



CANADIAN SUPPLY CHAIN FOOD SAFETY COALITION

COALITION CANADIENNE DE LA FILIÈRE ALIMENTAIRE POUR LA SALUBRITÉ DES ALIMENTS

Comments on the Proposed Regulations under
the *Safe Food for Canadians Act* – Published in
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Submitted by the Canadian Supply Chain Food Safety
Coalition

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Introduction

The Canadian Supply Chain Food Safety Coalition (hereafter either CSCFSC or Coalition) appreciates this opportunity to comment on the Proposed Regulations under the *Safe Food for Canadians Act* published in the Canada Gazette, Part I on 21 January 2017. Over the past three years we have had the opportunity to comment on two drafts of these proposed regulations, one partial draft in 2014 and one full draft in 2015. Our involvement in this initiative goes back further, to 2011, when the government of Canada initiated consultations on the proposed Act. Throughout this long gestation period, we have appreciated the openness with which the Agency has approached these consultations and the willingness that it has shown to make improvements in the draft regulations. We fully expect the Agency to respond to our comments and to those of other stakeholders as, together, we shape the federal food safety regulatory regime for the next several decades. Opportunities such as we have now come rarely the government should seize it to ensure that Canada's food safety regulations are, indeed, world class.

Our Guiding Principles

The Coalition's comments on the proposed regulations are grounded in the four principles set out in our 2009 National Strategy¹:

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.

¹ <http://foodsafetycoalition.ca/wp-content/uploads/2014/03/National-Strategy-for-Industry-led-Food-Safety-Programs-Final-Version-31-March-20091.pdf>

Realization of these principles by Canadian industry, governments and other stakeholders should result in Canadians, *no matter where they reside or purchase their food*, having the same level of assurance about its safety; assurances that are based on common standards and expectations.

Other Important Considerations

From our formation in December 2000, the Coalition's vision has been that *"Canada's agriculture, fisheries and food industry will have a world-class reputation for producing and selling safe food"*. This is a goal that we share with the government of Canada.

Determining what is required to attain and retain a "world class reputation" is a challenging exercise.

The criteria evolve and the goal posts move. For example, in the early 1990s Canada was an innovator and world leader in the development and implementation of voluntary food safety programs using the HACCP principles and in mandating HACCP in fish processing facilities. In the mid to late 1990s, Canada pioneered the development of government recognized, HACCP-based, industry-led on-farm food safety programs and in the establishment of an integrated approach to food safety inspection with the creation of the Canadian Food Inspection Agency. In this century, Canada started several times but failed until 2012, to launch a successful regulatory modernization initiative

Other countries innovated and modernized. The United States was the first to mandate HACCP in meat processing facilities. The European Union was the first to extend food safety controls to the full supply chain based on HACCP principles starting in 2006. Australia and New Zealand established a joint food safety agency and both separately launched major changes to their regulations. Countries as diverse as India and China followed with modernization initiatives taking the whole chain approach and utilizing HACCP principles. And, in 2011, the United States finalized a long process of revising the *Food, Drugs and Cosmetics Act* with the passage of the *Food Safety Modernization Act (FSMA)*, a more radical and aggressive intervention covering domestic and imported foods, transportation, food defence, economically motivated adulteration, etc.. The impact of FSMA is still reverberating around the globe.

Working collaboratively since the 1990's the members of the Codex Alimentarius Commission, including Canada, continue to develop a wide range of intergovernmental standards related to food safety, traceability, HACCP's methodology, etc.. And, the Codex Committee on Food Hygiene has recently launched an initiative to revise and modernize its General Principles for Food Hygiene and its HACCP Annex and to integrate them into a common document.

Each of these government and intergovernmental initiatives raised the bar as to what was meant by a first class regulatory regime for food safety.

During this period, the global market was also raising its expectations of food safety in business-to-business transactions. The mid-to-late 1990's saw the development multiple retailer-led food safety management system certification schemes. In 2000, global retailers established a benchmarking

standard and process for establishing the comparability of these schemes – the Global Food Safety Initiative. In 2005, the International Organization for Standardization (ISO) published *ISO 22000:2005 Food safety management systems -- Requirements for any organization in the food chain*. This standard set the industry bar for the next decade. It is currently being revised and updated.

In developing its comments, the Coalition has taken these external developments in both the public and private sectors into account. If Canada is to be in the first class, it must utilize globally recognized best practices.

Comments on the Proposed Regulations

Our Scope

The Coalition’s mandate from its members is to focus on broad, horizontal issues or matters related to food safety and traceability. Vertical issues, for example those narrowly pertaining to a particular commodity or service, and non-food safety horizontal matters, such as labelling, standards of identity, grades, etc., are outside of our scope.

The proposed regulations under the *Safe Food for Canadians Act* cover a wide range of regulatory activities, not all of which relate to food safety. The Coalition will primarily confine its comments to those Parts of the proposed regulations that deal with food safety and traceability - that is Parts 1 to 5 – and also comment on several issues related to Parts 6 and 7.

Categories of Comments

In our submission we will make two types of comment. One will deal with specific themes or broader more general issues. The other will deal with specific technical issues. In both cases we identify sections of the regulations. In some cases we will identify specific changes to the text of the proposals.

Where relevant, our comments will also indicate whether or not we have identified the issue in our previous comments on the 2014 and 2015 draft texts.

Where appropriate, we will indicate our appreciation for changes and improvements that have been made to the 2017 text, including those which were based on our earlier comments.

Finally, in some instances, we will recommend specific changes to the text of the regulations that would resolve our concerns if accepted or implemented using other wording.

General Concerns with the Proposed Regulations

Take the time to do it right

As we have indicated before parliamentary committees and in other fora, the *Safe Food for Canadians Act* and the successive versions of proposed regulations are a very positive step forward in modernizing Canada's food safety regulatory regime. They clearly embody the Coalition's guiding principles of shared responsibility (Principle #1) and indicate that the government of Canada is moving to update and improve its oversight of industry's food safety controls (Principle #4). Although the outcomes-based approach embodied in the proposed regulations will present new challenges for those businesses and for the Agency and its inspectors, it strikes the right balance given the diversity of food businesses that will be covered.

However, as we have strongly indicated since the publication of the first partial draft of the regulations in 2014 there are issues that must be resolved prior to the final publication of these proposed regulations in the Canada Gazette Part II.

