A New Regulatory Framework for Federal Food Inspection:

THE CANADIAN FOOD INSPECTION AGENCY'S FOOD SAFETY REGULATORY FORUM

Overview of Proposed Regulations

Canadian Food Inspection Agency
Agence canadienne d'inspection des aliments

Canada

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Preface

Recent decades have seen significant changes in the global food environment. Over 70% of processed food and fresh fruit and vegetables are now imported into Canada. An increasingly global marketplace for food commodities means that there are more opportunities for the introduction and spread of contaminants. 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. Global commerce and consolidation in the food sectors have led to new business models that have effectively changed the makeup of the industry. At the same time, the food industry is pioneering new approaches to traceability, third party certification, and other ways to make food safer.

In response to these and other developments, governments around the world are rethinking their approach to food safety and consumer protection, including renewing legislative frameworks and better leveraging oversight resources.

Canada has one of the best food safety systems in the world. However, continuous improvement is needed not only to maintain the existing levels of food safety, but to drive the system to be even more effective at prevention of food risks to consumers and, when necessary, allow for a rapid response to food safety incidents.

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. The legislation, which will come into force with the adoption of new regulations, marks the first step in the transformation of Canada's food safety system.

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 to better manage risks facing Canadian families. The Plan represents an ambitious transformation agenda in four strategic areas:

- Stronger food safety rules
- More effective inspection
- Renewed commitment to service

- More information for consumers

The Action Plan is a key component of the Healthy and Safe Food for Canadians Framework introduced by the Government of Canada in October 2013 to inform consumers about healthy and safe food choices, to minimize food safety risks, and to protect Canadians when unsafe food enters the marketplace.

In June 2013, the Canadian Food Inspection Agency (CFIA) released a discussion paper entitled Proposed Regulatory Framework for Federal Food Inspection that marked the first consultation step in the CFIA's regulatory transformation process under the SFCA. It highlighted key elements of the proposed regulations and posed a number of questions to stimulate debate and generate ideas. Over the course of the consultation period, which closed on November 30, 2013, CFIA consulted with close to 2 100 stakeholders in person and through webinars. In addition, the CFIA received 78 written submissions and responses to on-line questions from associations, individuals and other governments. A summary of what we heard during the consultation is included in Annex 1 to this document.

Feedback from the comprehensive engagement with stakeholders confirmed the policy direction in most areas, while providing important feedback on some outstanding policy issues.

The CFIA intends to pre-publish the proposed regulations under the SFCA in *Canada Gazette Part I* in late Fall 2014 followed by a formal consultation period of 75-days. The proposed regulations are expected to be published in *Canada Gazette Part II*, in mid-2015.

The following document provides an overview of the proposed regulatory framework and an early look at the initial regulatory draft of the key elements of the proposed regulations -- licensing, trade, preventive control plans and requirements related to the preparation[1] of food and traceability. It represents an additional opportunity for stakeholders to consider the intent of the proposed regulations and provide feedback before the formal regulatory consultation process through *Canada*

[1] The use of "prepare/preparation/preparer" when speaking of regulated activities throughout this document means "manufacture, prepare as defined in the SFCA, store, package and label" except when referring to licensed activities. Reference to "prepare" in the context of licensing in this document means, "manufacture, process, treat, preserve, grade, slaughter, package and label".

Gazette Part I. The document builds on the feedback from the engagement in 2013, clarifies the policy direction on a number of questions posed in the 2013 document and highlights some significant regulatory proposals.

The document is intended to inform stakeholders of the proposed changes and provide initial draft regulatory language of the most transformational elements in advance of the formal regulatory consultation process. Comments received by July 21, 2014 will be taken into consideration for *Canada Gazette Part I*. Stakeholders will have an opportunity to comment on the full set of proposed regulations during the formal 75-day consultation period following publication in *Canada Gazette Part I* in late Fall 2014.

The document also contains, in Annex 2, an overview of preliminary findings with respect to the potential major impacts (costs and benefits) associated with the proposed regulations.

Once the SFCA is in force, two federal legislative regimes will apply to food in Canada – the *Food and Drugs Act* (FDA) and its Regulations, which apply to all food sold in Canada, and the SFCA and its Regulations. The result will be a streamlined and comprehensive set of legislative tools focussed on prevention and providing improved capacity to respond to food safety incidents.

While not addressed in the following document, the CFIA is planning to release future regulatory proposals related to: disclosure of information; violations that are subject to penalties under the *Agriculture and Agri-Food Administrative*

Beyond the regulations:

The SFCA and the proposed regulations are only part of CFIA's transformation story.

Implementation of the proposed regulations will be achieved through a number of complementary initiatives, including:

- New guidance documents that facilitate compliance;
- New compliance promotion tools and model systems to assist industry to meet the regulatory requirements;
- A new Learning and Training Architecture, including a national, career-spanning curriculum for food inspectors;
- An updated science-based approach to risk rating of food commodities to better utilize inspection resources;
- A modernized and integrated approach to inspection;
- Modern IMIT systems and tools,
- A new performance measurement framework that considers a range of systemic indicators and accountabilities; and,
- Increased emphasis on government-industry partnership on food safety.

The result is systemic change that will ultimately strengthen the food safety culture in Canada, and better protect Canadian consumers through improved prevention.

Monetary Penalties Act; and recall and review mechanisms under the *Canadian Food Inspection Agency Act*.

The proposed SFCA regulations align well with legislative changes in other countries, such as those underway in the United States with the *Food Safety Modernization Act*.

Changes to Canada's regulatory framework for food inspection will not end in 2015 with the proposed coming into force of the SFCA. The CFIA, in the context of its Food Labelling Modernization Initiative, is reviewing responses from its 2013 consultation, and will further engage on options in 2014. This could lead to further regulatory changes in areas such as labelling, grades and standards of identity. In addition, over the course of the engagement on the proposed regulations, several areas were identified that could be addressed in a future round of regulatory changes, such as requirements for transporters, warehouses and distribution centres. The CFIA hopes to begin consultations on these issues in 2016.

Your opinion counts

The CFIA welcomes feedback from its stakeholders and the public on the proposed regulatory changes presented in this document.

Written comments regarding any element of the proposed regulations should be forwarded 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
Comments received by July 21, 2014 will be taken into consideration prior to publication of the proposed regulations in *Canada Gazette Part I.*

Overview of the Proposed Regulatory Changes

The SFCA has provided an opportunity for Canada to fundamentally change its regulatory framework for food inspection and oversight and to continue to position Canada as a leader in food safety prevention and incident response.

Rather than making incremental changes to existing CFIA commodity regulations, the proposed regulations would consolidate them in a single set of food regulations and establish minimum food safety requirements for all food imported or prepared for interprovincial trade or export. It is proposed that commodity-specific requirements would be continued where necessary.

The proposed regulations would reflect internationally recognized standards and management-based requirements, including HACCP[2] principles and good manufacturing practices, and would support the implementation of the CFIA Improved Food Inspection Model which was developed following extensive consultations in 2012 and 2013.

The proposed regulations also move toward more outcome-based requirements where it makes sense, to provide industry with flexibility and the opportunity for innovation. For example, many of the proposed food safety requirements are outcome-based to allow for their application to a wide range of foods and processes and to reflect differences in the size of businesses and processing complexity. Certain commodity-specific requirements and processes would maintain their current approach, but be re-written to streamline, consolidate and achieve a specific outcome while allowing for innovation.[3]

The proposed regulatory framework would further:

- focus on prevention and enable regulated parties to rapidly mitigate emerging food safety risks;
- confirm industry responsibility and accountability for preparing safe food;
- enable the CFIA to apply a consistent science and risk-based approach to inspection;

2 Hazard Analysis Critical Control Point

[3] The proposed regulations will be made under the SFCA only. The *Food and Drug Regulations* will not be modified.

- apply consistent approaches to procedural elements of the regulations (e.g. seizure and detention, applications for Ministerial Exemptions, use of inspection marks); and,
- address non-food safety requirements in a more consistent manner.

The proposed regulations would be supplemented by a suite of new guidance documents that outline the intent of the requirements and will assist regulated parties in complying with the requirements, along with model systems that have been demonstrated to achieve compliance when properly applied. The CFIA s releasing examples of guidance documents and plain language model systems developed to assist small businesses to meet the requirements in May and intends to hold a series of focus groups with small businesses in 2014 to determine how best to draft guidance documents to help industry achieve regulatory compliance. Additional information on the guidance documents is available in this document.

The following sections provide an overview of the key elements of the proposed regulations: licensing, trade, traceability, requirements related to the preparation of food and preventive control plan. These elements represent the most transformational changes to the food inspection framework and impact all food imported, exported or traded inter-provincially.

Annex 3 presents most of the preliminary regulatory text for some elements of the proposed regulations relating to licensing; import, export and inter-provincial trade; traceability; and requirements for everyone importing, or preparing, growing or harvesting food for interprovincial trade or for export.

The draft text is being released by the CFIA as part of the consultation process for discussion purposes only and to inform stakeholders of the regulatory intent well in advance of the formal consultation process through *Canada Gazette Part I*. The preliminary regulatory text for these clauses are likely to change over the course of drafting and based on feedback from this on-going consultation.

Annex 4 includes an outline of the proposed requirements related to preparation of a written Preventive Control Plan (PCP).

Licence Requirements

Under the proposed regulations, everyone importing, preparing food for export or for inter-provincial trade, or exporting a food for which they are requesting an export certificate, would be required to have a licence and comply with the requirements of the SFCA and its Regulations. This would improve the existing system by:

- Extending the coverage of licensing beyond the 9 sectors currently under CFIA regulations to all food types[4];
- Providing an accurate and complete picture of who is involved in the preparation of food for inter-provincial trade or export (in some cases) and import of food into Canada;
- Allowing for the collection of essential data to conduct oversight on the basis of food safety risk;
- Having a single, consistent approach to authorization, as opposed to the range of existing commodity requirements for licensing and registration.

Proposed Approach To:

Importers: All licence holders would require a fixed place of business in Canada **or** in a foreign state that has a food safety system that provides a similar level of protection to that of Canada.

CFIA will be releasing a draft Framework for Foreign Food Safety Systems Recognition. Canada is currently engaged in a reciprocal assessment of the operation of the respective food safety systems with the US FDA, under the Canada-US Regulatory Cooperation Council Action Plan.

Mandatory systems recognition would continue to be a requirement for meat products. This is consistent with Codex standards.

In addition, industry would be able to take a more systemic approach to licences and PCPs to cover activities in multiples locations.

The proposed licence would be valid for a period of two years, for a fee of approximately $250[5], and regulated parties would be able to apply for multiple licences (for each establishment, activity or food commodity) or a single licence (for all their establishments, activities and food commodities).
The licence application would collect basic information about the licence holder, where food businesses are located and key activities (e.g. preparing food to be exported or traded inter-provincially, importing and exporting with a certificate). Licence numbers would be generated, as well

[4] Exemptions are proposed for food additives and alcohol.
[5] Subject to a comprehensive user fee assessment.

as a number for each establishment covered by the licence. It may also collect information to enable risk-based oversight such as:

For establishments in Canada:

- product type (e.g. fish, cheese, meat, vegetables)
- intended use (e.g. ready-to-eat, raw, preserved)
- processing (e.g. canning, pasteurization, freezing, drying)
- annual volume of production
- consumer susceptibility (e.g. general population or at-risk groups)

For importers:

- product type (e.g. fish, cheese, meat, vegetables)
- intended use (e.g. ready-to-eat, raw, preserved)
- processing (e.g. canning, pasteurization, freezing, drying,
- annual volume of imported products
- typical country of origin of products

Licence renewal every two years would ensure CFIA has up-to-date information on licence holders and their activities. This information is necessary for risk-based oversight.

