



CANADIAN SUPPLY CHAIN FOOD SAFETY COALITION

COALITION CANADIENNE DE LA FILIÈRE ALIMENTAIRE POUR LA SALUBRITÉ DES ALIMENTS

Consolidated Comments on CFIA Regulatory Modernization Discussion Papers

Submitted by the
Canadian Supply Chain Food Safety Coalition

8/29/2014

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Introduction

The Canadian Supply Chain Food Safety Coalition appreciates this opportunity to comment on the discussion papers, issued in May and June 2014 by the Canadian Food Inspection Agency, respecting the modernization of Canada's food safety regulatory system and the implementation of the *Safe Food for Canadians Act* and Regulations.

The Coalition was an early supporter of these modernization initiatives and continues to support the broad thrust of the government of Canada's initiatives in this regard.

Canadian Supply Chain Food Safety Coalition

The Canadian Supply Chain Food Safety Coalition was formed in December 2000 and incorporated in 2007 to act as "a single strong voice for Industry along the food chain, with the public and government on industry-wide food safety issues". Our membership is composed of national, provincial and regional associations involved in the agri/aqua-food industry and of individual companies that provide services to the industry (see below) .

These organizations represent businesses at every link in the food supply chain from input suppliers through primary production, transportation, processing, manufacturing, distribution and importing to final marketers at export, retail and food service.

Our Vision is that:

"Canada's agriculture, aquatic and food industry will have a world-class reputation for producing and selling safe food."

Our Mission is to:

"facilitate, through dialogue within the food industry and with all levels of government, the development and implementation of a national, co-ordinated approach to food safety to ensure credibility in the domestic and international marketplaces".

Our Approach

In preparing these comments, the Coalition has focussed on the broad and horizontal aspects of the proposed regulations and other discussion documents that are interest to all our members. Matters of particular concern to segments of the supply chain or vertical chains within the supply chain will no doubt be raised by those members in their submissions.

The Coalition uses an iterative process to develop its policy positions. Starting initially from the guiding principles, goals and actions established in Coalition's 2009 National Strategy, a draft set of comments is

prepared and circulated first to the board of directors and then to the members. Comments and proposals are requested, received, integrated and recirculated to the members for further input.

The CFIA discussion papers considered for this submission were:

- *A New Regulatory Framework for Federal Food Inspection: Overview of Proposed Regulations;*
- *CFIA Guidance Documents Supporting Compliance with the Proposed Safe Food for Canadians Regulations;*
- *Enhancing Risk Analysis: A more systematic and consistent approach;*
- *Private Certification to Inform Regulatory Risk-Based Oversight;*
- *Foreign Food Safety Systems Recognition: Proposed Framework Incorporation by Reference; and,*
- *Incorporation by Reference.*

In addition, the CFIA's Inspection Modernization Integrated Agency Inspection Model Consultation Draft (April 24, 2014) was reviewed as a background document.

Each discussion paper will be dealt with in its own Part of this submission.

Membership of the Canadian Supply Chain Food Safety Coalition - August 2014

National Organizations (28)

CropLife Canada
Canadian Animal Health Institute
Canadian Trucking Alliance
Canadian Federation of Agriculture
Canadian Hatching Egg Producers Association
Turkey Farmers of Canada
Chicken Farmers of Canada
Egg Farmers of Canada
Canadian Pork Council
National Cattle Feeders Association
Dairy Farmers of Canada
Canadian Horticultural Council
Canadian Produce Marketing Association
Canadian Meat Council
Canadian Poultry & Egg Processors Council
Further Poultry Processors Association of Canada
Dairy Processors Association of Canada
Fisheries Council of Canada
Food and Consumer Products of Canada
Food Processors of Canada

Canola Council of Canada
Canadian National Millers Association
Baking Association of Canada
Canadian Association of Importers and Exporters
Canadian Association of Regulated Importers
Retail Council of Canada
Canadian Federation of Independent Grocers
Canadian Restaurant & Food Service Association

Provincial/Territorial Groups (3)

Alberta Egg Producers Council
Ontario Produce Marketing Association
Small Scale Food Processors Association

Allied Members (4)

SAI Global
NSF/Guelph Food Technology Centre
GS1 Canada
CanadaGAP

Part I – Proposed Draft Regulations and Supporting Guidance

Documents:

A New Regulatory Framework for Federal Food Inspection: Overview of Proposed Regulations

(<http://inspection.gc.ca/about-the-cfia/accountability/consultations/federal-food-inspection/eng/1400782729114/1400782730114>)

CFIA Guidance Documents Supporting Compliance with the Proposed Safe Food for Canadians Regulations

(<http://inspection.gc.ca/about-the-cfia/accountability/consultations/supporting-compliance/eng/1402207040405/1402207041624>).

Integrated Agency Inspection Model – Consultation Draft (April 24, 2014)

(<http://inspection.gc.ca/about-the-cfia/accountability/inspection-modernization/integrated-agency-inspection-model/iaim-consultation/eng/1390935174455/1390935603829>)

General Comments:

The Coalition appreciates that the prepublication of the proposed draft regulations and the supporting guidance documents, in draft, prior to their publication in the Canada Gazette, Part I, is not a common practice. The government of Canada is to be commended for taking this approach to consultations with industry and other stakeholders.