In this submission we are recommending numerous changes. Some of these recommendations involve major amendments which could necessitate the re-publication of the proposed regulations in the Canada Gazette Part I. The Coalition urges the Minister and the Agency to take the extra time necessary – we estimate six or so months – to make these changes. This would put in place an improved and comprehensive set of regulations and secure Canada place in the top ranks.

The alternative is to make only cosmetic changes to what was, even in 2015, recognized by the Agency as an imperfect draft. Over the past six (6) years while the Act and the proposed regulations have been in development, the Agency has often indicated that there would be several rounds of regulatory activity. The current proposals were always identified as Round 1. Improvements could be made in Round 2. The Coalition prefers that the improvements be made now – that the job be finished and done right this first time.

Scope of the Regulations

This third version of the proposed draft regulations stops well short of encompassing all the segments of the supply chain that fall within the scope of the Act. As indicated 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 and licensed. In this submission we are recommending changes that would extend the scope respecting both licensing and preventive control plans to add some, but not all segments of the supply chain.

Clearly articulating the HACCP approach

With respect to our Principle #3, the Coalition notes that while the concept of HACCP was mentioned seven (7) times in the text of the 2014 version of the consultation document and has been stated by the Agency on many occasions to be the foundation of its proposed approach to preventive control plans (PCPs), it does not appear in either definitions (s. 1) or in any other part of this version of the proposed regulations. There are allusions to the HACCP approach in sections 44 and 87. However, the international approach, developed by the Codex Alimentarius Commission and further developed in international standards and food safety management system certification schemes that are utilized by industry as best practice is neither clearly nor fully articulated. 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). Canada should do the same.

In our technical comments we have expressed serious concerns about the how the HACCP approach has been incorporated. These concerns include unacceptable changes to the Codex approach in:

- the definitions of “control measure” and “critical control point” (s. 42);
- the expected outcome of the hazard analysis (s. 44(1)(a));
- the requirements for treatments and processes (s. 45(1));
- the requirements concerning the land upon which an establishment is located (s. 54(1));
- the requirements for the location of establishments (s. 54(2)); and
- the content of a preventive control plan (s. 87(1)(c)(i).

In all these instances, the Agency has used either “prevent or eliminate” and not the traditional Codex wording of “prevent, eliminate or reduce to an acceptable level” or just the word “eliminate”. Our technical comments on these sections recommend amending the text and supply new or amended wording.

Interface with the Food and Drugs Regulations

All the provisions of the *Food and Drugs Act* and Regulations, applicable to food, will remain in force alongside these new regulations under the *Safe Food for Canadians Act*. Prior to the drafting of the latter, the Coalition had strongly supported the drafting of a new *Food Act* that would incorporate the provisions needed from the *Food and Drugs Act* as well as the four Acts whose provisions were melted into the *Safe Food for Canadians Act*. This would have permitted the modernization of all elements the federal food laws and regulations.

While there were many reasons put forward by the Coalition and other industry stakeholders as to why this was a good idea, one of the most important was that it would provide the opportunity to harmonize the treatment of naturally occurring contaminants in food with the provisions of the US *Food, Drugs and Cosmetics Act* and rules.

The Canadian *Food and Drug Act* provisions respecting naturally occurring contaminants remain unchanged and absolute:

*4(1) No person shall sell an article of food that
(a) has in or on it **any** poisonous or harmful substance;*

The equivalent provision in the US Act is similar but has a very important caveat:

*402 A food shall be deemed to be adulterated:
(a) Poisonous, insanitary, or deleterious ingredients.
(1) If it bears or contains any poisonous or deleterious substance which may render it injurious to health; **but in case the substance is not an added substance such food shall not be considered adulterated under this clause if the quantity of such substance in such food does not ordinarily render it injurious to health;***

The Coalition believes that introducing the concepts of “adulteration” and of the test that the quantity of the contaminant “does not ordinarily render it injurious to health” would be a significant improvement in Canada’s food safety regulatory regime. It would eliminate many of the friction points between industry, CFIA and Health Canada, provide greater certainty to industry and to CFIA’s inspectors, and, quite frankly, recognize what is in fact a reality for many safe products.

The Coalition realizes that this change s. 4(1)(a) of the *Food and Drugs Act* is outside the scope of the proposed regulations, however, we believe that it should be accomplished prior to the coming into force of the *Safe Food for Canadians Act* regulations. The Coalition asks that the Minister bring forward a bill to make this change in this session of Parliament.

National food safety strategy

To truly achieve the Coalition’s primary goal - an integrated, co-ordinated and national approach to food safety policy and regulation – **we strongly encourage the Minister of Health and the Agency to engage their provincial and territorial counterparts in a new round of negotiations on the harmonization of food safety regulations.** The new Act and regulations provide a strong foundation for these discussions. As we noted above - Canadians, no matter where they reside or purchase their food, should have the same level of assurance about its safety; assurances that are based on common standards and expectations.

Technical Comments

PART 1 – INTERPRETATION

1(1) – Interpretation – The Coalition has reviewed the definitions utilized through the proposed regulations. In some instances, the Coalition is recommending that to improve the clarity of the regulations either new definitions be inserted or definitions already included in the *Safe Food for Canadians Act* be also included in the text of the Regulations because they are used frequently. These recommendations are dealt with under the heading “Definitions to be Added”. Where there is a need for clarification, the Coalition is recommending amending the text of the definitions in the proposed text. These recommendations are dealt with under the heading “Definitions to be Amended”. In some instances, these recommendations are repeated at the relevant section of the proposed text.

Definitions to be added to s. 1:

***competence* means having the ability to apply knowledge and skills to achieve intended results** [Taken from ISO Glossary]

***conveyance* means a vessel, aircraft, train, motor vehicle, trailer or other means of transportation, including a cargo container.** [Taken from the Act – s 2]

***establishment* means any place, including a conveyance, where a food commodity is manufactured, prepared, stored, packaged or labelled.** [Taken from the Act – s 2]

***evidence* means a collection of scientific, technical and observational information that shows a control measure, or a series of control measures, is capable of preventing or eliminating a hazard or reducing it to an acceptable level to meet the food safety outcome”. [Definition provided to during consultations as amended to be consistent with proposed amendment to definition of “control measure”]**

***facility* means a building or place that provides a particular service or is used for a particular industry and can be used to refer to an establishment or a component of an establishment such as a washroom or a storage area.** [Taken from the CFIA Lexicon]