Proposed Approach To:

Establishment Numbers: In addition to a licence number, a unique establishment number, based on the licence number, will be generated for each establishment in Canada at the time of licence issuance.

The CFIA will cross-reference new establishment numbers with existing establishment registration numbers to minimize trade disruptions.

Establishment identification is necessary for risk-based oversight and identification.

Based on the information received in the licence application, an inspection prior to the issuance, renewal, or amendment of a licence may be required depending on product risk and compliance history. This is likely to be the case initially for food that has historically been recognized as having higher food safety risks, such as meat, fish, dairy and eggs.

When there is non-compliance, the proposed regulations would allow the Minister to suspend a licence. For example, a licence would be suspended immediately, upon notice, where there is a risk of injury to human health. This enforcement tool would be in addition to other compliance and enforcement measures available to inspectors.

Annex 3 includes preliminary regulatory text for most elements of licensing.

Import, Export and Inter-provincial Trade

The proposed regulations would require everyone importing or preparing food for export or inter-provincial trade to be licensed and comply with all the requirements of the Act and Regulations, including labelling, packaging, standards and documentation requirements, unless an exemption applies to their situation (see below).

It is further proposed that food sent or conveyed from one province to another or outside of Canada would need to be prepared by a licence holder. This would assure that those who send or convey food – such as brokers, distribution centres and internet sales – source their food from a licence holder.

The proposed regulations would include certain exemptions that are similar to those that exist in current regulations, including: food for personal use; carried on any conveyance intended for the crew or passengers; for scientific analysis, trade shows or market analysis; or products not intended for human consumption (e.g. pet food). Transshipment of food commodities through Canada is also proposed for exemption, provided the shipment travels in bond.

Several regulated parties currently import food commodities into Canada to be subsequently brought into compliance before 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. In order to allow existing practices to continue, the proposed regulations would permit non-compliant food to be imported or traded inter-provincially on the condition that the food is clearly labelled with, "For further preparation only" and that it is brought into compliance within three months after the day on which it is imported or traded inter-provincially (unless a longer period is specified by the Minister).

A prohibition is proposed against the mixture/dilution of contaminated food with non-contaminated food in order to bring the product into compliance. This is in keeping with international practice in the food sector and current regulations.

Exemptions are also being proposed for:

- alcoholic beverages which are covered under the *Importation of Intoxicating Liquors Act* which are subject to provincial oversight: and,
- food additives, which are regulated under the FDA and *Food and Drug Regulations* (FDR) and therefore will continue to be covered under the FDA.

Annex 3 includes preliminary regulatory text for most elements of import, export and inter-provincial trade.

Proposed Approach To: Exports

The proposed approach to exports reflects two primary policy drivers: Safe food and facilitating market access.

A. Canadian exporters have a responsibility to ensure that exported food is safe.

Regulatory proposal: All persons preparing food for export would be required to have a licence and to meet the requirements of the SFCA and its Regulations with respect to food safety.

Anyone who exports food (e.g. manufacturer, export brokers, internet sales) would need to ensure that the food was prepared by a CFIA licence holder and ensure that the food meets foreign state requirements.

Where foreign state and the requirements of the SFCA and its Regulations differ, foreign requirements can apply.

B. CFIA has a role in facilitating market access by certifying that food meets foreign state requirements.

Regulatory proposal: Anyone who requires an export certificate from the CFIA for the purpose of export would be required to have a licence and a preventive control plan to cover their operations. A fee would apply for an export certification.

Traceability

While many companies have implemented voluntary, and in some cases comprehensive, traceability systems, others often lack the basic record-keeping practices necessary for timely food safety investigations, recalls or withdrawals. The resulting information gaps within the food supply chain can lead to a less efficient response to a food safety incident.

The proposed regulations would apply the international standard for traceability established by *Codex Alimentarius* to licence holders and persons importing, exporting or trading inter-provincially. The Codex standard calls for tracking of food *forward* to the immediate customer and *backwards t*o the immediate supplier ("One step forward, one step back"). These requirements are aimed at enhancing consumer protection during a food safety incident by providing for more accurate information to facilitate the rapid identification of the origin and movement of a food through the food supply chain.

> **It is proposed that…**
>
> Given that better protection of consumers from food-borne illness is the objective for traceability requirements, and that many pathogens can survive the freezing process, the proposed regulations would require traceability records to be retained for 3 years for all products, including those that are perishable.

Currently, in some recall situations, information is provided to the CFIA but crucial time is lost deciphering company encryptions or codes, or illegible records. The proposed regulations would address this challenge by requiring that traceability information be provided electronically, upon request, in plain text and in a format that can be imported and manipulated by standard commercial software, in French or English. The information would need to be **accessible** in Canada.

The requirements would apply to regulated parties receiving food animals. Canada already has robust livestock traceability requirements for several animal species under the *Health of Animals Regulations* and initiatives in place that meet or exceed the minimum requirements of the proposed regulations.

Enhancements to traceability requirements could be included in future regulatory changes to build on the foundation that would be established through the current regulatory proposal. In the interim, the

CFIA encourages regulated parties to be proactive in enhancing their traceability and record-keeping systems beyond the proposed minimum requirements.

Annex 3 includes preliminary regulatory text for traceability.

Food Safety Requirements

It is proposed that the regulations under the SFCA establish minimum requirements for everyone who imports, prepares, grows or harvests food for inter-provincial trade or export, regardless of the commodity or size of operation. This would be a fundamental improvement in Canada's food safety regulatory framework. This would include requirements that address seven key elements to good manufacturing and agricultural practices:

1. Products and processes;
2. Sanitation, pest control, sanitizers and chemical agents;
3. Hygiene and competencies;
4. Equipment and conveyances to be used in an establishment;
5. Physical structure and maintenance of the establishment;
6. Receiving, transportation and storage; and
7. Investigation and notification, complaints and recall procedures.

The proposed requirements are integral to any food safety system. They are recognized pre-requisites for safe food and require that industry anticipate and take the necessary measures to address the hazards that can be present in a food, on the equipment or in the establishment and its facilities where that food is prepared. Each element would address specific hazards in the food preparation continuum. Regulated parties would still have to comply with all the other requirements of the proposed regulations and FDA and FDR.

Annex 3 includes preliminary regulatory text for some of the food safety requirements.

In addition to the above-mentioned baseline requirements, the proposed regulations would include commodity-specific requirements necessary for food safety. A side-by-side review of existing and proposed regulatory requirements is being done to determine current provisions that are addressed by horizontal requirements, those that are no longer needed, and, and those that would be new for a given commodity. In addition, commodity-specific requirements to be maintained are being assessed

as to whether they could be streamlined or made more outcome-based, while still achieving the same regulatory outcome.

Annex 5 contains examples of some of the anticipated commodity-specific food safety requirements.

Preventive Control Plan

A PCP would be required from:

- Every licence holder importing a food or preparing a food to be sent or conveyed from one province to another.
- Every person who grows or harvests fresh fruit or vegetables to be sent or conveyed from one province to another for direct sale to the consumer without being further manufactured, prepared, stored, packaged or labelled.
- Persons preparing food for export, exporting, or growing and harvesting fresh fruit and vegetable for export, that require a certificate from the CFIA.

It is proposed that…

Control measures will need to be validated by evidence that demonstrates they effectively control identified hazards.

CFIA will provide "model systems", drawn initially from existing manuals, that have been validated and proven effective, when properly applied.

CFIA will also provide guidance on "validations", consistent with Codex.

The requirement for a PCP would improve food safety by requiring that these regulated parties implement a system-based approach to their operations that focusses on prevention and management systems. The steps related to the preparation of a PCP in the proposed regulations are expected to be consistent with HACCP which is the internationally recognized approach to food safety. They include the identification of:

I. All hazards
II. Critical control points and related control measures that are validated by evidence
III. Critical limits
IV. Monitoring procedures
V. Corrective action procedures
VI. Verification procedures
VII. Record keeping procedures

In preparing the PCP, , which is based on HACCP principles , the regulated party would need to identify and document the potential hazards associated with their food or processes, and demonstrate how those hazards will be controlled. PCP preparation and maintenance strengthens the management of the operations by requiring the regulated party to be actively engaged in the development of food safety systems, including proactively determining how they will monitor their operations, respond and correct deviations as they occur, and maintain ongoing compliance.

The regulated party would be required to maintain the PCP and associated records to assess its ongoing effectiveness and ensure its continuous improvement.

The PCP would need to address how specified requirements, including elements 1-7 listed in the previous section, would be met, as applicable. It would also be where regulated parties would identify the measures they have taken to comply with other relevant regulatory requirements, including those FDR requirements that will be incorporated in the proposed regulations e.g. packaging and labelling provisions of FDR.

The PCP will be one of the key tools used by the inspector in verifying compliance with the Act and Regulations.

Annex 4 contains the proposed requirements for a written PCP.

Other Proposed Regulatory Elements

Grade Standards

The proposed regulations would outline the conditions for grading and grade labelling, and could incorporate by reference a Compendium of Canadian Grade Standards (Compendium) that would consolidate existing Canadian grade standards in a single document, organized by commodity for ease of reference.

> **It is proposed that…**
>
> A Compendium of Canadian Grade Standards will be incorporated by reference into the proposed regulations.
>
> Incorporation by reference would enable grade standards to be more easily updated to reflect industry and international changes.
>
> Changes to the Compendium by the CFIA would be guided by strict policies for the use of the incorporation by reference (IBR) as a legislative tool. A CFIA discussion paper on IBR will be available on the CFIA website.

The proposed regulations would state that a food may only be graded with a Canadian grade if it:

- meets the requirements of the SFCA and Regulations, including any standards of identity, colour, classification, packaging and labelling requirements;
- meets the requirements for a grade set out in the Compendium;
- was prepared by a licence holder; and
- is graded by the licence holder, a grader or an inspector…

The CFIA is also considering inclusion of changes to the grade standards for fresh and processed fruits and vegetables for which Test Market Authorizations have been issued and that were previously identified by CFIA for potential regulatory amendments in current regulations.

Ministerial Exemptions

Under the current regulatory regime, ministerial exemptions from requirements are granted for two main purposes: to alleviate shortage of fresh and/or processed fruits and vegetables; and to allow test marketing to promote innovation. These exemptions are only related to non-food safety requirements – in all cases, food safety requirements must still be met.

The proposed regulations would maintain the authority of the Minister to issue exemptions to alleviate a shortage and for test marketing, for a period of two years. Exemptions could be granted only when they would not result in a risk of injury to human health, confuse or mislead the public or disrupt the normal trading patterns of the industry or the normal pattern of food pricing.

The proposed regulations would harmonize and eliminate differences between existing regulations, and reduce administrative burden with respect to procedures, submission requirements, timeframes etc. This should allow the CFIA to implement a streamlined, transparent and common approach for the administration of exemptions for all food.

Labelling and Standards of Identity

The proposed regulations would not fundamentally change the approach to labelling and standards of identity. They would, however, streamline the current regulations covering different commodities.

Labelling provisions exist in the FDR, *Meat Inspection Regulations* (MIR), *Fish Inspection Regulations* (FIR), *Consumer Packaging and Labelling Act* (CPLA) and its regulations and the regulations under the *Canada Agricultural Products Act* (CAPA). Some requirements are found in all of these regulations (e.g. common name, net quantity). Other requirements are commodity-specific (e.g. percentage of milk fat declaration on certain dairy products).

The intent with these proposed regulations is to reduce duplication and differing requirements that exist across the labelling-related regulatory provisions that CFIA enforces and adjust the provisions to make the wording more consistent with that of the SFCA without altering current policy.