The Coalition's comments on the proposed draft regulations and the supporting guidance materials are grounded in the four principles set out in our 2009 National Strategy:

Principle #1: Food safety is a shared responsibility of all participants in the supply chain, input suppliers, businesses involved with the production, processing, manufacturing, importing, distribution, retailing and marketing of food, all levels of government and consumers;

Principle #2: Governments at all levels, the agri-food industry and other stakeholders should foster and facilitate the development of an integrated, co-ordinated, and national approach to food safety policy and regulation based on sound scientific risk assessment and risk management principles and on international standards.

Principle #3: Industry and government food safety initiatives should encourage the implementation of HACCP and/or HACCP-based food safety systems by businesses all along the supply chain.

Principle #4: Food businesses, governments and other stakeholders have a responsibility to adequately resource, proactively manage, update, maintain and continually improve their individual and collaborative food safety systems and food safety initiatives.

With respect to Principles #1 and #4, the CSCFSC notes that the *Safe Food for Canadians Act* and the proposed regulations are a very positive step forward. They embody the principles of shared responsibility and indicate that the government of Canada is moving to update and improve its oversight of industry's food safety controls and other related initiatives.

It is noted, however, that the regulations stop well short of encompassing all the segments of the supply chain that fall within the scope of the Act. As stated in the Coalition's Principles #1, #2 and #3, it is the Coalition's expectation that where the federal government has jurisdiction all businesses, all along the supply chain should be included as regulated parties. As provided for in the Act and the proposed regulations, exemptions from licensing may be granted and this approach could be used where justified.

With respect to Principle #2, the CSCFSC notes that within the federal jurisdiction, the new regulatory approach should provide for greater consistency in oversight. The proposed transition to an "outcome-based" approach and the substantial reduction in the number of prescriptive requirements is positive, but, it will also create a substantial new burden particularly for micro, small and medium sized regulated parties. The Coalition will provide further comments on this challenge in the context of the discussion paper on compliance promotion. **To truly achieve an integrated, co-ordinated and national approach to food safety policy and regulation, the CSCFSC strongly encourages the responsible minister and the Agency to engage their provincial and territorial counterparts in a new round of negotiations on harmonization of food safety regulations.**

With respect to Principle #3, the CSCFSC notes that while the concept of HACCP is mentioned seven (7) times in the text and is stated to be the basis of the proposed approach to preventive control plans (PCPs) (e.g. pp. 6, 15 and 16), it does not appear in either definitions (s. 1) or in any other part of the text of the regulations. This is disappointing. Other jurisdictions have decided to explicitly reference HACCP or HACCP-based approaches in either their legislation or their regulations (e.g. EU, US, China, and India).

Technical Comments:

In this part, the focus will be on the draft text of the regulations (i.e. Annexes 3 and 4) and the associated draft guidance.

1. Disclaimer and Partial Draft:

The Coalition notes the Agency's "disclaimer" that Annex 3 is "preliminary draft text for some elements of the proposed regulations". While we understand the difficulties faced by the Agency in trying to produce a full draft of the regulations by late May of this year, the absence of a full draft of text for key parts of the regulation, in particular, the proposed text concerning preventive control plans (Annex 4) presents a very serious challenge to the preparation of these comments. **The CSCFSC looks forward to commenting on these key elements when they become available.**

2. Annex 3 – Part 1 - Interpretation – Definition of Contamination (Overview p. 40)

It is noted that a definition of “contaminated” is included in s. 1 of the draft proposed regulation. This raises a long-standing concern of the Coalition and its members, the definition of “contamination” in paragraph 4(1)(a) of the Food and Drugs Regulations. As the Coalition indicated in its presentations to the Senate and the House committees during the consideration of Bill S-11, the passage of the Safe Foods for Canadians Act does nothing to remove the absolute prohibition of the sale of a food that “has in or on it any poisonous or harmful substance”. The counterpart legislation in the US acknowledges that contaminants can be present at levels that would not ordinarily present a health risk. **The CSCSFSC recognizes that the required legislative change is outside the scope of the proposed regulations; however, it strongly recommends that the CFIA raise this matter with the Minister of Health with the objective of amending the Food and Drugs Act prior to the implementation of the Safe Food for Canadians Act regulations.**

3. Annex 4: Written PCP – Food Safety Management System: (Overview p. 55, Guidance pp. 52-65):

A regulated party’s written and implemented preventive control plan (PCP) is the foundation of its food safety controls, management system, etc.. The Overview document indicates that the PCP requirements are to be based on international standards and management-based requirements, including HACCP. Annex 4, at the highest level of abstraction – the bullet point – sets out these requirements in the context of the prerequisite programs in Elements 1 to 7 of the draft regulation. It requires the identified regulated parties to prepare, keep, maintain, implement and validate the PCP, document it and keep records, etc.. The Annex also identifies five (5) aspects of the PCP that require mandatory procedures (i.e. monitoring, corrective action, verification, record-keeping and maintenance and review of the PCP). In addition, there are at least eight (8) procedures identified as mandatory in Elements 1 to 7 (i.e. purchasing, cleaning and sanitization, environmental sampling, pest control, control of animals (other than pests), visitor/contractors, complaints and recall). Taken together these requirements give the appearance to a PCP of a food safety management system approach. However, as is clearly demonstrated by the 14 pages of detailed guidance (Part 4, PCP 1.1 to 1.8) – the current draft of Annex 4 is not adequate.