***food commodity* means**

- (a) any food as defined in section 2 of the Food and Drugs Act;**
- (b) any animal or plant, or any of its parts, from which food referred to in paragraph (a) may be derived; or**
- (c) anything prescribed to be a food commodity.** [Taken from the Act – s 2]

lot code means any code that can be used to identify a defined quantity of food. [Taken from the Agency’s draft *Interpretive Guidance on Part 5*]

sell includes agree to sell, offer for sale, expose for sale or have in possession for sale — or distribute to one or more persons whether or not the distribution is made for consideration . [Taken from the Act s 2]

Definitions in s. 1 to be amended:

“contaminated” – With respect to the matter of contamination, the Coalition notes that the *Food and Drugs Act* sets out the primary regulatory requirements respecting “adulteration” in s. 4(1) but does not provide a definition of either “adulteration” or “contamination” or any variants thereupon. Section 4(1) reads as follows:

4(1) No person shall sell an article of food that
(a) has in or on it any poisonous or harmful substance;
(b) is unfit for human consumption;
(c) consists in whole or in part of any filthy, putrid, disgusting, rotten, decomposed or diseased animal or vegetable substance;
(d) is adulterated; or
(e) was manufactured, prepared, preserved, packaged or stored under unsanitary conditions.

(2) A food does not have a poisonous or harmful substance in or on it for the purposes of paragraph (1)(a) — or is not adulterated for the purposes of paragraph (1)(d) — by reason only that it has in or on it a pest control product as defined in subsection 2(1) of the *Pest Control Products Act*, or any of its components or derivatives, if the amount of the pest control product or the components or derivatives in or on the food being sold does not exceed the maximum residue limit specified under section 9 or 10 of that Act.

The Codex Alimentarius Commission [Codex] for “contaminant” is found in 25th (2016) edition of its Procedural Manual and reads as follows:

Contaminant means any substance not intentionally added to food or feed for food producing animals, which is present in such food or feed as a result of the production (including operations carried out in crop husbandry, animal husbandry and veterinary medicine), manufacture, processing, preparation, treatment, packing, packaging, transport or holding of such food or feed, or as a result of environmental contamination. The term does not include insect fragments, rodent hairs and other extraneous matter.

The Codex General Principles for Food Hygiene contains a slightly different definition of “contaminant” and a definition for “contamination” which are as follows:

Contaminant - any biological or chemical agent, foreign matter, or other substances not intentionally added to food which may compromise food safety or suitability.

Contamination - the introduction or occurrence of a contaminant in food or food environment.

The words “adulterant”, “adulterate” and “adulteration” share, according to the Canadian Oxford Dictionary, the concept of “debasement” by the *intentional* addition of inferior ingredients or by the removal of ingredients. This is the generally accepted usage in various regulatory regimes.

The Coalition believes that the clear definition of both “contaminant” and “adulterant” in the regulations would be appropriate.

“egg” – The definition refers exclusively to chicken and turkey eggs. It is assumed that this was done to facilitate the incorporation of the requirements from the *Egg Regulations* into these regulations. However, there are eggs, for example from ducks, geese, quail and other birds that move in interprovincial trade and may be imported. The narrow definition of “egg” may leave the impression that these eggs are not covered by the regulation although they clearly are as “food”. **The Coalition recommends that this matter may be resolved either by amending the definition of “egg” or elsewhere in the regulations. We note that the definition of “poultry carcass” includes species in addition to chickens and turkeys.**

“fish”, “food animal”, “game animal” and “meat product” – These definitions are confusing with respect to “marine mammals”. The definition of “food animal” excludes “marine animals”, however it is not clear that the definition of “fish” which includes “marine animals” also includes “marine mammals” (e.g. seals) that are slaughtered for meat. The definition of “game animal” which might cover “marine mammals” refers back to “food animal” which excludes “marine animals”. The definition of “meat product” adds further confusion when it introduces the concept of a “food commonly recognized as fish” – which would appear to exclude “marine mammals”. **Clarification of the inclusion of “marine mammals” in either the definition of “fish” or “food animal” is required.**

“game animal” – The definition includes a requirement that the “food animal” be “is hunted under a licence issued by a province”. However, in s. 43(4) and 43(5) the regulations include “game animals” that are “slaughtered”. Slaughtering is not consistent with the concept of hunting as both involve the killing of the animal prior to butchering. **Clarification of this inconsistency is required.**

on-farm food safety program means a program , assessed by the Agency as meeting the Category I criteria set out in the document entitled Private Certification Policy (Food Safety), prepared by the Agency and published on its website, as amended from time to time , that relates to a food or food commodity animals that is operated on a farm or at a similar place at an establishment and under which hazards relating to the safety of the food or food commodity meat products or products that may be derived from those the food animals commodity are identified, analyzed and controlled.
[Moved from s. 118 and amended]

on-farm food safety program means a food safety program operated on a farm

PART 2 – TRADE

General (Sections 10 to 24)

Part 2 – Division 1 – General - The Coalition notes with appreciation the acceptance of its 2015 recommendation that where feasible, the regulations provide more information about the sections of the Act are being cross referenced.

s. 7(2)(a) (i)(A) – exemption of fresh fruit and/or vegetable producers from the requirement for licencing ss. 13(2) if they ship product interprovincially to a license holder. As noted in our 2015 submission the Coalition is of the firm view that all participants in the supply chain should not only be covered by the regulations but identified within the regulatory regime with a license. The creation of exemptions needlessly complicates the regulations, where some elements apply and not others, as well as introducing convoluted language. The Coalition recommends that 7(2)(a)(i)(A) be deleted. The amended wording would then read:

Subsection 13(2) of Act

7 (2) For the purpose of subsection 13(2) of the Act, the prescribed food commodities that are to be exported or to be sent or conveyed from one province to another are a food, other than a food referred to in paragraph 9(2)(a) or (b), and a food animal and the prescribed activities that it is prohibited to conduct in respect of those food commodities without a licence are
(a) in the case of a food,
(i) manufacturing, processing, treating, preserving, grading, packaging and labelling, other than
~~(A) the packaging of fresh fruits or vegetables in the field by a person who grows or harvests them if they are to be sent or conveyed from one province to another to be subsequently manufactured, processed, treated, preserved or graded by a licence holder, and~~
~~(B) the packaging and labelling of a food referred to in subparagraph 9(2)(c)(i) if, when the food is exported or is sent or conveyed from one province to another, it has a label applied or attached to it that bears the expression “For Further Preparation Only” or “pour conditionnement ultérieur seulement” and it is not a consumer prepackaged food, and~~

(ii) if the food is a meat product, in addition to the activities set out in subparagraph (i), storing and handling, in its imported condition, for the purposes of the exercise of an inspector's powers under the Act; and
(b) in the case of a food animal, slaughtering.

s. 9 – imported food must meet requirements in sections 41 to 79 - The rationale for not including the requirement for a written preventive control plan (s. 80 to s. 83) is not apparent. **The Coalition recommends that all imported food be required to demonstrate that in its manufacture, preparation, storage, packaging and labelling has met the level of protection as that provided by sections 41 to 83. The amended wording would then read:**

Import

9 (1) Any food that is imported must have been manufactured, prepared, stored, packaged and labelled in a manner and under conditions that provide at least the same level of protection as that provided by sections 44 to ~~82~~ 87.