The CFIA and Health Canada are working closely together to modernize food labelling, including through the Food Labelling Modernization Initiative and the nutrition labelling consultations announced in the 2013 Speech from the Throne.

They will continue to actively coordinate and integrate food labelling modernization efforts, as well as to collaborate on a plan to modernize food standards of identity, as committed to in the 2014 Budget (Economic Action Plan).

The labelling requirements in the FDR are outside the scope of the proposed regulations and will not be amended as part of this exercise. Where there is duplication with the FDR, the intent is to make a reference to the FDR in the proposed regulations, where appropriate, rather than having the same requirement in two sets of regulations.

The existing requirements of the CPLA and its regulations apply to prepackaged food sold in Canada, including food sold intra-provincially. These requirements would be maintained in the proposed regulations under the SFCA.

Standards of identity for food will also remain unchanged. However, where there is currently duplication, the FDR standard of identity will be referenced in the proposed regulations. In some cases, the FDR standard of identity may be referenced but additional requirements from the regulations under CAPA, the *Meat Inspection Act* (MIA), and the *Fish Inspection Act* (FIA) will need to be included. Standards of identity that are uniquely in the CAPA, MIA and FIA Regulations would be kept, although wording could be modified to reflect the language of the SFCA. Standards of identity currently only under the FDR would remain under the FDR and will not be addressed in the proposed regulations at this time.

The CFIA will engage stakeholders to discuss these provisions under Phase II of the Food Labelling Modernization Initiative which is expected to result in recommendations for changes to regulations related to labelling and standards of identity.

Membership Requirements for Buyers and Sellers of Fresh Fruit and Vegetables

The Canada-US Regulatory Cooperation Council (RCC) agreement included a commitment to address financial risk mitigation in the trade of fresh fruit and vegetables. A key area of concern for the industry was the "dual licensing system" which required that buyers and sellers of fresh fruit and vegetables have a licence from the CFIA under the *Licensing and Arbitration Regulations* (LAR), or be a member of the Fruit & Vegetable Dispute Resolution Corporation (DRC). The LAR was put in place before industry had developed its own mechanism for ensuring fair and ethical trading. In the wake of the North American Free Trade Agreement, the industry established its own non-government arbitration mechanism, the DRC, of which over 80% of the industry is already a member.

The Government of Canada, through the *Budget Implementation Act 2014*, has proposed an amendment to the SFCA to provide a regulation-making authority to require buyers and sellers of fresh fruit and vegetables to be members of a non-government organization. With this amendment to the SFCA, the intent is to include such a requirement in the proposed regulations rather than continue the licensing requirements current under the LAR.

It is proposed that…

The Fruit and Vegetable Dispute Resolution Corporation (DRC) be the entity in which membership is required for buyers and sellers of fresh fruit and vegetables. This proposal is based on the strong and unanimous feedback from stakeholders during the engagement of 2013.

The DRC is a non-profit organization consisting of fresh fruit and vegetable dealers and transportation companies from Canada, Mexico and the United States. The DRC was established in February 2000 under the North American Free Trade Agreement to minimize trade irritants and facilitate effective trade dispute resolution. While membership in the DRC is voluntary, the organization currently has over 1 400 members.

Expected Coming into Force of the Proposed Regulations

The proposed regulations are expected to be published in *Canada Gazette Part II* by mid-2015.

The CFIA recognizes that industry is at widely different levels of readiness:

1) Those sectors "federally-registered" or licenced under current regulations (meat, fish, dairy, egg, processed fruit and vegetables, honey and maple) are already under CFIA oversight and would largely meet the proposed requirements. Coming into compliance should be relatively straightforward. In addition, CFIA will identify changes specific to these sectors to assist these businesses with the transition.
2) The fresh fruit and vegetable sector is currently regulated under the *Fresh Fruit and Vegetable Regulations*, with most requirements related to non-food safety. The proposed regulations would create substantial new requirements for this sector, particularly with regards to the activities of growing and harvesting.
3) While the "non-federally-registered" sector (sector that is not required to be registered under current federal regulations) includes some large industry players and others who are very familiar with internationally recognized food safety practices and the CFIA, it also includes a large number of small and medium businesses that may have a steeper learning curve. CFIA is also less familiar with these businesses.

As such the Agency is proposing a staged implementation approach for the proposed regulations to come into force.

	Currently "Registered"	FFV	Non-Registered
Licence	2015	2015	2016
PCP	2015	2016	2017

Guidance Documents and Model Systems

The CFIA recognizes that good guidance documents will assist in a successful implementation of the proposed regulations… Guidance documents should facilitate compliance with regulations. The most important benefit of effective guidance and compliance promotion is improved food safety through the effective implementation of HACCP-based preventive control measures.
Currently the CFIA has over 250 food manuals (over 44 000 pages) to provide guidance with respect to existing Acts and Regulations. These manuals differ significantly in terms of their content and intent. Some include operational procedures for inspectors. While filled with important and useful information for industry, the existing manuals can be difficult to navigate to find the necessary information.

The CFIA is developing a new suite of regulatory guidance documents that will significantly improve the format, content and accessibility of its guidance material. This new suite of documents will replace existing manuals to help industry to comply with the SFCA and Regulations including:

- Guidance to clearly explain the intent of regulatory requirements.
- Model systems to provide examples that when properly applied have been demonstrated to achieve compliance with the regulatory requirements. These would initially be drawn from existing commodity manuals and systems recognized by the CFIA Food Safety Recognition Program, but in time could include other validated generic models.
- Additional "plain language" resources for small and medium size businesses.

The CFIA is intending to hold a series of focus groups with small and medium enterprises to determine the most appropriate format, language and methods of communicating guidance material.

The CFIA is releasing draft guidance related to preventive control requirements as a companion document to the proposed regulations and is seeking feedback from industry on the overall organization, language style and level or nature of detail included. The draft guidance is also intended to help industry to prepare and plan for the proposed regulations.

Unlike regulations, guidance documents do not have a formal timeline or process for consultation. As such, they will continue to evolve over time. However, feedback on the drafts by September 30, 2014 would be appreciated to inform the initial development of material.

The CFIA is also developing a comprehensive compliance promotion strategy, the details of which are contained in a discussion document which it intends to release in June 2014 and make available on the CFIA website.

Support for Small Businesses

The CFIA is sensitive to the needs of small businesses and aware of the importance of finding the right balance between maximizing food safety and minimizing administrative burden.

The following two elements of the proposed regulations were deemed essential elements of the food safety framework, regardless of organizational size:

1) Licensing: So the CFIA knows **who** is doing **what** with food for the purpose of oversight and, if necessary, enforcement. In addition, the CFIA would be able to reach out to small and medium businesses to ensure they are aware of their regulatory obligations, and to share compliance promotion information.
2) Food safety requirements: The proposed regulations would establish basic requirements for food safety (e.g. sanitation, hygiene, pest control) with which everyone who prepares food for human consumption would be required to comply.

It is proposed that…

Licence holders with total food revenue from the 12 previous months of $30 000 or less at the time of application for a licence will be exempt from the PCP requirements to alleviate some administrative burden and cost.

These micro-businesses would still be required to meet all other requirements, including those related to food safety.

What are your views on not extending the micro-business exemption to exporters requiring a certificate from the CFIA?

It is, however, proposed that micro-businesses with total food revenue from the 12 previous months of $30 000 or less at the time of application for a licence be exempt from preparing a written PCP. The exemption would reflect the fact that these micro-businesses are generally less complex. However, the proposal is that this exemption will not be available for licence holders preparing food that are already required to meet food safety requirements similar to those in the proposed regulations and are internationally recognized as having food safety risks which require appropriate controls (i.e. meat, fish, dairy, egg, processed egg and processed products). As risk ranking tools evolve, additional foods could be excluded from the exemption through regulatory amendment.

In addition, since the vast majority of small and micro-businesses are part of the current "non-federally registered" sector, they would be given additional time to comply with certain requirements

of the proposed regulations. This sector would have until 2016 to get a licence and, when applicable, would have until 2017 to have a PCP.

The CFIA will also develop a comprehensive compliance promotion strategy for small and medium businesses. Using the licensing information CFIA will be able to identify and reach out specifically to these businesses with plain language guidance material on how to comply with their regulatory obligations.

Finally, the CFIA will work with industry leaders and academic institutions to encourage a culture of food safety, sharing of best practices in Canada and new opportunities for training.

User Fees Policy

Concurrently with the Agency's Regulatory and Program Modernization initiatives, the CFIA is reviewing its services, user fees and service standards in order to bring them into line with the new Single Food Program design and regulations. The CFIA currently collects 542 user fees for food, which have not been updated since the creation of the Agency in 1997 because of a fee moratorium. The moratorium was lifted in 2009 and the CFIA undertook a review of its user fees, beginning with nine priority areas. In 2011, the review was expanded to address all of the CFIA's user fees. Canada's trading partners are also modernizing their cost recovery approaches, and the CFIA will be doing international benchmarking to compare the proposed fees with those for similar services in other countries.

The proposed single food program services (such as licensing, inspection, certification and testing) will be common across all food commodities and activity groups (domestic, import, and export). The commonality of services enables the Fees Notice to be streamlined down to fewer than 60 separate services, plus lab tests. This puts the focus of cost recovery on what service the CFIA is delivering and the resources it is expending, rather than the food that is involved or the size of the operation of the service recipient.

The service standards for individual services will be based on current service delivery targets, and where relevant, to service standards Canada is committed to under international agreements. Once the new service standards are formalized, the CFIA will be reporting on its success in meeting these targets in the annual Departmental Performance Report.

The new food user fees will reflect the costs incurred by the CFIA in delivering a particular service, whether the service is of benefit to the Canadian public or to private parties, and based on other considerations. Services that benefit industry to a greater extent than the general public will have a higher cost recovery ratio than services that have a public safety element. If the new fee will be an increase of over 100% compared to the old fee, the new fee will be phased in over several years. Though the CFIA expects to see user fee revenues form a greater percentage of its budget when the new fees are implemented, there is no target revenue.

The user fee proposal for the new Single Food Program will contain the list of services, the proposed user fees and service standards, as well as information on how the cost recovery ratios were determined and international benchmarking. Consultations with industry on the user fee proposal are expected to start in the Summer of 2014.

Inspector Training

The need for a comprehensive training system to support Agency transformation and modernization of the CFIA was the focus of many stakeholder comments during the 2013 consultation.

The CFIA is building a Learning and Training Architecture Forward Plan 2013-2019 (Plan) to support a modernized Agency. Currently, CFIA training reflects a commodity-specific inspection approach, and paper-based record keeping and interactions with stakeholders. The proposed Plan moves the CFIA to a single inspection approach consistent across food commodities, supported by standardized training, technology information solutions, enhanced proactive science capacity and improved services to stakeholders.

To support this initiative, CFIA will undertake three key activities in responding to Agency Transformation, including:

- Design and development of new science and technical training initiatives, including training on the SFCA and the proposed regulations;
- Delivery of refresher training to current CFIA inspectors; and
- Development of the CFIA Learning and Training Architecture. This may include activities such as trainer qualification, e-learning design and development, virtual learning, and classroom learning.

CFIA has also been looking at training best practices around the world – one that stands out is the International Food Protection Training Institute (IFPTI) based in Battle Creek, Michigan. The IFPTI is the training initiative of the Global Food Protection Institute (GFPI). GFPI is a model for private-public partnerships that addresses issues related to food protection. The IFPTI collaborates with industry, academia, federal and state government, and other national and state organizations to develop effective and relevant materials that advance food protection.