CFIA has identified in its discussion papers on private certification and risk-based oversight the fact that many companies that will be regulated under the Act are already implementing internationally accepted food safety management systems. As a consequence, CFIA compliance officers reviewing PCP documentation and implementation will, in a large number of food businesses, find these embedded in the regulated party’s food safety management system and be expected to be both familiar with such systems and competent to assess their effectiveness. These systems are, at their core, are based on ISO management system principles and Codex HACCP principles as are the criteria for CFIA’s official recognition programs and the provincially sponsored food safety certification schemes. There is tremendous convergence in the requirements of these Canadian and international schemes – a convergence that will continue with each new upgrade in the international voluntary standards or private sector benchmarking requirements.

The CSCFSC recommends that CFIA clearly state its expectations for a written preventive control plan in one section of the regulations and that it include in its food safety expectations for a PCP the current internationally accepted requirements for a food safety management system and the use of either a site specific hazard analysis (based on the Codex HACCP principles) or a generic hazard analysis (HACCP-based).

4. Preventive Control Plan – Seven Key Elements (Overview (p. 15), IAIM (p. 21))

The Coalition recognizes that the discussion documents and draft proposed regulations that are currently available for comment were developed and finalized at different times. It is, therefore, to be expected that there are some discontinuities. The Canada Gazette Part I version of the regulations will, no doubt, resolve most of these. However, the significant difference between the language used to describe the seven key elements of a preventive control plan (PCP) that are apparent in the text of the Integrated Agency Inspection Model (IAIM) and the proposed draft regulations require comment. The IAIM list of headings (p. 21) and the details in Annex B (pp. 58 – 79) are, for some elements, different from those set out in the Overview (p. 14) and Annex 3 (pp. 40-54). In particular, in the IAIM list and details, Element 2 references requirements respecting “biosecurity” and “biocontainment” and Element 3 references “biosecurity”. These references are absent in the Overview list and details,.

The Coalition has, in previous consultations on the new food safety regulatory regime and in this set of comments, noted that there are a number of areas which could be considered for inclusion in the preventive control plan requirements, such as intentional contamination (e.g. food defense, malicious acts, etc) and food fraud. Biosecurity and biocontainment, for some segments of the supply chain, could also be considered for inclusion. These potential additions all require careful review, including consideration of developments in other countries and in the global marketplace.

The CSCFSC requests clarification as to whether or not the Agency proposes to include “biosecurity” and “biocontainment” in the requirement for a PCP and, if so, how it plans to distinguish between regulated parties to which these requirements apply and those that it does not.

5. PCP 1.2 Food Safety Hazard Identification and Control (Overview pp. 55-57):

The draft text of Annex 4 indicates that “critical control points and related measures” should be validated. PCP 1.2 appears to set an Assessment Criteria that would include all control measures. **The CSCFSC requests CFIA to clearly indicate in the regulation its expectations for validation.** Does it intend for validation to include just control measures associated with critical control points (CCPs) or the full system or both separately.

6. “Food” or “Food Commodity”: (Overview pp. 42, 44)

The proposed text of the draft regulations for the most part limits the scope of the regulation to a “food commodity” that *“is a food other than a food additive and a beverage that contains more than 0.5% absolute ethyl alcohol by volume”* (e.g. s.2 dealing with licences, s. 14 dealing with trade, etc.), that is “food” as defined by section 2 of the Food and Drug Act. **As noted above, the CSCFSC recommends that**

the regulations be applied to all businesses, all along the supply chain covered by the scope of the *Safe Food for Canadians Act*, including, for example, international or interprovincial conveyance companies, storage facilities involved in trade, etc. and where justified, that certain regulated parties be exempted from some requirements.

7. Part 4, Element 1 – Products and Processes (Overview s. 27 to s. 28, pp. 47-48, Guidance 4.1.a and 4.1.b, pp. 6-8):

The Guidance discussion paper raises, at 4.1.a, the absence of requirements addressing “specifications and control of incoming ingredients, raw materials, agricultural inputs, packaging/labelling materials and rework in the context of Element 1 - Products and Processes”. It is noted that internationally accepted food safety management system standards and certification schemes, the provincially sponsored food safety certification schemes, the Food Safety Enhancement Program (FSEP) and the criteria for the CFIA-led recognition programs all include requirements for these specifications and controls. The Guidance in 4.1.a proposes three (3) options for control processes for ingredients, raw materials and packaging and labelling materials: periodic evaluation of incoming items, lot inspection and supplier verification. The latter is a requirement of the internationally-accepted food safety management system certification standards and schemes. It is also noted that US FDA is consulting as to whether or not to include supplier verification in the FSMA regulations. **The CSCFSC recommends that the Agency clarify its expectations respecting the content of a purchasing procedure, either in Element 1 or in Element 6, or perhaps in a separate element and include in those expectations a requirement for supplier verification.**

8. Part 4, Element 3 – Hygiene and Competency (Overview s. 33 to s. 38, p 49 and Guidance 4.31 to 4.3.4, pp. 19-23):

The proposed regulatory text combines requirements for clothing and footwear, personal hygiene, health and competency in one Element. The Coalition recognizes and supports the proposed inclusion of the concept of competence (i.e. the ability to apply knowledge and skill to achieve intended results) alongside qualifications in the regulations. This is an important, albeit challenging, paradigm shift. As such it should be given greater prominence in the regulations. **The CSCFSC recommends that Competency (s. 38) be clearly identified as a separate element.**