For further clarity, the Coalition also suggests that references to sections 88 to 90 also be added to s. 9 to emphasize the importance of the traceability provisions.

s. 15(3) – Prohibition – mixture – ss. 4(1)(a) of the *Food and Drugs Act* sets out an absolute prohibition of the sale of a food that “*has in or on it any poisonous or harmful substance*”. Does this proposed subsection of the *Safe Food for Canadians Act* regulations presume that the *Food and Drugs Act* will be amended to remove this prohibition or that some other regulatory change will be implemented to permit the Minister to authorize mixing based on “the no risk” criteria? **The Coalition supports an amendment to 4(1)(a) of the Food and Drugs Act to directly incorporate the “no risk to human health” criteria.**

s. 19 - Exemption — conveyers - **The Coalition notes with grave concern that s. 19 adds an exemption for that segment of the supply chain that provides third party conveyance of food products. As noted in our introductory comments, the first of the Coalition’s guiding principles is that “food safety is a shared responsibility of all participants in the supply chain ...” this includes those involved in supplying the key inter-segment service of conveyance.**

This exemption in concert with the requirements set out in s. 70 – Conveyances puts the full burden of the safety of the food or food commodity on the shipping and receiving establishments or food businesses. This exemption also places third party conveyers in the position of having to respond to multiple demands for different preventive controls for the same or similar products. The exemption also places food businesses that internally supply establishment to establishment conveyance in a different regulatory category – covered for both licensing and preventive control plans.

The Coalition's preferred solution to this set of problems would be to bring third party conveyers within the scope of the regulations for both licensing and preventive controls. This solution may present practical problems with respect to licensing. If this is the case, then at the very least third party conveyers providing services for imports, exports and interprovincial movement of food or designated food commodities should be required to have a written preventive control plan.

The Coalition notes that a HACCP-based food safety program has been developed by the Canadian trucking industry with federal funding assistance and that that program has completed Technical Review Part I of the recognition process under the National Food Safety Recognition Program.

The Coalition recommends that s. 19 be deleted and that third party conveyers be required to be licensed and to have preventive control plans appropriate to their activities.

s. 22(1)(a) and 22(1)(e) – Exemption – import, export and interprovincial trade – The Coalition does not support this exemption in 22(1)(a) or in 22(1)(e). It puts the consumer (crew and passengers or inmates in federal penitentiaries) at risk. Indeed, there were reports in June 2015 that recalls had been undertaken by airline catering facilities and that the US Food and Drug Administration (FDA) had issued several warning letters to such facilities concerning food hygiene and HACCP implementation non-compliances over the period 2012 to 2015. **The Coalition supports the application of the regulations to all food businesses along the supply chain that are involved in the import, export and interprovincial trade in food and food commodities. The amended wording would then read:**

22 (1) The Act and these Regulations do not apply in respect of a food that is imported, exported or sent or conveyed from one province to another if

- ~~(a) the food is carried on a conveyance for use by the crew or passengers;~~*
- ~~(b) the food is intended and used for analysis, evaluation, research or a Canadian or international food exhibition and is part of a shipment that weighs 100 kg or less or, in the case of eggs, is part of a shipment of five or fewer cases;~~*
- ~~(c) the food is not intended or sold for use as food and a label that indicates its intended use and bears the expression "Not for Use as Human Food" or "ne peut servir à l'alimentation humaine" is applied or attached to it;~~*
- ~~(d) in the case of a food that is imported, the food~~*
 - ~~(i) is imported from the United States into the Akwesasne Reserve for use by an individual who has established permanent residence on that Reserve, or~~*
 - ~~(ii) is part of a bonded shipment that is sent or conveyed from a foreign state to a cruise ship or military ship in Canada for use by the crew or passengers; or~~*
- ~~(e) in the case of a food that is sent or conveyed from one province to another, the food is sent or conveyed from one federal penitentiary to another.~~*

Division 2 – Trade in Fresh Fruits and Vegetables (Sections 205 and 26)

The Coalition notes that sections 21 and 22 concern trade in fresh fruits and vegetables and do not deal with food safety. However, it is confusing that the definition set out in s. 1 of the regulation does not apply in these sections and that no other definition is provided. **A clear definition should be provided for this division.**

PART 3 – LICENSES (Sections 23 to 38)

The Coalition is of the firm view that all participants in the supply chain that import, export or sell or convey food interprovincially should not only be covered by the regulations but identified within the regulatory regime with a license.² These exemptions provided for in this Part needlessly complicate the regulations and introduce convoluted language which makes them difficult to understand.

PART 4 – PREVENTIVE CONTROLS (sections

s. 42 – Definitions - The Coalition has several concerns with the proposed definitions in s. 42. First, the use of the new regulations would be enhanced by the placement of all definitions in s. 1(1). This would ensure that users have only one location to look for any word or concept that might be defined. Second, there are some definitions that require amendment.

“control measure” – The Coalition notes that the Agency accepted its 2015 proposal to include a definition of “control measure”. However, the definition inserted is not the Codex Alimentarius Commission definition suggested by the Coalition. That definition reads:

Control measure: Any action and activity that can be used to prevent or eliminate a food safety hazard or reduce it to an acceptable level.

In the initial discussions with the Agency about the 2017 proposed regulation, it was erroneously indicated that the proposed definition was the Codex definition. The failure to include the concept of “reduce to an acceptable level” is a major and unacceptable change.

Furthermore, the proposed definition is not consistent with the current CFIA approach in its Food Safety Enhancement Program, Quality Management Program and in the requirements of the National Food Safety Recognition Programs. Nor is it consistent with the international voluntary standards established by ISO or the requirements of the private certification schemes benchmarked by the Global Food Safety Initiative (GFSI). And, it is a much narrower approach

² One member of the Coalition, the Canadian Federation of Agriculture does not support the implication of this recommendation – that all farms producing a prescribed food commodity and engaged in interprovincial trade should be required to have a written preventive control plan and be licensed.

than that adopted by the US Food and Drug Administration in the *Food Safety Modernization Act* and other food sector rules under the *Food, Drugs and Cosmetics Act* and by the US Department of Agriculture in its rules for meat establishments.