The IFPTI has produced a National Curriculum of evidence-based, career-spanning training for food protection officials. This National Curriculum supports a fully integrated national food safety system as outlined in the U.S. Food and Drug Administration's *Food Safety Modernization Act*.

Under the new private-public partnership, Safe Food Canada – The Learning Partnership, the CFIA is collaborating with key stakeholders from industry, academia and provincial/territorial governments to coordinate a Canadian effort to explore the potential of creating a model system similar to IFPTI in Canada to operationalize national training and certification in support of a professional and competent workforce. In following the IFPTI model, the development of a consistent curriculum framework for regulatory compliance and enforcement has the potential to standardize the professional development of federal, provincial and local food regulators in Canada and all employees working in the food industry.

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.

The proposed regulations will represent a significant stride in the application of preventive control plans to food safety in Canada and a clear raising of the bar for food safety in Canada.

This document presents in greater detail the policy direction intended by the proposed regulations, as well as some proposed draft regulatory text, to give stakeholders another opportunity for feedback before the proposed regulations enter into the formal consultation process.

These proposed regulations will not be the final step in the evolution of Canada's regulatory framework under the SFCA. Rather, an effective food safety control system is marked by ongoing policy review and continuous improvement. The CFIA is committed to such a process and welcomes feedback on future improvements, as well as those addressed in this round of regulatory change.

Looking Forward….

Warehouses and distribution centres would not be required to have a licence or preventive control plan unless they are conducting an activity subject to the licensing and PCP requirements (e.g. packaging). This was identified during consultation as a potential gap in the food safety supply chain. Therefore, it is proposed that any food that is exported or sent or conveyed from one province to another from a warehouse or distribution centre will have to be prepared by a licence holder.

CFIA will consider including these industries in future rounds of regulatory change, following the policy analysis and appropriate consultation.

The CFIA will also be looking at the issue of adulteration and food defence as a potential element for future regulatory development.

Next Steps

The CFIA welcomes feedback from stakeholders and the public on the proposed regulatory changes presented in this document.

Written comments regarding any element of the proposed regulations should be forwarded by July 21, 2014 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

Comments received by July 21, 2014 will be taken into consideration prior to publication of the proposed regulations in *Canada Gazette Part I*.

Annex 1: What We Heard from Consultations

The CFIA received considerable feedback over the course of consultations, which took place between June 4, 2013 and November 30, 2013.

The CFIA participated in 84 external stakeholder events, including 9 external webinars that reached 1010 participants. In total, the CFIA estimates it reached as many as 2 100 individuals. In addition, the CFIA received 78 written submissions from individual businesses, foreign governments, and associations representing hundreds of members.

The following are the key messages and themes that were heard.

Strong support for approach, including:

- Move to single set of regulations that covers all food commodities significantly improves consistency and reduces duplication and regulatory complexity.
- Having the same regulatory requirements for domestic producers and importers creates a level playing field.
- Ability for businesses to hold multiple licences and structure according to their business needs.
- Preventive control plans (PCP) – applies a consistent approach to demonstrating how compliance with the regulations is achieved; consistent with US *Food Modernization Act* approach.
- More "outcome-based" regulations is a positive move that will allow for innovation and flexibility, *provided* provisions needed for food safety are maintained, inspectors are well trained and interpretation is consistent.

Strong support for HACCP-based approach in regulations:

- Strengthens Canada's food safety system; internationally recognized.
- Several HACCP based systems already exist and are recognized by CFIA (Food Safety Enhancement Program, Quality Management Program for fish, CanadaGAP for fresh fruit and vegetable)

Strong support from domestic and international Fresh Fruit and Vegetable industry for:

- New food safety requirements at the farm level that reflect the industry's efforts to date with CanadaGAP
- Requirement for membership in the DRC to replace the LAR. This addresses a Canada/US Regulatory Cooperation Council priority to eliminate the "dual licensing" under the LAR and the DRC.

Several areas of concern were also expressed, including:

- Many importers currently operate from outside Canada – requirements to have a Canadian address could result in significant costs to these importers who would need to either set up an office in Canada or obtain a broker who would accept accountability.

CFIA Response: The proposed regulations would allow for importers who do not have a fixed place of business in Canada but who have a fixed place of business in a foreign state that has a food safety system that provides a similar level of protection to that of Canada.

- The new regulations could present a significant burden to small businesses that are currently not familiar with the CFIA, or have limited knowledge of HACCP. However, there was strong opposition expressed during the consultations to an exemption for small businesses because food risks/hazards are not dependent on size of operation.

CFIA Response: The proposed regulations would include an exemption from the PCP documentation requirements for businesses with total food revenue from the previous 12 months of $30 000 or less at the time of applying for the licence. These businesses will still, however, require a licence for basic oversight and compliance promotion, and must meet other regulatory requirements.

Annex 2: Preliminary Cost Benefit Analysis

Introduction

The CFIA is undertaking a cost-benefit analysis of potential impacts of the proposed regulations under the SFCA. The analysis will be completed for the pre-publication of the proposed regulations in *Canada Gazette Part I*. Based on stakeholder feedback during the pre-publication comment period, the draft may be revised for the publication of the final regulations in *Canada Gazette Part II*.

The following are preliminary findings with respect to the potential major impacts (i.e. costs and benefits) associated with the proposed regulations. It should be noted that the FDA currently applies to all food sold in Canada (whether manufactured in Canada or imported) and many regulated parties also need to meet the requirements under current CFIA legislation (CAPA, MIA, FIA, CPLA and their Regulations) so preparers of food are presently undertaking activities to ensure the safety of food. Therefore, businesses will only incur costs if they need to do more or do things differently when the proposed regulations come into force.

This preliminary analysis provides qualitative descriptions only of potential major impacts. The cost-benefit analyses to come with the pre-publication of the proposed regulations in *Canada Gazette Part I* will present more detailed analyses and include estimated potential monetary impacts. The upcoming analyses will also include Small Business Lens analysis, which will focus on potential costs incurred by small businesses, and "One-for-One" Rule analyses, which will focus on potential administrative burden impacts on all businesses.[6]

The cost-benefit analysis approach compares the baseline scenario – where the current regulations under the CAPA, FIA, MIA, and the food-related provisions of CPLA would continue to exist and be enforced – with the proposed regulatory scenario whereby the SFCA and Regulations will come into

[6] As per Treasury Board Secretariat of Canada (TBS) guidance, administrative burden includes planning, collecting, processing and reporting of information, and completing forms and retaining data required by the federal government to comply with a regulation. This includes filling out licence applications and forms, as well as finding and compiling data for audits and becoming familiar with information requirements. An exhaustive list of administrative burden activities is available on the TBS website at http://www.tbs-sct.gc.ca/rtrap-parfa/cabtrib-lfarie/cabtrib-lfarie14-eng.asp .

force and replace CAPA, FIA, MIA and their Regulations, and the food-related provisions of CPLA and its Regulations.

Potential Major Impacts

The potential impacts listed here represent incremental differences between the established baseline and regulatory scenarios. These impacts have been considered 'major' as they would have the most significant impact on Canadians and Canadian businesses. A description is provided for each listed major impact. These descriptions all contain information on how the forthcoming cost-benefit analyses will account for the impact (i.e. will the impact be monetized, quantified or described qualitatively) and whether there would be potential small business and administrative burden implications associated with the impact.

Major Benefits

Reduced Food Safety Risk

It is expected that the regulations under the SFCA would have stronger food safety rules overall than the current regulations under CAPA, MIA, FIA and CPLA. Some examples of this would be in relation to the proposed licensing, traceability and PCP requirements; and in food sectors where no such requirements were previously required (e.g. the non-federally registered and fresh fruits and vegetable sectors).

While the CFIA does not know the magnitude of the positive impact that stronger rules would have, it would be a reasonable assumption that these measures would reduce the food safety risk for Canadians to some degree. This reduction in risk would mean that the number of food-borne illnesses across Canada would be reduced when comparing the baseline scenario to the regulatory scenario.

Impact type: Monetary
Small business impact: No
Administrative burden impact: No

Level Playing Field for Food Industry

Currently, some food importers and preparers of food for inter-provincial trade and/or export have to comply with commodity-specific regulatory requirements while others do not. Also, some of these

regulatory requirements, such as establishment registration and PCP, vary between different commodities. This is a result of the current commodity-specific regulatory approach. With the proposed regulations, CFIA would move to a single-food regulatory approach. This would mean that there would be a leveling of the playing field for all regulated parties across commodities. The only exceptions to this would be micro-businesses[7] and preparers of food exclusively for export who would not be required to have a written PCP.[8]

Impact type: Qualitative
Small business impact: Yes
Administrative burden impact: No

Outcome-Based Regulatory Approach

The current regulations under CAPA, MIA, FIA and CPLA generally take a prescriptive approach to food safety, which arguably has the potential to limit the way a food business can operate. In comparison, the proposed regulations would modify, where appropriate, the current prescriptive approach, by moving to a system of requirements that articulates the expected outcomes as it relates to food commodities. This outcome-based approach would provide businesses with the opportunity for innovation without having to wait for regulatory changes to allow for it, which could lead to reduced compliance costs (e.g. processing costs) over time as businesses find more efficient/effective methods of compliance.

Impact type: Qualitative[9]
Small business impact: Yes
Administrative burden impact: No

More Efficient and Effective Food Safety Recalls and Investigations

As a result of the proposed traceability requirements, it is expected that recalls and investigations would be conducted in a more efficient and effective manner, potentially minimizing economic loss. Traceability information would be more readily available. These factors could potentially reduce the duration of recalls/investigations and minimize unnecessarily wasted food through improved

[7] A preparer of food for inter-provincial trade and/or export is considered to be a micro-business if its annual gross revenue derived from the trade in food is $30 000 or less. A food importer is deemed to be a micro-business if its annual imports are valued at $30 000 or less.
[8] Preparers of food exclusively for export that require a CFIA certificate would need a PCP.
[9] The cost-benefit analysis may provide a monetary value for this impact depending on data availability.

targeting of affected product. The magnitude of this benefit would be dependent on the current traceability practices of stakeholders.

Impact type: Monetary
Small business impact: Yes
Administrative burden impact: Yes

Improved CFIA Knowledge of Food Establishments

Currently, CFIA is knowledgeable about food establishments that are registered under CAPA, MIA and FIA, but has limited to no knowledge about non-licensed or registered food establishments. As a result of the proposed licensing requirements, CFIA would have improved knowledge of those involved in importing, exporting and trading of food from one province to another. This would provide CFIA with a means of communicating with all regulated parties, which would allow for an improved emergency response when food safety incidents occur. Additionally, CFIA would be able to more strategically focus its food safety efforts.

Impact type: Qualitative
Small business impact: No
Administrative burden impact: No

No Establishment Registration Applications

Establishments that are currently required to be registered and licensed under MIA would no longer need to be registered. Therefore, meat establishment operators would no longer have to take the time to register. Registration requirements vary across the current regulations, but generally establishments under CAPA, MIA and FIA are required to renew their registrations annually.

Impact type: Monetary
Small business impact: Yes
Administrative burden impact: Yes

Major Costs

Licence Applications

Food importers and preparers of food for inter-provincial trade/or export would be required to obtain a licence from CFIA. In order to do this, a business would have to take the time to apply to the Agency. Licences would be required to be renewed every two years.

It should be noted that the CFIA would streamline the proposed licensing requirements in comparison with the current registration/licensing requirements (e.g. a regulated party could apply for a single licence or multiple licences if they wanted to).