The current draft text of s. 38 includes a list of activities for which competency must be demonstrated. It is, however, not complete. For example, it does not include activities related to the preparation and review of the PCP. The Guidance discussion paper, in addition to noting the generic requirement mentions at least seven functions where competency is important (i.e. pest control, equipment maintenance, calibration, complaints investigation, monitoring control measures, verification, and PCP review). For six of these, it also indicates that a person or persons should be “named” or “identified” as having responsibility for the activity. **The CSCFSC recommends that the proposed Element for Competency be drafted to include, at a minimum, a general requirement concerning the assignment of responsibilities and authorities or more prescriptively, a clear list of functions such as PCP (food**

safety) team leader, person responsible for complaints investigation, person responsible for implementing the recall procedure, etc..

9. Part 4, Element 5 – Design, Construction and Maintenance of Establishments (Overview, s. 40 to 53, pp. 50 – 53).

It is noted that there is considerable repetition of requirements concerning conveyances in Elements 2, 4, 5 and 6. It is also noted that s. 51 requires an operator to have “adequate areas and means for the cleaning and sanitizing of equipment and conveyances” but that in this section, unlike s. 29 where the text is “conveyance in it”, appears to cover any and all conveyances. Requiring all regulated parties to provide a cleaning area for conveyances (e.g. transport trailers) would clearly be burdensome. **The CSCFSC recommends that the wording of s. 50 be amended to clearly indicate that it applies to “conveyances in” the regulated party’s facility.**

10. Part 4, Element 6 – Receiving, Transportation and Storage (Overview s. 54 to 57, p. 53, and Guidance 4.6.1 to 4.6.3, pp. 42-47):

The Agency’s intention is unclear with respect to the responsibilities of the regulated party (operator) with respect to storage. In ss. 57 (1) the reference to “storage” appears to include storage of food at any location. However, the description in the Guidance to this section (4.6.3, p. 46) clearly indicates that this is “Storage at the Establishment”, which one assumes would be at an establishment under the control of the operator. **The CSCFSC recommends that the wording of ss. 57(1) be amended to clearly identify that it pertains to a facility or establishment under the direct control of the regulated party.**

11. Part 4, Element 7 – Investigation and Notification, Complaints and Recall (Overview s. 58 to s. 60, pp. 53-54, Guidance 4.7.1 to 4.7.3, pp. 48-51):

The proposed text for ss. 58(2) requires the operator to immediately inform the Minister of the results of any investigation that identifies food that presents “a risk of injury to human health”. Regulated parties will undertake “investigations” for many reasons and will, in all likelihood, identify food that presents “a risk to human health”. If the regulated party’s PCP is operating properly, corrective actions will be taken and the food will not be released into the market. The current wording appears to cover all instances and could result in a massive documentation burden for regulated parties and the Agency. **The CSCFSC recommends that the wording of ss. 58(2) be amended to indicate that the immediate notification is required only in cases where the food has left the control of the regulated party..**

12. Part 5 – Traceability (Overview s. 61 to 66, p. 54):

The proposed text of paragraph 62(2)(d) requires the regulated party have a record of the “name of the contact person for each of the addresses referred to in paragraphs (a) to (c)” (i.e. its suppliers of food or ingredients and customers). It is likely that the actual “person” could change regularly (e.g. holidays, shifts, departures, retirements, etc.), especially over the period of the 3 year record-keeping requirement and that continual updating of names would be required by all regulated parties. **The**

CSCFSC recommends that para. 62(2)(d) be amended so that the requirement would be for the functional contact (i.e. company function responsible for recalls) not a personal name.

The proposed text for ss. 62(2) requires that the traceability records referred to in ss. 62(1) must be kept for three years. It is noted that most food safety management system requirements relate the time for retention to the expected use of the product or to that use plus one (1). It is also expected that the Food Safety Modernization Act regulations would likely have a two (2) year retention requirement for high risk foods. **The CSCFSC recommends that the Canadian requirement be harmonized with the US requirement.**

The proposed text of s. 64 requires that on the request of the Minister a regulated party must provide “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”. While it is noted that the Agency has indicated that this requirement would be utilized only in cases where a regulated party was demonstrably recalcitrant, there is a concern that the provision could be used arbitrarily and that very short and unreasonable time limits could be set under any circumstances. **The CSCFSC recommends that the wording of s. 64 be amended to include a minimum number of hours, if a time shorter than 24 is requested (e.g. x number of hours such as 4, 6 or 8).**

The proposed text for s. 66 requires certain food to be “labelled to enable its traceability using a lot identifier, bar code, Universal Product Code or other similar identifier”. It is noted that this wording could create confusion and includes redundancies (e.g. bar code and Universal Product Code are basically the same thing). It is also noted that most traceability standards (e.g. the Can-Trace Data Standard, the GS1 Global Traceability Standard, ISO 22005:2006, the Produce Traceability Initiative, etc.) have a common core of basic requirements and that these focus on the “lot” and its identification. Under all these standards each food business, at each link in the supply chain, is expected to define “lot” for their own purposes. It was also noted that the data requirements in 62(1)(a) to (c) drew upon these same principles of traceability and that it would be consistent with the overall preventive control plan approach to require regulated parties to use these same principles. **The CSCFSC recommends that the wording of s. 66 be amended by deleting the words after “labelled to enable its traceability”.**