The Coalition also notes that the Codex Committee on Food Hygiene in its on-going work on the revision of the General Principles of Food Hygiene and the HACCP Annex is considering removing “eliminate” from its vocabulary respecting “control measures”. The rationale for this is that “elimination”, that is the reduction to zero for any biological, chemical or physical hazard is, with today’s testing methodologies, most likely not possible.

The Coalition recommends that the definition of “control measure” be amended to either mirror the existing Codex definition or to include only the concepts of “prevent” and “reduce to an acceptable level”. The amended wording would then read either:

Control measure: Any action and activity that can be used to prevent or eliminate or a food safety hazard or reduce it to an acceptable level.

Or,

Control measure: Any action and activity that can be used to prevent ~~or eliminate~~ or reduce to an acceptable level a food safety hazard.

“critical control point” – The issues raised and the solutions proposed with the definition of “control measure” are also applicable to this definition. It is also not consistent Codex definition, current usage by the Agency and in international standards, private certification schemes and in regulations established by other governments. **The Coalition recommends that the definition of “control measure” be amended to either mirror the existing Codex definition or to include only the concepts of “prevent” and “reduce to an acceptable level”. The amended wording would then read:**

critical control point means a step at which a control measure can be applied and is essential to prevent or eliminate or reduce to an acceptable level any biological, chemical or physical hazard that presents a risk of contamination of a food.

Or,

critical control point means a step at which a control measure can be applied and is essential to prevent ~~or eliminate~~ or reduce to an acceptable level any biological, chemical or physical hazard that presents a risk of contamination of a food.

s. 44(1) – Identification, analysis, prevention and elimination of hazards – The Coalition notes that the Agency has incorporated several of the Coalition’s suggested revisions to the 2015 draft. The words “determined” and “validated” have been replaced by the concepts of “identified” and “shown to be effective”. **However, 44(1) raises new and very serious concerns. By substituting “prevent or eliminate” for “control”, the text no longer includes the concept of “reduce to an acceptable level”.**

As indicated in our discussion of the proposed definition of “control measure”, this approach is not consistent with the current CFIA approach in its Food Safety Enhancement Program, Quality Management Program or in the requirements of the National Food Safety Recognition Programs. Nor is it consistent with intergovernmental standards set out by the Codex Alimentarius Commission, the international voluntary standards established by ISO or the requirements of the private certification schemes benchmarked by the Global Food Safety Initiative (GFSI). Furthermore, it is a much narrower approach than that adopted by the US Food and Drug Administration in the *Food Safety Modernization Act* and other food sector rules under the *Food, Drugs and Cosmetics Act* and by the US Department of Agriculture in its rules for meat establishments. The Coalition also notes that the Codex Committee on Food Hygiene in its work on revision of the *General Principles of Food Hygiene and the HACCP Annex* is considering removing “eliminate” from its vocabulary respecting “control measures” because elimination is, with modern testing capacity, virtually impossible, particularly for biological and chemical hazards.

Coalition members have also expressed the concern that not all regulated parties will have the capacity to undertake a site-specific hazard analysis. This challenge for small and/or less developed organizations has been recognized by the Agency and the government of Canada for the past two (2) decades and was the impetus for the collaborative initiative between the federal and provincial governments and many national industry associations to develop HACCP-based, industry-led food safety programs. In this work, the governments and industry developed a very clear definition of a “HACCP-based program” and established both the requirements for one and the policy and procedures for “officially recognizing” these program as being technically sound and administratively effective. More recently, the Agency in its *Private Certification Policy (Food Safety)* has defined these recognized programs as meeting regulatory requirements (Category I).

The Canadian definition of a HACCP-based program is:

“Where the hazard analysis is generic (i.e. covers all producers or users in a given sector or commodity) and results in a list of commonly accepted hazards (biological, chemical & physical) and related controls that are then translated into a series of prerequisite programs (e.g. good agricultural practices (GAPs), good manufacturing practices (GMPs), etc) and critical control points (CCPs) to which users shall adhere.”

The Coalition recommends that 44(1) be amended to include the concept of “reduce to an acceptable level” and to provide for the use of HACCP-based controls as set out in a “food safety program” [see proposed definition under s. 1 above.] The amended wording would then read:

Identification, analysis, ~~prevention and elimination~~ and control of hazards

44 (1) An operator must

(a) identify and analyze the biological, chemical and physical hazards that present a risk of contamination of a food and must prevent, eliminate or reduce to an acceptable level [Or “must prevent or reduce to an acceptable level”] those hazards using control measures that are shown by evidence to be effective, including, in the case of a meat product, the control measures that are set out in the document entitled Preventive Control Plan Requirements for Biological Hazards in Meat Products, prepared by the Agency and published on its website, as amended from time to time; or

(b) adapt to its circumstances the control measures set out in an appropriate food safety program assessed by the Agency as meeting the Category I criteria set out in the document entitled Private Certification Policy (Food Safety), prepared by the Agency and published on its website, as amended from time to time.

Imported food

(2) The holder of a licence to import must comply with subsection (1) in respect of food that is imported.

s. 44(2) – Imported Food – The Coalition supports the clear requirement in 44(2) that it is the responsibility of the “holder of a license to import” to undertake a hazard analysis regarding the food being imported and, if 44(1) is amended as we have proposed, have the option to use HACCP-based controls or a “food safety program”.

s. 45(1) – Treatments and processes– The Coalition notes that the text of the requirement has been significantly revised from the 2015 draft. However, the focus on “elimination” as the sole outcome of any process or treatment has not been changed as we recommended. This is not acceptable. We would remind the Agency that the wording in the 2014 version (s. 27), which concerned only “treatments” and not all other processes, recognized that control measures can also be used to “**reduce**” or to “**prevent**” hazards. This broad approach is also embodied in the Codex definition of control measure with its inclusion of prevention and reduction alongside elimination. . The wording also fails to recognize the longstanding practices under the Food Safety Enhancement Program where a food business identifies a hazard on Form 9 as “not controlled by the establishment” and documents how the hazard is subsequently controlled and a similar approach in the Quality Management Program and in the two National Recognition Programs for industry-led, HACCP-based food safety programs. This concept also needs to be covered by the wording of the regulation.