Impact type: Monetary
Small business impact: Yes
Administrative burden impact: Yes

Preparation of Preventive Control Plans (PCP)

A PCP would be required for:

- Every licence holder importing a food or preparing a food to be sent or conveyed from one province to another[10].
- Every person who grows or harvests fresh fruit or vegetables to be sent or conveyed from one province to another for direct sale to the consumer without being further manufactured, prepared, stored, packaged or labelled.
- Persons preparing food for export, exporting, or growing and harvesting fresh fruit and vegetable for export, that require a certificate from the CFIA.

Costs associated with this would include the time needed to develop the plan and potentially hiring external expertise for assistance. It should be noted that CFIA is developing guidance material and model systems in an effort to assist businesses with this requirement.

Additionally, the cost-benefit analysis would have to take into account that many establishments are currently required to or voluntarily have a PCP in place which in some cases has been certified by a third-party (i.e. current industry practices). The analysis would take this into account by only estimating the cost associated with the additional effort required to comply with the proposed regulations.

[10] Exemptions are proposed for food additives and alcohol.

Impact type: Monetary
Small business impact: Yes
Administrative burden impact: No

Implementation of PCP

Costs would likely be associated with the implementation of the PCP, including cost related to implementing control measures, training/education for employees, validation that preventive controls measures are working and record-keeping. The magnitude of this cost is dependent on current industry practices.

Impact type: Monetary
Small business impact: Yes
Administrative burden impact: Yes

Maintenance of PCP

The PCP would need to be kept and maintained. This cost would include reviewing, assessing, adjusting and documenting changes to the PCP.

Impact type: Monetary
Small business impact: Yes
Administrative burden impact: No

Implementation of Traceability

Under the proposed regulations, regulated parties would be required to prepare, keep and maintain documents and label food for traceability purposes. These systems would need to be implemented at the establishment level. Licence holders, importers, exporters and persons who send food from one province to another would have to keep documents on each food, and each food commodity incorporated into that food or from which that food is derived, received or sent by them. Additionally, these persons would potentially have to train staff on how to prepare, keep and maintain documents in accordance with the regulatory requirements.

Impact type: Monetary
Small business impact: Yes
Administrative burden impact: Yes

Comments on the preliminary cost-benefit analysis and any information/data pertaining to any costs or benefits that has or has not been cited here as major impacts should be forwarded by July 21, 2014 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 3: Preliminary Text for Key Provisions of the Proposed Regulations

Disclaimer: *This annex presents preliminary regulatory text for some elements of the proposed regulations relating to licensing; import, export and inter-provincial trade; traceability; and requirements for everyone importing, or preparing, growing or harvesting food for interprovincial trade or for export. The draft text is being released by the CFIA as part of the consultation process for discussion purposes only. The preliminary regulatory text for these and other clauses are likely to change over the course of drafting and based on feedback from this ongoing consultation.*

SAFE FOOD FOR CANADIANS REGULATIONS

PART 1
INTERPRETATION

1. The following definitions apply in these Regulations.

"Act"

"Act" means the Safe Food for Canadians Act.

"case"

"case" means a package made to contain 30 dozen eggs.

"contaminated"

"contaminated", in respect of a food, means that the food

(a) contains a chemical, drug, food additive, heavy metal, industrial pollutant, ingredient, medicament, microbe, pesticide, poison, toxin or any other substance not permitted by, or in an amount in excess of limits set out in regulations made under, the FDA, the Canadian Environmental Protection Act, 1999 or the Pest Control Products Act; or

(b) contains, or has come in contact with, any thing that causes the food to become adulterated or inedible.

"edible"

"edible" means fit for use as food.

"egg"

"egg" means

(*a*) in the case of processed egg products, an egg of a domestic hen belonging to the species *Gallus domesticus* or of a domestic turkey belonging to the species *Meleagris gallopavo*, but does not include an ovum; and

(*b*) in all other cases, an egg of a domestic hen belonging to the species *Gallus domesticus*.

"FDA"

"FDA" means the Food and Drugs Act.

"FDR"

"FDR" means the Food and Drug Regulations.

"Fees Notice"

"Fees Notice" means the Canadian Food Inspection Agency Fees Notice.

"food"

"food" has the same meaning as in section 2 of the Food and Drugs Act.

"food additive"

"food additive" has the same meaning as in subsection B.01.001(1) of the FDR.

"inspection station"

"inspection station" means a place designated by the President of the Agency.

"licence"

"licence" means a licence issued under paragraph 20(1)(a) or (b) of the Act.

"maple product"

"maple product" means any food obtained exclusively by the concentration of maple sap or maple syrup, excluding any substitute.

"maple sap"

"maple sap" means the sap obtained exclusively from trees of the genus Acer.

"maple syrup"

"maple syrup" means the syrup obtained exclusively by the concentration of maple sap or by the dilution or solution of a maple product, other than maple sap, in potable water.

"meat product"

"meat product" means

(a) a carcass;

(b) the blood of an animal or a product or by-product of a carcass; or

(c) anything containing a thing referred to in paragraph (b).

"ovum"

"ovum" means the partly formed egg yolk that has been removed from a domestic hen belonging to the species Gallus domesticus, or from a domestic turkey belonging to the species Meleagris gallopavo, that was slaughtered in accordance with a licence.

"processed egg product"

"processed egg product" means any food for which a standard is prescribed in Part XX [Processed Egg Product Standards].

"processed fruit and vegetable product"

"processed fruit and vegetable product" means any food that is made wholly or in part from any fruit or vegetable and that is canned, cooked, frozen, concentrated, pickled or otherwise prepared to assure preservation of the food in transport, distribution and storage.

"scheduled work shift"

"scheduled work shift" means a work shift that

(a) in the case of a slaughter shift, does not exceed 7.5 hours per inspection station in one day and 37.5 hours per inspection station in one work week, excluding meal times; and

(b) in the case of a work shift other than a slaughter shift,

(i) does not exceed 7.5 hours in one day and 37.5 hours in one work week, excluding meal times, or

(ii) is scheduled between 6:00 a.m. and 6:00 p.m.

"slaughter shift"

"slaughter shift" means a work shift during which the ante-mortem inspection and slaughter of animals and the post-mortem inspection of carcasses is carried out.

"substitute"

"substitute" means, in respect of a maple product, any food that resembles a maple product in appearance and is prepared for the same uses as a maple product but is not obtained exclusively from maple sap.

"unsanitary conditions"

"unsanitary conditions" means conditions or circumstances that might contaminate a food.

PART 2
LICENCES

2. (1) For the purpose of the issuance of a licence to import under paragraph 20(1)(*a*) of the Act, the prescribed food commodity is a food other than a food additive and a beverage that contains more than 0.5% absolute ethyl alcohol by volume.

(2) For the purpose of the issuance of a licence under paragraph 20(1)(*b*) of the Act, the prescribed food commodity that is to be exported or to be sent or conveyed from one province to another is a food other than a food additive and a beverage that contains more than 0.5% absolute ethyl alcohol by volume and the prescribed activities are manufacturing, processing, treating, preserving, grading, packaging, labelling and slaughtering of animals from which meat products may be derived.

3. (1) An application for the issuance, renewal or amendment of a licence must be made to the Minister in a form approved by the President of the Agency and be accompanied by the fee set out in the Fees Notice.

(2) An application for the issuance, renewal or amendment of a licence for the processing, treating, preserving, grading, manufacturing, packaging or labelling of meat products or the slaughtering of animals from which meat products may be derived must include a proposed scheduled work shift for each establishment in which the activity is conducted.

4. The Minister may issue, renew or amend a licence if

(a) the applicant has prepared a preventive control plan;

(b) the information submitted in the application is complete, truthful and not misleading;

(c) the requirements set out in Part 4 are met;

(d) in the case of an application for the issuance, renewal or amendment of a licence for the processing, treating, preserving, grading, manufacturing, packaging or labelling of meat products or the slaughtering of animals from which meat products may be derived, a scheduled work shift has been approved by the President of the Agency for each establishment in which the activity is conducted;

(e) in the case of an application for the issuance, renewal or amendment of a licence to import, the applicant carries on business related to the food identified by that licence in a fixed place of business that is

(i) in Canada, or

(ii) in a foreign state that has a food safety system that provides a similar level of protection to that of Canada;

(f) the Minister is of the opinion, based on the information that was made available to the Minister, that no risk of injury to human health will result; and

(g) in the case of issuance, the applicant has no fees payable under the Fees Notice.

5. The Minister may refuse to issue, renew or amend a licence if

(a) in the five years before the day on which the application is submitted, the applicant or, if the applicant is a corporation, partnership or cooperative, any of its officers, directors, partners or members, as the case may be, has

(i) been convicted of an offence under the Act or the FDA for which a pardon has not been granted or for which a pardon was granted but subsequently revoked, or

(ii) had a licence suspended or cancelled; or

(b) in the case of amendment or renewal, the applicant has fees payable under the Fees Notice in respect of that licence.

6. If a licence holder is unable to conduct an authorized activity in an establishment identified by a licence or if they have not conducted an authorized activity at an establishment identified by a licence for more than 12 consecutive months, the Minister may amend their licence to remove the authorization to conduct that activity in that establishment, without having received an application for the amendment.

7. (1) A licence expires two years after the date of issuance that is set out in it, unless the licence is cancelled before that date.

(2) If the Minister amends a licence, its expiry date remains unchanged.

8. A licence becomes invalid if

(a) the licence holder is subject to a receivership or makes an assignment in bankruptcy;

(b) the licence holder ceases to conduct all activities authorized by that licence for more than 12 consecutive months; or

(c) the licence holder surrenders the licence, unless a cancellation procedure has been commenced in respect of that licence.

9. The Minister may suspend a licence if

(a) the licence holder does not comply with any provision of the Act, these Regulations, the FDA or the FDR;

(b) the licence holder has fees payable under the Fees Notice in respect of that licence; or

(c) the Minister is of the opinion that a risk of injury to human health may result if the licence holder continues to conduct the authorized activity.

10. (1) If an inspector determines that grounds for suspension of a licence exist, the inspector must notify the licence holder of that fact and provide the licence holder with a copy of an inspection report that sets out the grounds for suspension and the date by which corrective measures must be implemented in order to avoid the suspension.

(2) If the licence holder does not take corrective measures by the date set out in the inspection report, the Minister must notify the licence holder in writing of the grounds for the suspension and the date on which it takes effect.

(3) Despite subsections (1) and (2), if the Minister is of the opinion that a risk of injury to human health may result if the licence holder continues to conduct the authorized activity, the Minister may, on the delivery to the licence holder of a notice of suspension and an inspection report that sets out the grounds for suspension, suspend the licence effective immediately.

11. A suspension of a licence remains in effect until an inspector determines that the grounds for suspension no longer exist.

12. The Minister may cancel a licence if

(a) the licence holder or, if the licence holder is a corporation, partnership or cooperative, any of its officers, directors, partners or members, as the case may be, has been convicted of an offence under the Act or the FDA for which a pardon has not been granted or for which a pardon was granted but subsequently revoked;

(b) the licence has already been suspended twice since its issuance or renewal;

(c) since the issuance or renewal of the licence, the licence has already been suspended for non-compliance with the same provision of the Act, these Regulations, the FDA or the FDR;

(d) the licence holder provided false or misleading information in their application for the issuance, renewal or amendment of the licence or at any time during which the licence has been valid;

(e) corrective measures are not taken within 90 days after the day on which the licence was suspended or within any longer period that is granted by the Minister on the request of the licence holder; or

(f) the licence holder continues to conduct the authorized activity while their licence is suspended.

13. (1) The Minister must notify the licence holder of the existence of any grounds for cancellation and of the opportunity to be heard in respect of the cancellation.

(2) The Minister must notify the licence holder in writing of the grounds for the cancellation and the date on which it takes effect.