Part II - Enhancing Risk Analysis

Documents:

Enhancing Risk Analysis: A more systematic and consistent approach (<http://inspection.gc.ca/about-the-cfia/accountability/consultations/enhancing-risk-analysis/eng/1401877060366/1401877061647>)

General Comments:

The CSCFSC supports, in principle, the proposal by CFIA to establish a “proactive, systematic risk-based approach for its oversight activities”. We recognize that under the *Safe Food for Canadians Act* and Regulations, the Agency’s mandate has been significantly increased. The number of new regulated parties, including importers, fresh produce producers, currently non-registered food manufacturers, etc., is unknown but will be substantial. It is one of the guiding principles of the Coalition’s National Strategy that “food businesses, governments and other stakeholders have a responsibility to adequately resource, proactively manage, update, maintain and continually improve their individual and collaborative food safety systems and food safety initiatives”. **Given the broader mandate and larger clientele, the Coalition has urged in its 2014 pre-budget submission that the government of Canada make significant new investments in the implementation of the new food safety regulatory system.**

Technical Comments:

1. Program Approach and Design:

The discussion paper indicates that the Agency’s new systematic approach to risk analysis and oversight will be grounded in the approaches adopted by the Codex Alimentarius Commission for food safety, the World Organization for Animal Health (OIE) for animal health and the International Plant Protection Convention (IPPC) for plant health. **The CSCFSC supports this decision to utilize international, intergovernmental standards and approaches.**

The discussion paper also clearly indicates (for example in Figure 3 (p. 10)) some of the factors that the Agency will take into account in its oversight decision-making process. The descriptions (pp. 11-12) of how these factors will be incorporated are, however, very general and do not provide sufficient information to permit an assessment of the proposals or their expected outcomes.

It is noted (p. 8) that the Agency has initiated a pilot program of its “risk assessment model” in meat, poultry and dairy establishments. **The CSCFSC recommends that the Agency publish and circulate a summary of the results of this pilot project and, thereafter, re-launch consultations on its approach to risk analysis and oversight in greater detail. The Coalition would be pleased to offer additional comments at that time.**

Part III - Private Certification to Inform Regulatory Risk-Based Oversight

Document:

Private Certification to Inform Regulatory Risk-Based Oversight

<http://inspection.gc.ca/about-the-cfia/accountability/consultations/regulatory-risk-based-oversight/eng/1391216173942/1391216243709>

General Comments:

The Coalition fully supports the decision by CFIA to take private certification into account in establishing its approach to risk-based oversight of food safety requirements. However, we are concerned that the proposed approach does not clearly include the official recognition of Canadian, industry-led food safety certification schemes. **The CSCFSC recommends that the Agency commit, at the earliest possible date, to the continuation of the two national recognition programs for Canadian, industry-led food safety certification schemes.**

The Coalition has, since its formation in 2000, been a strong supporter of the development in Canada of industry-led, HACCP or HACCP-based food safety management system certification schemes for the non-registered sector, including farms. It has fully supported the CFIA-led, federal-provincial-territorial initiative to establish national programs to recognize these certification schemes and championed both the schemes and the two official recognition programs in its dealings with parliamentary committees, FPT ministers of agriculture and health, the various FPT committees charged with responsibility for food safety and with successive management teams within federal departments and agencies.

The two national recognition programs (<http://inspection.gc.ca/food/safe-food-production-systems/food-safety-enhancement-program/recognition-program/eng/1299860970026/1299861042890>) were developed during an extensive round of negotiations, starting in 1998, between CFIA, the provinces and territories and representatives of industry associations from all along the supply chain. These recognition programs are securely built on a rigorous, step-wise process that assesses them for technical soundness and administrative effectiveness. The criteria for the recognition programs include the requirement that the certified farm or food business be in compliance with all pertinent regulatory requirements and be in conformity with the requirements established as a result of either the rigorous generic hazard analysis or the rigorous site-specific hazard analysis. In addition, the farm or business must meet the scheme requirements concerning documentation, record-keeping, training, certification, etc..

A study undertaken for Agriculture and Agri-Food Canada in 2011, compared the Canadian recognition program for on-farm food safety certification schemes with two industry benchmarking schemes (GlobalGAP and the Global Food Safety Initiative) and with the government recognition programs then

in place in the United States, the European Union, the United Kingdom and New Zealand. It concluded that Canada's programs then provided for the most rigorous review of a certification scheme's technical requirements and administrative effectiveness by any government program and that it was equivalent to and in some aspects superior to the review by the two private benchmarking schemes.

The Coalition has also fully supported the role that CFIA recognition has had for registered establishments through the Food Safety Enhancement Program (FSEP) and the Quality Management Program (QMP). Recognition, here, has meant that the Agency after a review process that concluded that "the establishment's HACCP system is complete (i.e., meets FSEP and regulatory/program requirements), and is implemented effectively as described" provided a letter of recognition.

Both these approaches to recognition are consistent with the Codex Alimentarius Commission definition of "recognition" (see Principles for Food Import and Export Inspection and Certification CAC/GL 20–1995).