The Coalition recommends that the wording of 45(1) should be amended to recognize that processes can “prevent” or “reduce to an acceptable level” or “eliminate” a hazard and that all are acceptable

outcomes or to include only prevention or reduction as is currently being discussed in the Codex Committee on Food Hygiene. The amended wording would then read:

Treatments and processes

45 (1) An operator must subject a food to any process or treatment that is necessary to prevent, eliminate or reduce to an acceptable level any biological, chemical or physical hazard that might be present in the food and that presents a risk of contamination of the food, including any treatment that is necessary for the food to meet the standards that are set out in the document entitled *Biological, Chemical and Physical Standards for Food*, prepared by the Agency and published on its website, as amended from time to time.

OR

Treatments and processes

45 (1) An operator must subject a food to any process or treatment that is necessary to ~~prevent, eliminate~~ or reduce to an acceptable level any biological, chemical or physical hazard that might be present in the food and that presents a risk of contamination of the food, including any treatment that is necessary for the food to meet the standards that are set out in the document entitled *Biological, Chemical and Physical Standards for Food*, prepared by the Agency and published on its website, as amended from time to time.

s. 48(1) – Clean and sanitary condition – The Coalition notes that the proposed regulations still present the issues that we identified in our 2015 comments, that is **the cleaning of certain types of equipment, for example, tow motors. This matter requires further clarification, perhaps in the common interpretive guidance provided to inspectors and regulated parties.**

s. 49(1) – Animals – establishment - The Coalition notes that the phrase “any animal that presents a risk of contamination” is not used consistently in the 2017 draft. The phrase “insects, rodents and other vermin” is still used in 55(ii) while other instances in the 2015 draft have been removed. The rationale for this difference is not clear in the wording. **The Coalition recommends that a consistent approach based on “any animal that presents a risk of contamination” be used. [See s. 55 below for our proposed amendment]**

s. 50 – Use of the words “suitable” and “appropriate” – The Coalition notes that the drafters are interchangeably utilizing the words “suitable” and “appropriate” in this and subsequent sections, subsections and paragraphs of the draft regulations (e.g. 51,55, 70, 74, 75). The Canadian Oxford Dictionary defines “appropriate” as “suitable or proper” and defines “suitable” as “well fitted for purpose, appropriate”. The Coalition understands from the consultations that the Agency may intend “suitable for its intended use” to refer to sanitizers, agronomic inputs, non-food chemical agents, conveyances, equipment etc. and “appropriate” to refer to the food and the activity. **The Coalition recommends that the Agency clarify its use either in the regulations or in guidance.**

s. 51 – s. 53 Heading – Conveyances and Equipment – The Coalition notes that the use of “conveyance” in s. 51, s. 52, s. 55, s. 57, s. 62 and s. 63 continues to create confusion as it did in the 2014 and 2015 drafts. **The Coalition recommends that the proposed regulations be amended to reduce this confusion if not eliminate it. The amendments should include:**

- **Adding the definition of “conveyance” from the Act to the regulations;**
- **Adding a definition of “facility” to the regulation; and,**
- **Clearly indicating when the word “conveyance” is being used to mean a “facility” by using the phrase “the facility or the conveyance where that person handles fish”.**

s. 51(i) – Conveyances and equipment – food – The Coalition notes that 51(i) respecting food contact surfaces is overly prescriptive given the range of food businesses that will now be covered by the regulations. This wording is appropriate to current registered establishments such as meat and dairy processing facilities and to non-registered establishment such as food processing facilities, but it is not practical for other sectors such as the fresh produce industry where fruits and vegetables from the point of harvest do have contact with containers and other surfaces that are not necessarily smooth, free from pitting and non-absorbent. **The Coalition recommends that the Agency amend the wording to be more outcome-based as is the case with earlier requirements in s. 51. The amended wording would read:**

Conveyances and equipment — food

51 Any conveyance or equipment that is used in the manufacturing, preparing, storing, packaging or labelling of a food or in the slaughtering of food animals must

(a) be appropriate for the food and for the activity being conducted and, if applicable, for the food animals that are to be slaughtered;

(b) be designed, constructed and maintained to prevent contamination of the food;

(c) be constructed of, and maintained using, materials that are suitable for their intended use 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 applicable, sanitizing, unless the equipment is intended for a single use, and

(iv) free of any noxious constituent;

(d) be equipped with instruments to control, indicate and record any parameters that are necessary to prevent contamination of the food;

(e) function as intended;

(f) be accessible and, if necessary, able to be easily disassembled, for cleaning, sanitizing, maintenance and inspection;

(g) be of sound construction and in good repair;

(h) be 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; and

(i) only have food contact surfaces that are constructed of, and maintained using, materials that are suitable for their intended use 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 applicable, sanitizing, unless the equipment is intended for a single use, and

(iv) free of any noxious constituent;

(i) smooth,

(ii) free from pitting, cracks and flakes, and

(iii) non-absorbent.

s. 53 Equipment – slaughtering – To reduce confusion and the potential for disputes, the Coalition recommends that the Agency consider incorporating by reference the Codes of Practice for the care and handling of farm animals developed by the National Farm Animal Care Council.

s. 54(1) – Land & 54(2) – Location – The Coalition notes that s. 54 is substantially changed from the text in s. 51 in the 2015 draft. While our comments respecting “animals” have been dealt with, the new wording presents new and substantial concerns. In both 54(1) and 54(2) the only outcome permitted is elimination of the risk. This is another instance of the proposed regulations narrow focus and deviation from current industry practice and from the Codex approach. The Coalition recognizes that this may not be the Agency’s intention; however, this will be the industry interpretation. We note that the *Draft Interpretive Guidance on Part 4 – Preventive Controls* uses the concept of prevention alongside elimination in its explanation of this section. This reading is, however, not clear in the text of the regulation.

As in other instances where only “eliminate” or only “prevent or eliminate” are used, the Coalition recommends that either the traditional Codex language of “prevent, eliminate or reduce to an acceptable level” or even the language currently being discussed in the Codex Food Hygiene Committee of “prevent or reduce to an acceptable level” be used here. The amended wording would then read:

Land

54 (1) Any land that forms part of an establishment must not present a risk of contamination of a food or, if it does present such a risk, measures must be taken to prevent, eliminate or reduce to an acceptable level the risk.

Location

54 (2) An establishment must not be located near any place or thing that presents a risk of contamination of a food unless measures are taken to prevent, eliminate or reduce to an acceptable level the risk.

OR

Land

54 (1) Any land that forms part of an establishment must not present a risk of contamination of a food or, if it does present such a risk, measures must be taken to prevent eliminate or reduce to an acceptable level the risk.