PART 3
TRADE

14. (1) For the purposes of subsections 10(1) and (3) and section 12 of the Act, the prescribed food commodity is a food.

(2) For the purpose of subsection 10(2) of the Act, the prescribed food commodity in the case of import is a food other than a food additive and a beverage that contains more than 0.5% absolute ethyl alcohol by volume.

(3) For the purposes of subsection 13(1) of the Act, the prescribed food commodity that is to be exported or to be sent or conveyed from one province to another is a food other than a food additive and a beverage that contains more than 0.5% absolute ethyl alcohol by volume and the prescribed activities are manufacturing, preparing, storing, packaging, labelling and slaughtering of animals from which meat products may be derived.

(4) For the purposes of subsection 13(2) of the Act, the prescribed food commodity that is to be exported or to be sent or conveyed from one province to another is a food other than a food additive and a beverage that contains more than 0.5% absolute ethyl alcohol by volume and the prescribed activities are manufacturing, processing, treating, preserving, grading, packaging, labelling and slaughtering of animals from which meat products may be derived.

15. (1) A person who imports a food referred to in subsection 14(2) must

(a) hold a licence issued under paragraph 20(1)(a) of the Act;

(b) if they do not have a fixed place of business in Canada from which they carry on business related to the food being imported, send or convey the food directly from a foreign state

(i) in which they have a fixed place of business from which they carry on business related to the food, and

(ii) that has a food safety system that provides a similar level of protection to that of Canada;

(c) in the case of apples, onions and potatoes, have them inspected[11]

(i) at the Canadian port of entry if that port is normally serviced by an inspector,

(ii) if the port of entry is not normally serviced by an inspector or if an inspector is not available at the time of import, at any other place as authorized by the Minister, or

(iii) at any other place that is authorized by the Minister on the person's request; and

(d) in the case of a meat product, ensure that

(i) at the time it was exported, the foreign state from which it was sent or conveyed directly, any foreign state in which the live animal from which it was derived was slaughtered and any foreign state in which the meat product was manufactured, processed, treated, preserved, graded, packaged, labelled or stored had a meat product safety system that provides a similar level of protection to that of Canada,

(ii) they provide an inspector with evidence that substantiates that the meat product meets the requirements of the Act and these Regulations for imported meat products, and

(iii) without delay, it is delivered, in the condition in which it is imported, to an establishment in which the manufacturing, processing, treatment, preservation, grading, packaging or labelling of meat products is conducted by a licence holder[12].

(2) For the purposes of paragraph (1)(*b*), if the person imports a food from any foreign state and the food only passes in transit through the foreign state from which they carry on business related to the food, the person does not meet the requirement set out in that paragraph.

16. (1) A licence holder who imports a food referred to in subsection 14(2) must pay the applicable fee set out in the Fees Notice and provide the following import information to the Minister:

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[11] The intent is to include current exemptions for apples, potatoes and onions that are imported from the United States and for apples from New Zealand that have been inspected in those countries by the competent authority.

[12] The intent is to include the current exemptions for meat products imported from the United States that are certified by the United States Department of Agriculture.

(a) the licence holder's name, address and licence number;

(b) the name and address of the person from whom the food is being imported;

(c) the name and address of any person who manufactured or processed the food in the foreign state;

(d) the destination address of the food; and

(e) a description of the food and of its packaging, including the food's common name, lot number, quantity and, if applicable, brand name.

(2) The licence holder must provide the import information prior to import or at any other time that is authorized by the Minister.

17. Sections 15 and 16 and sections xx of Part XX [Labelling] do not apply to a food that is subsequently imported after having been exported if the food is

(a) in the condition in which it was exported; and

(b) returned to the licence holder who was last in possession of the food prior to export.

18. Any food referred to in subsection 14(2) that is sent or conveyed from one province to another — or imported or exported — must

(a) not be contaminated;

(b) be edible;

(c) not be manufactured, prepared, stored or packaged under unsanitary conditions; and

(d) meet all other applicable requirements of the FDA and the FDR.

19. Any food referred to in subsection 14(2) that is sent or conveyed from one province to another — or exported — must meet the following requirements:

(a) the food must have been manufactured, processed, treated, preserved, graded, packaged and labelled in accordance with a licence; and

(b) if the food is a meat product, it must have been derived from a live animal that was slaughtered in accordance with a licence.

20. (1) A person may send or convey from one province to another — or import — a food that does not comply with the Act or these Regulations if

(a) the food bears a label that states "For further preparation only" and "Pour conditionnement ultérieur seulement"; and

(b) subject to subsection (2), the food will be subject to any manufacturing, processing, treatment, preservation, labelling or packaging by a licence holder that is necessary to make it compliant with the Act and these Regulations within

(i) three months after the day on which the food is sent or conveyed from one province to another — or imported —, or

(ii) any longer period that is specified by the Minister on the person's request.

(2) It is prohibited for a person to mix a food that does not comply with paragraph 18(*a*) with a food that is compliant with that paragraph in order to make the resulting food compliant with these Regulations.

21. (1) If a standard for a food has been prescribed, it is prohibited for a person to import or to send or convey from one province to another any thing that is intended for sale and that is likely to be mistaken for that food unless the thing complies with the prescribed standard.

(2) If a standard for a food has been prescribed, it is prohibited for a person to package or label any thing that has been imported or sent or conveyed from one province to another, or that is intended to be sent or conveyed from one province to another, in such a manner that it is likely to be mistaken for that food unless the thing complies with the prescribed standard.

22. For the purpose of section 19 of the Act, importing, exporting or sending or conveying from one province to another is carried out solely for personal use if the food is not intended for commercial use and

(a) is imported, exported, sent or conveyed by an individual, otherwise than in the course of business, and part of a shipment of a food in a quantity that is equal to or less than the quantity set out in the Maximum Quantity Limits for Personal Use Exemption, as amended from time to time (see table below

which is intended to be a CFIA generated document that is incorporated by reference in the proposed regulations); or

(b) in the case of import or export, is part of an immigrant's or emigrant's effects.

Maximum Quantity Limits for Personal Use Exemption

Item	Column 1	Column 2
	Category of Food	**Amount**
(a)	Dairy products	20 kg or 20 L
(b)	Egg	1 case* for import, 24 cases for export, unlimited for the sending or conveying from one province to another
(c)	Fish	20 kg
(d)	Fresh fruits, fresh vegetables, fresh nuts, and fresh edible fungi	20 kg
(e)	Honey	20 kg
(f)	Maple syrup	20 L
(g)	Maple product other than maple syrup	4 kg
(h)	Meat products	20 kg
(i)	Processed egg	20 kg or 20 L
(j)	Processed fruit and vegetable product	20 kg or 20 L
(k)	All other foods not mentioned in (*a*) to (j)	20 kg or 20 L

* "case" means a package made to contain 30 dozen eggs.

23. The Act and these Regulations do not apply to a food that is imported, exported or sent or conveyed from one province to another and that is

(a) carried on a conveyance for use as food for the crew or passengers;

(b) destined and used for analysis, evaluation, research or an international or Canadian food exhibition and is part of a shipment that weighs 100 kg or less or, in the case of eggs, consists of five cases or less;

(c) not intended or sold for use as food and bears a label that

(i) indicates its intended use, and

(ii) states "Not for human consumption" and "Impropre à la consommation humaine";

(d) a pharmaceutical;

(e) in the case of import, sent or conveyed from the United States onto the Akwesasne Reserve for use by an individual who has established permanent residence on the Akwesasne Reserve; or

(f) in the case of interprovincial trade, sent or conveyed from one federal penitentiary to another.

24. The Act and these Regulations do not apply to a food commodity that is sent or conveyed from one foreign state, through Canada, to another, if the shipment is bonded.

PART 4
PREVENTIVE CONTROL
INTERPRETATION

25. The following definitions apply in this Part.

"commercial sterility"

"commercial sterility" means the condition obtained in a food that has been thermally treated by the application of heat, alone or in combination with other treatments, to render the food free from viable forms of microorganisms, including spores, that are capable of growing in the food at temperatures at which the food is designed normally to be held during distribution and storage.

"critical factors"

"critical factors" means those physical and chemical factors that affect the ability of the thermal treatment to achieve commercial sterility.

"hermetically sealed package"

"hermetically sealed package" means a package that is designed to be and is secure against the entry of microorganisms, including spores.

"inedible egg"

"inedible egg" includes an egg that

(a) is contaminated with an odour foreign to that of a normal egg;

(b) is musty or mouldy;

(c) has been in an incubator; or

(d) has any internal defect other than a meat spot or blood spot that does not exceed 3.175 mm (1/8 inch) in diameter.

"inedible processed egg"

"inedible processed egg" means processed egg that contains inedible egg.

"low-acid food"

"low-acid food" means a food, other than a beverage that contains more than 0.5% absolute ethyl alcohol by volume, of which any component has a pH that is greater than 4.6 and a water activity greater than 0.85 after thermal treatment.

"operator"

"operator" means a licence holder or any other person who is responsible for the operation of an establishment where a food commodity that is to be exported or to be sent or conveyed from one province to another is manufactured, prepared, stored, packaged or labelled or, if the food commodity is a meat product, where animals from which the meat product may be derived are slaughtered.

"refrigerated"

"refrigerated" means exposed to a temperature of 4°C or less but does not mean frozen.

"scheduled process"

"scheduled process" means the thermal process, together with the critical factors for a given food formulation, package type and size and unit of thermal treatment equipment, that will achieve commercial sterility in the food.

"water activity"

"water activity" means the ratio of water vapour pressure of a food to the vapour pressure of pure water at the same temperature and pressure.

ELEMENT 0 - RESPONSIBILITY OF OPERATOR

26. Every operator must maintain and operate the establishment in accordance with this Part.

ELEMENT 1 - PRODUCTS AND PROCESSES

27. Every operator must ensure that the food is treated using

(a) the treatment set out in section 28, as applicable;

(b) the treatment set out in Part X [Standards of Identity], as applicable; and

(c) any other thermal treatment, drying treatment, chilling treatment, chemical preservation treatment and any other similar treatment as may be necessary to prevent, eliminate or reduce any biological, chemical or physical hazard that may be present in the food and that presents a risk of contamination of the food.

28. (1) Every operator who packages a low-acid food in a hermetically sealed package must thermally treat the low-acid food until commercial sterility is achieved.

(2) Subsection (1) does not apply to a low-acid food packaged in a hermetically sealed package if the low-acid food is kept refrigerated or frozen and the statements "Keep Refrigerated" and "Garder au froid", or "Keep Frozen" and "Garder congelé", as the case may be, are shown on the principal display panel.

(3) A low-acid food packaged in a hermetically sealed package must not be thermally treated unless

(a) the thermal treatment meets the requirements of the scheduled process; and

(b) if batch thermal treating is employed, a temperature-sensitive indicator that visually indicates whether or not the package has been thermally treated is shown on or attached directly or indirectly to the package.

(4) Every operator who packages a low-acid food in a hermetically sealed package and thermally treats it to achieve commercial sterility must prepare, keep and maintain documents that describe, for each of those low-acid foods,

(a) the scheduled process, together with the name of the person responsible for the development of the scheduled process; and

(b) the formulation of the food.

(5) The documents referred to in subsection (4) must be kept and maintained for three years after the day on which the scheduled process is last used.

(6) Every operator who packages a low-acid food in a hermetically sealed package and thermally treats it to achieve commercial sterility must prepare, keep and maintain documents that describe the low-acid food history, including

(a) the production volume and identification of the food;

(b) the equipment used and the time, the temperature and, if applicable, the pressure of the thermal treatment used;

(c) the maintenance of and modifications to the equipment used including the instruments for controlling, measuring and recording temperature, pressure, pH, time, concentration and density;

(d) any deviations from the scheduled process and any corrective action taken;

(e) the incubation results; and

(f) if applicable, the cooling water treatments that are used.