Technical Comments:

1. Assessment Process and Scheme Assessment Requirements (p. 6, 1st bullet 1 and p. 10):

The discussion paper outlines three components of a proposed assessment process and three key principles. To the depth that they are described, the steps are moving in the right direction. As noted above, the CSCFSC fully supports the continuation of the CFIA-led national recognition programs for Canadian industry-led food safety certification schemes. **The CSCFSC strongly supports the suggestion (p. 10) that the new CFIA "assessment approach" for non-Canadian food safety certification schemes utilize the same criteria and a similar review process as the national recognition programs.** These criteria and the associated review processes are clearly set out in the program Procedures Manuals. Some changes may be required to take into account new criteria related to the final regulatory requirements under the *Safe Food for Canadians Act*.

2. Outcome of the Assessment Process (p.6, 2nd bullet 2 and p. 7):

The discussion paper indicates that the assessment may conclude that a scheme "may partially – or fully, meet some – or all CFIA criteria" and that CFIA will not "recognize or endorse private certification schemes". However, it is silent on the question as to what the outcome of the assessment process will be. The existing recognition programs have very clear outcomes. After each stage in the review process CFIA issues a Letter of Completion and following the Implementation Assessment, CFIA issues a Letter of Recognition. **The CSCFSC requests that CFIA clarify the expected outcome of its proposed assessment process. Canadian food businesses will need to know what "status" a private certification scheme has vis-à-vis CFIA's criteria.**

3. **Certifying Body Competency** (p. 6, 1st bullet 2 and pp. 9-10):

The discussion paper proposes that one of the assessment criteria will be that schemes utilize certification bodies that are accredited to an international standard and cites the example of Standards Council of Canada accreditation programs for management system standards. It further indicates that the certification body will need to be “competent to carry out certification in specified food business sectors”. This approach is consistent with the requirements of private sector benchmarking schemes and with existing government recognition programs in the EU, US and other countries. It does vary from current Canadian practice with respect to the recognition of on-farm food safety programs where these schemes can organize their conformity assessment component internally, provided they meet a set of criteria and demonstrate that their assessments are impartial. **The CSCFSC supports including in the new assessment criteria a requirement for certification bodies to be accredited and recommends that the accreditation body be a signatory to the provisions of the International Accreditation Forum’s multilateral agreement respecting the audit and certification of food safety management systems.**

Key to the concept of certification body competency is that of auditor competency and for that matter the competency of the CFIA’s new inspectorate. CFIA is already collaborating with the CSCFSC on the development of common Canadian competency requirements for private and public sector food safety auditors that meet international expectations. These requirements could become part of the assessment criteria.

4. **“continued information sharing”** (p6, 2nd bullet 3):

The discussion paper proposes that for recognized schemes “there will be a need for continued information sharing between certification bodies and CFIA”. No rationale is provided for this. It is to be expected that food safety certification schemes seeking “assessment” would be required to update the Agency about changes to their schemes, indeed this is condition of recognition under the existing national recognition programs. However, certification is a matter between the company, the certification body and the scheme. The Canadian recognition programs, reflecting ISO standards respecting audit and certification (i.e. ISO/IEC 17065:2012 and ISO 22003:2013, which incorporates ISO/IEC 17021:2011), require that recognized schemes ensure that information concerning certifications are publicly available. Requiring assessed or recognized schemes to require the bodies providing certification to enter into a reporting relationship with CFIA requires justification and further discussion. **The CSCFSC supports in principle, subject to further discussions, a regulated party being asked to identify if it is certified under a private food safety management system certification scheme at the time of licensing or license renewal.**

5. **“the CFIA is not proposing to:”** (p. 7):

The discussion paper states four activities that the Agency will not do. The first bullet point has been discussed above. **The CSCFSC fully supports the decision by CFIA to not “assume accreditation or certification responsibilities” and to not “require submission of private certification scheme audit reports”.** With respect to the final bullet respecting imports, the CSCFSC requires clarification.

Currently the Agency requires California and Arizona suppliers of leafy greens to Canada to be certified under the California Leafy Green Products Handler Marketing Agreement (<http://www.caleafygreens.ca.gov/>) or its Arizona counterpart (<http://www.arizonaleafygreens.org/>). The status of these marketing agreements is unclear – are they government certification schemes or private certification schemes? **The CSCFSC requests clarification as to whether or not the Agency is proposing to end this requirement and if so, what the rationale for that decision is.**

6. Mutual Recognition (pp. 7-8) and **“harmonization”** (p. 9) and **“avoiding trade consequences”** (p. 12):

The discussion paper proposes that in situations where “Systems Recognition” has been agreed to and where “a Memorandum of Understanding has been developed regarding private certification scheme assessment” that there could be mutual recognition. **The CSCFSC supports, in principle, this proposal subject to the respective national assessment programs being “comparable” and on the basis that the assessment criteria and processes are transparent and accessible. The CSCFSC further recommends that CFIA also enter into MOUs respecting recognition of by other countries of Canadian schemes that have been “recognized” through the official recognition programs.**