Location

54 (2) An establishment must not be located near any place or thing that presents a risk of contamination of a food unless measures are taken to prevent eliminate or reduce to an acceptable level the risk.

s. 55(b)(ii) Interior of facility or conveyance - As noted in our comments on s. 49(1) there is an inconsistency in the use of “any animal that presents a risk of contamination” or “insects, rodents and other vermin”. The Coalition also notes that the outcome expected in this requirement is “prevention”. In reality, what can be achieved is “control”. **The Coalition recommends that the text be amended to take into account both this concerns. The amended wording would then read:**

55(b) (ii) the entry of ~~insects, rodents and other vermin~~ any animal that presents a risk of contamination is prevented controlled,

s. 55 (b) (iii) – Interior of facility or conveyance – The Coalition notes that this requirement is overly prescriptive given the range of food businesses that will now be covered by the regulations. Its wording is appropriate to current registered establishments such as meat and dairy processing facilities, but it is not practical for others, such as fresh produce packing houses which are frequently constructed of wood. We note the exception provided in 55(b)(iii) for areas where food animals are received, handled or held. The Coalition recommends that the Agency amend the wording to either reflect an outcomes-based approach for all regulated parties or to provide a separate requirement for the fresh produce sector. The amended wording for an outcomes-based requirement would then read:

55 The interior of any facility or conveyance where a food is manufactured, prepared, stored, packaged or labelled or where food animals are slaughtered must be
(a) of sanitary design to prevent the accumulation of contaminants including dust, dirt, micro-organisms and food particles and to permit effective maintenance, cleaning and, if applicable, sanitizing;

(b) designed, constructed and maintained in such a manner that

(i) the size and layout is adequate to accommodate the activity being conducted and the equipment used in the activity,

(ii) the entry of ~~insects, rodents and other vermin~~ any animal that presents a risk of contamination is prevented controlled,

~~(iii) any floors, walls, ceilings, windows and doors are smooth, non-absorbent and impervious to moisture~~ floors, walls, ceilings, windows and doors are made of materials that do not pose a risk of contamination and can be easily cleaned, except in areas where food animals are received, handled or held, and
(iv) any floors provide or permit good drainage;

s. 60 – Arrival at an establishment of certain food - As pointed out in our comments on the 2015 draft, this section deals with receiving and storage not design of the facility. **The Coalition recommends that it be moved to become a subsection of s. 72 Storing - food:**

Arrival at establishment of certain food

72(3) On arrival at an establishment of any food, whether or not it is to be exported or to be sent or conveyed from one province to another, that presents a risk of injury to human health, that is exempted from the application of the import requirements of the Act and these Regulations under section 21 or that does not meet the requirements of the Act or these Regulations, the food must be identified as such and placed in a designated area within the establishment and any other measures that are necessary to prevent contamination of any other food in the establishment must be taken.

s. 64 Removal and disposal of contaminated materials and waste - The Coalition supports the revision of 64(1) to make it more outcomes-based by including the phrase “if necessary”. However, the use of the phrase “is sufficient” in 64(2) may lead to disputes. **The Coalition believes that there is a need for clarification in common guidance to both regulated parties and inspectors.**

s. 65 Cleaning Stations, lavatories, etc. - The Coalition notes that the concern it raised about the use of the word “conducive” in the 2015 draft has been addressed by the substitution of the word “permits”. Members of the Coalition have, however, identified a number of other concerns with various parts of this section. These are dealt with individually as follows:

65(1) The Coalition supports the use of the outcomes-based approach and with inclusion of the concept “if they are necessary to meet the needs of the establishment”. However, the use of the phrases “appropriately equipped” and “appropriate in number and size” in 65(1)(a) may lead to disputes. **The Coalition believes that there is a need for clarification, either by including a definition of “appropriate” as suggested in our comments on s. 50 or by providing common guidance to both regulated parties and inspectors.**

65(2) The Coalition is concerned that this subsection deviates from the outcomes-based approach set out in 65(1) by prescribing that the stations must be supplied with water and excluding other effective hand cleaning options that are based in published, peer-reviewed science (e.g. the use of hand wipes plus hand sanitizer). **The Coalition recommends that 65(2) be amended to narrow its meaning. The amended wording would then read:**

65(2) “If hand cleaning and sanitizing stations supply water, the water must be at a temperature and pressure that permit the effective cleaning of hands.”

65(3) The Coalition is concerned that the requirement that “lavatories must not provide direct access to any area where a food is manufactured, prepared, stored, packaged or labelled...” may be overly prescriptive given the wide range of enterprises that will now be covered by the regulations. If the requirement was worded to focus on the “outcome” as opposed to the “means”, then the food business would have to demonstrate that it had achieved the “result”. **The Coalition recommends that 65(3) be amended to make it outcomes-based. The amended wording would then read:**

65(3) The lavatories must be located and maintained so as not to pose a risk of contamination to any area where a food is manufactured, prepared, stored, packaged or labelled or food animals are slaughtered.

s. 70 – s.72 – Heading – “Unloading, Loading and Storing” – The proposed set of preventive controls under this heading is deficient in that they does not include requirements for what are now called “supplier controls” or “supplier assurance” and what were formerly included as “purchasing”.

For example, the second prerequisite program under CFIA’s current Food Safety Enhancement Program is entitled “*Transportation, Purchasing/Receiving/Shipping and Storage*”.

The text on purchasing in the current (2012) FSEP Manual reads:

B.2.1.1

The establishment has and implements documented purchasing procedures to ensure that:

- *Ingredients are ordered from suppliers/sources approved by the establishment;*
- *The required information on ingredients is maintained on file (e.g., specifications, letters of guarantee, certificate of analysis);*
- *Construction materials, packaging materials and non-food chemical products are listed in CFIA’s Reference Listing of Accepted Construction Materials, Packaging Materials and Non-Food Chemical Products*. Otherwise, the manufacturer has a letter of no objection from Health Canada.*

This requirement clearly states the need for a purchasing procedure, a supplier approval process, ingredient and other input information (e.g. specifications, etc.).

The text on receiving in the current (2012) FSEP Manual reads:

B.2.1.3

- *Where applicable, receiving of live animals is controlled as per regulatory requirements.*
- *Only approved and properly labelled/identified ingredients, products and materials are received into the establishment.*
- *Incoming ingredients, products and materials are assessed at receiving to ensure that their conditions are satisfactory and that the purchasing specifications have been met.*

This requirement clearly states that the food business must check inputs for supplier approvals, specifications and condition prior to receipt.