(7) The documents referred to in subsection (6) must be kept and maintained for three years after the day on which the thermal treatment is used.

Element 2 — Sanitation, Pest Control, Sanitizers and Chemical Agents

29. Every operator must ensure

(a) that the establishment, and any equipment, facility and conveyance in it, is maintained in a clean and sanitary condition to prevent the contamination of the food; and

(b) that the cleaning and sanitation of the establishment, and of any equipment, facility and conveyance in it, are conducted in a manner that does not present a risk of contamination of the food.

30. Every operator must ensure that any conveyance that is used to transport the food and that is admitted to or leaves the establishment is clean and sanitary.

31. (1) Every operator must ensure

(a) that measures are taken to prevent entry into the establishment of any insects, rodents and other vermin that present a risk of contamination of the food; and

(b) that no other animal is present in the establishment, unless it is a food commodity that is to be manufactured, prepared, stored, packaged or labelled in the establishment.

(2) The measures taken for the purposes of complying with paragraphs (1)(*a*) and (*b*) must not present a risk of contamination of the food.

32. Every operator must ensure that any sanitizer and any chemical agent other than a food

(a) is properly identified;

(b) is appropriate for the purpose for which it is used and does not present a risk of contamination of the food; and

(c) is handled and used in a manner that does not present a risk of contamination of the food and, if applicable, that is in accordance with the manufacturer's instructions.

Element 3 - Hygiene and Competency

33. Every person who enters or is in an area of an establishment where a food that is to be exported or to be sent or conveyed from one province to another is manufactured, prepared, stored, packaged or labelled must wear clothing, footwear and coverings, including gloves, hairnets, beard nets and smocks, that are sound, clean and in sanitary condition and that are appropriate to the food and the activity being conducted.

34. Every person who enters or is in an area of an establishment where a food that is to be exported or to be sent or conveyed from one province to another is manufactured, prepared, stored, packaged or labelled must maintain personal cleanliness to prevent the contamination of the food, including by cleaning and, if appropriate, sanitizing their hands

(a) immediately upon entering the area;

(b) immediately before beginning or resuming the activity being conducted;

(c) immediately after using lavatories; and

(d) at a frequency appropriate to the food and the activity being conducted.

35. Every person who enters or is in an area of an establishment where a food that is to be exported or to be sent or conveyed from one province to another is manufactured, prepared, stored, packaged or labelled must refrain from spitting, chewing gum, using tobacco products, consuming food, having unnecessary contact with the food and doing any other act that presents a risk of contamination of the food.

36. Every person who enters or is in an area of an establishment where a food that is to be exported or to be sent or conveyed from one province to another is manufactured, prepared, stored, packaged or labelled must refrain from wearing any object and using any substance that presents a risk of contamination of the food.

37. (1) Every person who works in an area of the establishment where a food that is to be exported or to be sent or conveyed from one province to another is manufactured, prepared, stored, packaged or labelled who has a disease or illness, symptoms of a disease or illness or an open or infected lesion must report the disease or illness, the symptoms or the lesion to the operator.

(2) Every operator must ensure that no person who is suffering from or is a known carrier of a communicable disease or who has an open or infected lesion is present in an area of the establishment where the food is manufactured, prepared, stored, packaged or labelled if the person's condition presents a risk of contamination of the food.

38. Every operator must ensure that any person involved in the manufacturing, preparation, storage, packaging or labelling of the food has the appropriate competencies and qualifications to carry out their duties.

Element 4 - Equipment and Conveyances To Be Used in an Establishment

39. (1) Every operator must ensure that any equipment or conveyance used in the manufacturing, preparation, storage, packaging or labelling of the food

(a) is appropriate to the food and the activity being conducted;

(b) is designed of, constructed of and maintained using materials that are appropriate for the purpose for which they are used and, if the materials present a risk of contamination of the food, that are

(i) corrosion-resistant,
(ii) durable,
(iii) capable of withstanding repeated cleaning and, if appropriate, sanitizing, unless the equipment is of single-use, and
(iv) free of any noxious constituent;

(c) is designed, constructed, maintained and, if applicable, installed
(i) to not impart any substance that presents a risk of contamination to the food,
(ii) as appropriate, with instruments to control, measure and record parameters including temperature, pressure, pH, time, concentration and density,
(iii) to function as intended, and
(iv) to be accessible for cleaning and, if necessary, easily disassembled for cleaning, sanitizing, maintenance and inspection;

(d) is of sound construction and in good repair;

(e) has food contact surfaces, if any, that are
(i) smooth,
(ii) free from pitting, crevices and loose scale,
(iii) unaffected by the food, and
(iv) non-absorbent;

(f) is used as designed and constructed; and

(g) is used, maintained and, if necessary, calibrated
(i) in accordance with the manufacturer's instructions, and
(ii) in a manner that does not present a risk of contamination of the food.

(2) Any equipment used to handle contaminated materials, waste or anything that is inedible, including fish offal, inedible egg, inedible processed egg and inedible meat products, must
(a) be used only for that purpose;
(b) be identified as such; and
(c) satisfy the requirements of paragraphs (1)(a) to (g).

ELEMENT 5 - DESIGN, CONSTRUCTION AND MAINTENANCE OF ESTABLISHMENTS

40. Every operator must ensure that
(a) any land that forms part of the establishment
(i) is free of debris and refuse,
(ii) provides or permits good drainage, and
(iii) is maintained in a manner to prevent harbourage of insects, rodents and other vermin; and
(b) the establishment is not in proximity to anything that presents a risk of contamination of the food, including any source of pollution or any place that harbours insects, rodents or other vermin, unless measures are taken to eliminate any risk of contamination of the food as a result of the proximity.

41. Every operator must ensure that the interior of the facility or conveyance where the food is manufactured, prepared, stored, packaged or labelled is
(a) designed, constructed and maintained
(i) to be of sanitary design so as to prevent accumulation of contaminants including dust, dirt, micro-organisms and food particles and to permit effective maintenance, cleaning and, if appropriate, sanitizing,
(ii) to be of adequate size and layout to accommodate the activity being conducted and the equipment used in the activity,
(iii) of materials that are
(A) appropriate for the purpose for which they are used and appropriate to the food and the activity being conducted,

(B) durable,

(C) capable of withstanding repeated cleaning and, if appropriate, sanitizing, and

(D) free of any noxious constituent,

(iv) to prevent the entry of insects, rodents or other vermin,

(v) to have floors, walls, ceilings, windows and doors, if any, that are smooth, non-absorbent and impervious to moisture, and

(vi) to have floors, if any, that provide or permit good drainage; and

(b) of sound construction and in good repair.

42. Every operator must ensure that the facility or conveyance where the food is manufactured, prepared, stored, packaged or labelled is designed, constructed and maintained to effectively control the movement of persons, equipment, conveyances and food commodities within — and into and out of — the facility or conveyance so that the movement does not present a risk of contamination of the food.

43. Every operator must ensure that measures are taken to effectively control the movement of persons, equipment, conveyances and food commodities within — and into and out of — the facility or conveyance where the food is manufactured, prepared, stored, packaged or labelled, so that the measures and the movement do not present a risk of contamination of the food.

44. Every operator must ensure that incompatible activities or foods are separated by physical or other effective means.

45. Every operator must ensure that measures are taken to keep the food separate from

(a) any food that does not comply with these Regulations;

(b) anything that has been or is to be manufactured, prepared, stored, packaged or labelled that is not for human consumption; and

(c) any food that is to be sold solely within a province.

46. (1) Every operator must ensure that the facility or conveyance where the food is manufactured, prepared, stored, packaged or labelled is equipped with natural or artificial lighting that does not affect the food and is appropriate to the activity being conducted.

(2) Every operator must ensure that any light fixtures in the facility or conveyance where the food is manufactured, prepared, stored, packaged or labelled

(a) are capable of withstanding repeated cleaning and, if appropriate, sanitizing; and

(b) do not present a risk of contamination of the food in the event of breakage.

47. Every operator must ensure that the facility or conveyance where the food is manufactured, prepared, stored, packaged or labelled is equipped with a ventilation system that is designed, constructed and maintained to

(a) provide natural or mechanical ventilation with sufficient air exchange

(i) to provide only clean air to areas of the facility or conveyance where air presents a risk of contamination of the food,

(ii) to prevent accumulation of steam, condensation or dust that presents a risk of contamination of the food, and

(iii) to remove unclean air and odours that could affect the food;

(b) be accessible and, if necessary, disassembled, for cleaning, maintenance and inspection;

(c) be capable of withstanding repeated cleaning; and

(d) function as intended.

48. (1) Every operator must ensure that the temperature and humidity levels in the facility or conveyance where the food is manufactured, prepared, stored, packaged or labelled are appropriate to the food and to the activity being conducted.

(2) If the facility or conveyance is equipped with a heating, cooling or humidity control system, the system must be designed, constructed and maintained

(a) to have the appropriate instruments for indicating and recording the temperature and humidity levels;

(b) to be accessible and, if necessary, disassembled for cleaning, maintenance and inspection;

(c) to be capable of withstanding repeated cleaning; and

(d) to function as intended.

49. Every operator must

(a) provide effective means for the removal and disposal of contaminated materials and waste, including a drainage, sewage and plumbing system that is designed, constructed and maintained to

(i) adequately remove or dispose of all contaminated materials and waste in a manner that does not present a risk of contamination of the food,

(ii) be capable of withstanding repeated cleaning, and

(iii) function as intended;

(b) remove and dispose of contaminated materials and waste at a frequency that is sufficient to prevent the accumulation of contaminated materials and waste that presents a risk of contamination of the food; and

(c) when removing and disposing of the contaminated materials and waste, do so in manner that does not present a risk of contamination of the food.

50. (1) Every operator must provide and maintain handwashing stations, sanitizing stations, lavatories, water drinking stations, break rooms and change rooms, as appropriate to the food and activity being conducted, that

(a) are appropriately equipped and appropriate in number and size for the number of persons using them;

(b) are located so that they are readily accessible to the persons using them; and

(c) are capable of withstanding repeated cleaning and, if appropriate, sanitizing.

(2) Handwashing stations must have

(a) water at a temperature and pressure that is conducive to effective cleaning of hands;

(b) suitable materials for cleaning and, if appropriate, sanitizing hands; and

(c) means for hygienic drying of hands.

(3) Lavatories must not open into any area of the establishment where the food is manufactured, prepared, stored, packaged or labelled.

51. Every operator must have adequate areas and means for the cleaning and sanitizing of equipment and conveyances.

52. On the request of an inspector, an operator must provide an area for inspections that is appropriately equipped and sized and that is readily accessible to the inspector.

53. (1) Every operator must ensure that

(a) the establishment has a supply of potable water that is protected against contamination and that meets the standards set out in the Guidelines for Canadian Drinking Water Quality – Summary Table, prepared by the Federal-Provincial-Territorial Committee on Drinking Water of the Federal-Provincial-Territorial Committee on Health and the Environment and published by the Department of Health, as amended from time to time; (See the following link to the Guidelines which is intended to be incorporated by reference in the proposed regulations http://www.hc-sc.gc.ca/ewh-semt/pubs/water-eau/2012-sum_guide-res_recom/index-eng.php)

(b) any water that may come into contact with the food is potable water, unless the use of water other than potable water does not present a risk of contamination of the food;

(c) any steam or ice that may come into contact with the food is generated from potable water, unless the use of water other than potable water does not present a risk of contamination of the food; and

(d) there are no cross-connections between systems for potable water and any other system, unless measures are taken to effectively eliminate any risk of contamination of the food as a result of the cross-connections.