With respect to “trade consequences:”, it should be noted that in the period 1998-2002 there were discussions within the Codex Committee on Food Import and Export Inspection and Certification Systems “to develop guidelines for the utilization, as and when appropriate, of quality assurance systems to ensure that foodstuffs conform with requirements and to promote the recognition of these systems in facilitating trade in food products under bilateral/multilateral arrangements by countries”. These objectives are similar to those outlined in the discussion paper under the concept of “harmonization”. These discussions collapsed due to the resistance of various countries, including the US and India, both of which have subsequently undertaken significant reforms of their food safety legislation and one of which, the US, as the discussion paper notes is proposing to develop its own accreditation/recognition program. **The CSCFSC suggests that the Agency consider re-launching discussions of this matter, in the context of preventive control plans within Codex and utilize as the basis for these new discussions its existing recognition programs and its proposed assessment program.**

7. Global Benchmarking (p. 11):

The discussion paper notes that several global benchmarking schemes have developed, including GFSI. These schemes have matured and become more transparent over time, but they are private and controlled by a limited number of retail and manufacturing companies. In addition, the schemes have not demonstrated a capacity to continue to attract new entrants, particularly national schemes. **The CSCFSC encourages the Agency to review these schemes in detail (e.g. benchmark them against its proposed regulatory requirements and its existing recognition programs and its proposed assessment**

program) and, if it chooses to engage in discussions with them, do so in a transparent manner that ensures Canadian stakeholders have clear understanding of the basis and content of the discussions.

8. Concurrence Approach (pp. 11-12):

The discussion paper notes that the Conference Board of Canada has proposed a “concurrence approach” or more simply an alignment of public and private efforts and food safety requirements. This is consistent with the Coalition’s long standing proposals for the development of “an integrated, coordinated, and national approach to food safety policy and regulation based on sound scientific risk assessment and risk management principles and on international standards” that “encourages the implementation of HACCP and/or HACCP-based food safety systems by businesses all along the supply chain”. **The CSCFSC recommends that the Agency adopt this approach by ensuring that its food safety regulatory requirements under the *Safe Food for Canadians Act* be revised to bring them in line with international standards and international market expectations for food safety managements systems. The “best food safety system” cannot be built on the lowest common denominator.**

Part IV - Foreign Food Safety Systems Recognition: Proposed Framework Incorporation by Reference

Document:

Foreign Food Safety Systems Recognition: Proposed Framework

[\[www.inspection.gc.ca/about-the-cfia/accountability/consultations/foreign-food-safety-systems-recognition/eng/1401207633497/1401207634466\]](http://www.inspection.gc.ca/about-the-cfia/accountability/consultations/foreign-food-safety-systems-recognition/eng/1401207633497/1401207634466)

General Comments:

The Coalition supports, in principle, the development by the Agency of a modernized foreign food safety systems recognition (FFSSR) framework and process. FFSSR is an important tool to help meet not only the need for the efficient transfer of goods, but also help instill confidence that those goods meet the stringent food safety requirements Canadians demand and to foster the establishment of a level playing field. We note, however, that the concept set out in the discussion paper is at a very high and generic level.

The Coalition also strongly supports the continued use of existing foreign food safety system recognition approaches (e.g. for meat imports).

Technical Comments:

1. Guiding Principles (p.p. 5-6)

The nine (9) Guiding Principles proposed by CFIA for its foreign food safety systems recognition framework are reasonable. The challenge will be in their full articulation and implementation.

For example, under paragraph (c) Evidence-based it is noted that other criteria, in addition to microbiological hazard should be included as well as the exporting country's history of recalls (frequency and severity), food fraud and adulteration for economic gain.

With respect to paragraph (f) Transparency, the CSCFSC recommends that recognition criteria be established in a transparent manner including consultation with stakeholders.

2. Recognition Process (pp. 6-7):

Here again the discussion paper provides only the barest of outlines. It is noted that Canada and the US Food and Drug Administration are currently engaged in the development of "a reciprocal foreign food safety systems recognition initiative" (p. 4). The Coalition has supported this initiative in earlier communications with both the Agency and under the Regulatory Co-operation initiative. The US FDA

has developed a tool – International Comparability Assessment Tool (ICAT). This was used in the pilot project for US recognition of New Zealand’s food safety system. **Does CFIA intend to adapt this tool or to develop a totally new tool?**

With respect to “pre-assessment”, the CSCFSC supports the proposed criteria (p. 6). The resources that will be required to undertake an assessment will be significant and a careful pre-assessment will ensure that only advantageous reciprocal initiatives are undertaken. It is noted, however, that the Sanitary and Phytosanitary Chapter in the draft Canada-EU Trade Agreement appears to include a reciprocal agreement on recognition. **If this is a correct interpretation, then the CSCFSC would strongly suggest that the basis for this assessment be released at the earliest practical date.**

With respect to the “assessment” (pp. 6-7, it is noted that the proposed framework relies on a documentary comparison of the exporting country’s system. This may be acceptable in many or most cases. **However, the CSCFSC recommends that CFIA build into its assessment process the option of undertaking an audit in advance of recognition and to also include this option in the “maintenance of FFSSR” (p. 7) as well.**

Part V – Incorporation by Reference

Document:

Incorporation by Reference

<http://inspection.gc.ca/about-the-cfia/accountability/consultations/incorporation-by-reference/eng/1391430825822/1391430827275>)

General Comments:

The Coalition is supportive, in principle, of the government of Canada’s initiative to expand the use of incorporation by reference of either government or externally developed documents following an open and transparent process. CFIA’s proposed approach, including the Guiding Principles (pp. 8-9) and the process steps (Annex A) are for the most part acceptable.

