, tests and other evaluations, in addition to monitoring, to determine whether the control measure is or has been operating as intended. *(CODEX, Guidelines for validation of food safety control measures, CAC/GL 69-2008)*
Violation *(Infraction)*	Any contravention of the acts or regulations administered or enforced by the CFIA or any refusal or neglect to perform any duty imposed by or under the acts or regulations.