(2) Every operator must provide, as appropriate to the food and activity being conducted,

(a) water at adequate quantity, temperature, pH and pressure;

(b) steam at adequate quantity and pressure; and

(c) ice at adequate quantity.

(3) Every operator who treats water, steam or ice must do so in a manner that does not present a risk of contamination of the food.

Element 6 - Receiving, Transportation and Storage

54. It is prohibited for an operator to admit to the establishment any conveyance that contains the food, or to allow such a conveyance to leave the establishment, unless the conveyance is

(a) designed, constructed and maintained

(i) of materials that are

(A) appropriate for the purpose for which they are used and appropriate to the food and the activity being conducted,

(B) durable,

(C) capable of withstanding repeated cleaning and, if appropriate, sanitizing,

(D) free of any noxious constituent,

(ii) to not impart any substance that presents a risk of contamination of the food,

(iii) with the appropriate instruments for indicating and recording the temperature and humidity levels, and

(iv) to establish and maintain the temperature and humidity at a level that is appropriate to the food;

(b) of sound construction and in good repair;

(c) capable of protecting the food from a risk of contamination; and

(d) not being used and has not been used for the transport of animals, pest control products as defined in the *Pest Control Products Act* or any other material or substance that presents a risk of contamination the food.

55. Every operator must ensure that the loading and unloading of the food onto or from a conveyance at the establishment is done in a manner that does not present a risk of contamination of the food.

56. Every operator must ensure that any food that is admitted to the establishment and that presents a risk of injury to human health, is returned under section 17 or does not meet the requirements of the Act or these Regulations must be identified as such and moved to a designated area within the establishment and must not present a risk of contamination to any other food.

57. (1) Every operator who stores the food must do so in manner that does not present a risk of contamination of that or any other food, including by keeping the food separate from anything that presents a risk of contamination.

(2) Every operator who stores packaging material, labels, sanitizers, chemical agents, equipment or conveyances must do so in manner that does not present a risk of contamination of the food.

Element 7 - Investigation and Notification, Complaints and Recall

58. (1) Every operator, and every licence holder authorized to import a food, who learns that the food might present a risk of injury to human health or might not meet the requirements of the Act or these Regulations must investigate the matter as soon as feasible.

(2) If the results of the investigation indicate that the food presents a risk of injury to human health, the operator or the licence holder must notify the Minister without delay.

59. (1) Every operator, and every licence holder authorized to import a food, must prepare, keep and maintain a document that sets out a procedure for receiving, investigating and responding to complaints received in relation to the food.

(2) If a complaint is received, the operator or the licence holder must implement the procedure and prepare, keep and maintain a document that sets out the complaint information, the results of the investigation and the actions taken based on those results for a period of three years from the day on which the actions are completed.

60. (1) Every operator, and every licence holder authorized to import a food, must prepare, keep and maintain a document that sets out a recall procedure to enable the effective recall of the food and must conduct a recall simulation based on the recall procedure at least once a year.

(2) If the food is recalled, the operator or the licence holder must without delay notify the Minister and implement the recall procedure and must prepare, keep and maintain, for a period of three years from the day on which the recall is initiated, a document that sets out the date of the recall and how the recall was carried out.

PART 5
TRACEABILITY

61. This Part does not apply to the activities referred to in section 22.

62. (1) Any person who sends food from one province to another — or imports or exports it — and any licence holder who processes, treats, preserves, grades, manufactures, packages or labels food that is to be exported or to be sent or conveyed from one province to another must prepare, keep and maintain documents that identify

(a) if that food was received from another person, that food, the date on which it was received, the address at which it was received and the name and address of the person who sent it;

(b) if the person or licence holder received a food commodity that is incorporated into that food or from which that food is derived, that food commodity, the date on which it was received, the address at which it was received and the name and address of the person who sent it;

(c) if the food is sent to any other location, that food, the date on which it was sent, the name and address of the person who conveys it, the name of the person to whom it was sent and the address of the location to which it was sent; and

(d) the name of a contact person for each of the addresses referred to in paragraphs (a) to (c).

(2) The documents referred to in subsection (1) must be kept for three years from the latest of the dates referred to in paragraphs (1)(*a*) to (*c*).

63. A person who is required to prepare, keep and maintain documents under section 62 must ensure that those documents are accessible in Canada.

64. A person must, on the request of the Minister, provide the Minister with the documents referred to in section 62 within 24 hours of the time of the request or, if the Minister is of the opinion that a risk of injury to human health may result, within any shorter time limit specified in the request.

65. (1) A person who provides documents under section 64 must ensure that

(a) the information referred to in paragraph 62(1)(d) is up to date; and

(b) the documents are provided electronically, in English or French, in plain text that can be imported into and manipulated by standard commercial software.

(2) In paragraph (1)(*b*), "plain text" means data, the semantic content of which is available without using cryptographic techniques.

66. Food referred to in paragraph 62(1)(*c*), other than food that is to be exported, must be labelled to enable its traceability using a lot identifier, bar code, universal product code or other similar identifier.

Annex 4: Written PCP

The proposed requirements for a written PCP could be reflected in the regulations as follows:

A Preventive Control Plan (PCP) means in respect of a food or the manufacturing, preparing, storing, packaging, labelling, growing, harvesting and importing of a food, a written preventive control plan that effectively:

- Identifies for Elements 1-7:
  - all hazards that must be prevented, eliminated or reduced;
  - critical control points and related control measures that are validated by evidence that demonstrates that the control points and related control measures effectively control the hazards identified ;
  - critical limits;
  - monitoring procedures;
  - corrective action procedures;
  - verification procedures; and
  - record keeping procedures; and
- Identifies the measures they have taken to comply with other relevant regulatory requirements, including those FDR requirements that will be incorporated in the proposed regulations e.g. packaging and labelling provisions of FDR.

Every licence holder and every person who grows or harvests a fresh fruit or vegetable that is to be sent or conveyed from one province to another must:

- prepare, keep and maintain a PCP;
- implement the PCP;
- prepare, keep and maintain documents that substantiate that the food has been imported, manufactured, prepared, stored, packaged, labelled, grown and harvested in accordance with the PCP;
- prepare, keep and maintain documents that substantiate that the manner in which the food was imported, manufactured, prepared, stored, packaged, labelled, grown and harvested is in compliance with the Act and the Regulations; and
- prepare, keep and maintain a document that sets out a procedure for the maintenance and review of the PCP, and implement that procedure.

Every person who prepares a food that is to be exported and every person who grows or harvests fresh fruits and vegetables that is to be exported must prepare, keep, maintain and implement a PCP as described above if they request an export certificate.

Annex 5: Commodity-Specific Requirements

In addition to the basic requirements for food safety that apply to all regulated parties, the proposed regulations will maintain some commodity-specific requirements from current regulations.

A side-by-side review of existing and proposed regulatory provisions is underway to determine:

- current provisions that are addressed horizontally through the key elements that will apply to all regulated parties;
- current provisions that do not need to be retained for food safety or market access;
- provisions that would be new for a given commodity; and
- current provisions that are not covered in the horizontal key element that need to be maintained.

Commodity-specific requirements to be maintained are being assessed as to whether they could be streamlined or made more outcome-based, while still achieving the same regulatory outcome.

Note: Most commodity-specific requirements not related to food safety (e.g. standards of identity, grades, labelling requirements) will also be maintained.

Examples of some commodity specific elements are presented below.

NOTE: The following is a preliminary list of examples of specific requirements likely to be in the regulations. The detailed review of commodity regulations is still underway and will result in additional commodity specific requirements.

Horizontal

The following categories of requirements exist for more than one commodity. Where they are currently prescribed for a given commodity, they would be retained:

1. Microbiological criteria e.g. coliform and viable bacteria counts in processed egg.
2. Requirements for inedible products including handling and labelling.
3. Licensing of cold-storage facilities.

Egg

Ungraded Eggs

Provisions for the movement of ungraded eggs including imports.

Processing Requirements

Requirements for heat treatment, washing and cooling.

Fresh Fruit and Vegetables

Primary Producers

Provisions specifically for primary producers are being developed to address the growing and harvesting of fresh fruit and vegetables, including:

- environmental condition of the production site including previous, present and adjacent land usage, access to domestic animals and wildlife,
- use of agronomic inputs including agricultural chemical, biological controls, compost, soil amendments

Fish

Import prohibitions
Mitten Crab and Puffer Fish; and shellfish from non-approved growing waters, to control for toxins.

Vessels
Provisions related to "onboard waste containment management" and "grandfathering" older vessels from certain current requirements.

Unloading, Holding, Handling, Transportation (UHHT)
Specific requirements related to the holding and handling of fish during transportation and unloading.

Vessels/UHHT
Specific exemptions for fish, crustaceans undergoing minimal handling, and product not subject to processing and intended for delivery to a licence holder.

Sport-caught fish
Issuance of certificates for sport-caught fish for export to EU, even though the product is for personal use/consumption.

Shellfish
Specific requirements related to scallops for holding and packing, and the type of containers that must be used.
Record-keeping requirements specific to shellfish, in part related to Canada/U.S. shellfish agreement.

Meat

Facility Requirements – For areas where live animals are received, handled, kept.

Official tags – Held, Condemned – for ante and post mortem inspection:
Official identification tags for animal or meat product held or condemned during routine ante mortem and post mortem inspection procedures.

HACCP – FSEP:
HACCP provisions and other requirements of the FSEP Manual will be maintained, likely through continued use of incorporation by reference.

Animal Information Documents:
Information from the producer/owner of food animal presented for slaughter respecting risk assessment for ante and post mortem examination and inspection procedures; food safety and suitability; disease control; market access; and animal welfare.

Humane handling and slaughter:
Requirements for the humane handling and slaughter of food animals in establishments. A number of provisions are harmonized with the proposed humane transport regulations (Health of Animal Regulations).

Ante mortem procedures:
Provisions respecting ante mortem examination (screening) of food animals by the operator, and ante mortem inspection procedures by CFIA.

Post mortem procedures:
Provisions respecting post mortem examination of carcass of food animals by the operator, and post mortem inspection procedures by CFIA.

Shared Inspection Programs:
Enabling regulations to support the modernization of slaughter inspection programs. Provisions currently exists in the *Meat Inspection Regulations*, 1990 only for poultry (Modernized Poultry Inspection Program (MPIP), Poultry Rejection Program (PRP))

Edible meat products standards:
Provisions to cover *listeria* and *E. coli* policy requirements; *Trichinella*; *Cysticercosis*; moisture retention in dressed carcasses and parts; microbial performance standards for dressed carcasses; defects disposition for carcass and parts.

Water use and reuse:
Provisions to cover possibility of using safe water in lieu of potable water under specific circumstances, provided no impact on food safety and suitability.

Inedible meat products identification and controls:
Inedible meat products (e.g. animal food, pharmaceutical, for education, for research) identification and controls. Requirements for Specified Risk Material SRM (denaturing/staining).

Trade exemptions
Carcass and parts of hunted game animal for personal use.

Commercial trade of hunted game animal:
The commercial harvest of muskox, reindeer and caribou will be done through a licensing scheme under the new regulations. Currently addressed through an exemption scheme under the *Meat Inspection Regulations, 1990.*

Preparation service for carcass of game animal for own use:
Licence holders will be allowed to offer preparation services for carcass of game animals brought by the owner (e.g. the hunter). Services could include cutting, boning, preparation of sausages. These meat products will not be inspected and will not bear any inspection marks. The proposed regulatory amendments for this scheme was published in the *Canada Gazette Part I* on April 7, 2012 (Vol. 146, No. 14 — April 7, 2012).