Technical Comments:

1. Guiding Principles – “reasonableness” (p. 8, initial paragraph):

It is noted that the discussion paper sets “reasonableness” as one of the key guiding principles and that it articulates this principle under a number of subsequent bullets such reasonable notice, reasonable comment time , and one assumes a reasonable administrative burden. However, the concept of “reasonableness” extends beyond these examples. **The CSCFSC recommends that where requirements are incorporated by reference, they be assessed as to whether or not they are practical to implement given current technologies, science, etc...**

2. Guiding Principles– “notification of proposed changes”: (p. 8 bullet 4)

The notification process needs to be clarified, formalized and, perhaps expanded. The discussion paper proposes that CFIA will post a notice on its “external website”. Proposed regulations and changes to regulations are required to be published in the Canada Gazette Parts I and II. **The CSCFSC recommends that notices of proposals to incorporate documents by reference under the *Safe Food for Canadians Act* regulations and to amend incorporated documents be published in the Canada Gazette Part 1 to enhance their visibility. The CSCFSC also recommends that when external or 3rd party documents are incorporated, CFIA needs to ensure that mechanisms are in place to ensure proper notification of itself and stakeholders.**

3. Guiding Principles– “post a summary of the comments”: (p. 9 bullet 1)

Summaries of comments are often difficult to develop and depending on the format of the summary and depth presented can at times be misleading. **The CSCFSC recommends that CFIA consider a standard format for summaries and responses that provides sufficient detail and clarity so as to be both meaningful and factual.**

4. Annex A Step 1 – Review and Final Approval – CFIA or other federal department documents: (p. 11)

The discussion paper indicates that some final approvals on changes or updates to CFIA or other federal department documents will be made at the level of the “Executive Director of the relevant program area” while others may require the approval of the “President of the CFIA or the Minister responsible”. This is insufficient information on this key step in the process and gives rise to concerns that arbitrary or unilateral decisions could be made within CFIA or other federal departments without consultation or the possibility of redress. **The CSCFSC requests that CFIA provide an expanded description of its thinking, including specifics on what triggers will or will not allow an amendment to a government of Canada document to proceed.**

It is also noted that persons occupying the position of “Executive Director” are not, for the purposes of the *Lobbying Act*, the *Lobbyist Registration Regulations* or the *Designated Public Office Holder Regulations* “public office holders” and, as a consequence, lobbying activities related to documents proposed for incorporation by reference need not be registered. **The CSCFSC recommends that all final approvals should be at the level of the President of the CFIA or the Minister responsible and that the Agency clearly indicate which types of document and or modification would be approved at which level.**

5. Annex A Step 2 – Domestic and International Notification: (p. 11)

The discussion paper indicates that “the duration of the comment period will be specified in the notice and varies depending on the nature of the change”. This is insufficient information on this key step in the process. **The CSCFSC requests that CFIA provide a clear description of its thinking, with examples, on the lengths of comment period for various types of documents (e.g. for “minor administrative changes”, for new incorporations by reference, for amendments to government documents, for third party documents, etc.). And, the CSCFSC recommends that consideration be given to a minimum consultation timeframe of at least 90 days for an initial consultation and 75 days for a second consultation following Step 5. In setting timeframes for specific consultations, the Agency should also take into account the time of year (e.g. summer holiday season or Christmas/New Year break) and the volume of documents out for consultation.**

6. Annex A Note on Proposed Changes due to Immediate Risks to Health: (p. 11)

The discussion paper indicates that situations may arise where there is an “immediate risk to health and safety” and proposes that in these cases the Agency may “forgo the comment period and proceed

immediately with modifying the document ...”. Again, no examples are given. While it may be prudent for the Agency to reserve this right, the provision of examples of previous situations where this action could/would have been used would address concerns that it would not be used arbitrarily. **The CSCFSC requests further information on how the Agency envisions the use of this power.**

7. Annex A Step 5 – Final Publication of Modified Document: (p. 12)

The discussion paper indicates that final publication will be on the CFIA external website. **Once again, the CSCFSC recommends that notice of the final publication be given in the Canada Gazette to enhance its visibility.** Publication of the actual document would be on the CFIA external website.

8. Annex A Note on Transition Periods: (p.12)

The discussion paper indicates that in some cases “a transition period may be required ...”. **The CSCFSC recommends (a) that the initial notice of the proposed incorporation by reference or modification of an incorporated document include the Agency’s proposals vis-à-vis transition (a period and its length or no period) and (b) that in all cases where regulated parties will be required to make substantive changes to their preventive control plans a transition period be permitted.**

9. Annex A Documents Created by 3rd Parties: (p. 14)

CSCFSC agrees with CFIA’s requirements to ensure the incorporation of 3rd party documents only where a proper revision notification process exists. **The CSCFSC would recommend CFIA to consult with stakeholders as to appropriate 3rd party documents to be incorporated rather than CFIA being the sole determinate.**

10. Annex A Documents Created by 3rd Parties – Step 2 (Analysis of Comments): (p. 14)

CSCFSC agrees with CFIA having the ability to initiate a regulatory amendment to the regulations that incorporated the reference from an ambulatory document to an earlier static version of the document. **The CSCFSC recommends that 3rd Party documents be reviewed on a structured periodic basis (e.g. at least very five (5) years).**