All of the industry-led on-farm and post-farm food safety programs are designed to conform to the requirements of the CFIA-led National Food Safety Recognition Program which are based on the FSEP requirements. The food safety certification programs developed by the provinces specifically for small and medium-sized manufacturers include the concepts of “purchasing and receiving” or “supplier controls” as integral components of an effective food safety system.

The international food safety management standards and industry food safety management system certification schemes also include these concepts.

The rule for human foods under the *Food Safety Modernization Act* have as a key requirement the establishment of a supplier control program (117.405 – 117.435). Without this requirement it may be challenging for Canada to continue to demonstrate that its food safety system is comparable with that in the United States.

And, CFIA’s new “Establishment-based Risk Assessment Model”, now being piloted with several commodity sectors, assigns high priority to several “mitigation factors” including “control of incoming supplies”. This is clear recognition of the importance of this activity.

The Coalition recommends that the proposed regulations be revised to include a requirement for the control of incoming supplies (e.g. ingredients, packaging materials, etc.) and services (e.g. pest control) and that these require, inter alia:

- **a purchasing procedure;**
- **the setting of specifications;**
- **a supplier approval process;**
- **procedures at receiving; and,**
- **documented information.**

s. 70 Conveyances – Further to our comments on s. 19, the Coalition supports the setting of preventive control requirements for conveyances. Implementing these requirements should be the responsibility of the owner of the conveyance and demonstrated by having in place a preventive control plan and of

the shippers and the receivers of the food through both their supplier control programs (see comments above) and their implementation of it and the requirements of s. 71 Loading and unloading.

In our 2015 comments, we raised concerns about the wording of some elements of s. 70, these have not been dealt with in the 2017 proposals:

70(e) is problematic because typically, unless the shipper owns the conveyance, then they are likely to only know the history of the trailer to its last load. Better wording would include “unreasonable risk”.

70(e) the inclusion of “animals” in this requirement is prescriptive not outcomes-based. The assessment as to whether or not to use the conveyance should be based on whether or not its previous use for any material or substance “presents a risk of contamination of the food”.

The Coalition recommends that 70(e) be amended to deal with the issues identified above. The amended wording would then read:

Conveyances

70 Any conveyance that is used to convey a food to or from an establishment and that is unloaded or loaded at the establishment

(a) must be designed, constructed and maintained to prevent contamination of the food;

(b) must be constructed of, and maintained using, materials that are suitable for their intended use and, if the materials present a risk of contamination of the food, that are

(i) durable,

(ii) capable of withstanding repeated cleaning and, if applicable, sanitizing, and

(iii) free of any noxious constituent;

(c) must be capable of maintaining the temperature and humidity at levels that are appropriate for the food and, if necessary, be equipped with instruments that control, indicate and record those levels;

(d) must be of sound construction and in good repair;

(e) must not ~~contain or have contained animals, pest control products as defined in subsection 2(1) of the Pest Control Products Act or any other material or substance~~ that present a risk of contamination of the food; and

(f) must be clean and in sanitary condition at the time of unloading or loading, as the case may be.

s. 72 – “storing of food” – The current draft of the proposed regulations scatters requirements vis-à-vis storing of food and other things used in several places: s. 59 – with products that are not food, s. 60 – with foods arriving at the establishment that pose a risk; and, s. 72 – with food and other things at the

establishment. **Consistent with our comments on s. 60, the Coalition recommends that these proposed sections be consolidated under a new heading “Storage” or “Storing” to facilitate the understanding of regulated parties.**

s. 73 – Heading – “Competency” – The Coalition supports the requirement for persons to “have the competencies and qualifications that are necessary to carry out their duties”. **To improve this section, the Coalition recommends that a definition of competence be included s. 1(1) and that the wording of s. 73 be amended to clearly indicate that importers must also be competent. The new and amended wording would then read:**

1(1) *competence* means having the ability to apply knowledge and skills to achieve intended results

~~Competencies~~–Competence and qualifications

73 Any person who is involved in the manufacturing, preparing, storing, packaging, ~~or~~ labelling or importing of a food or in the slaughtering of food animals must have the competencies and qualifications that are necessary to carry out their duties.

ss. 80(2) – Results – risk of injury - The Coalition notes that the wording of 80(2) has been amended. The revised wording responds in part to the concerns expressed by the Coalition in 2014 and in 2015. Our previous comments noted that regulated parties will undertake “investigations” for many reasons and will, in all likelihood, identify food that presents “a risk to human health”. We noted that a requirement to report all instances where food presents a risk to human health would result in a massive documentation burden for regulated parties and the Agency. If the regulated party’s PCP is operating properly, action will be taken and the food will not be released into the market. The new wording provides relief from notifying the Minister only if “the results of the investigation establish that the food does not present such a risk”. In 2015, recommended that “immediate notification [be] required only in cases where the food has left the control of the regulated party”.

The Coalition stands by this comment and recommendation. Notification, with or without delay, of the Minister should only be required when the “food has left the control of the regulated party”. The Coalition also understands that the Agency means ““without unnecessary delay” when it says “immediately”. This meaning should be clarified as well. To achieve these objectives, the Coalition is proposing that 80(2) be split in two with one part covering action to mitigate and the other part covering notification of the Minister and the wording amended. The amended wording would then read:

Results — risk of injury

80(2) If the results of the investigation indicate that the food presents a risk of injury to human health, the operator take action to mitigate any risk of injury to human health.

Notification of the Minister

80(3) If the food that presents a risk of injury to human health has left the operators control, it must implement a recall (82(3)) and notify the Minister ~~immediately~~ immediately without unnecessary delay.

PREVENTIVE CONTROL PLAN

s. 84 – Licence holders – The Coalition agrees that all licence holders should be required to have a preventive control plan. The current wording of s. 84 presents several issues that need revision. We will deal with each issue separately. **Consistent with our comments on the 2105 draft regulations, the Coalition considers a written preventive control plan to essential as evidence of the activities indicated in ss. 84(1). It should be a required of all license holders and operators.**

ss. 84(1) - List of activities required of a licence holder – The current list of activities (i.e. prepare, keep and maintain) is not consistent with industry expectations, international food safety standards and requirements set out in the rules to the US *Food Safety Modernization Act*. As frequently noted in our comments on the various draft of the proposed regulations the dictionary definition of “maintain” does not include the concept of “updating”. For example, The Canadian Oxford Dictionary defines the verb “maintain” as “cause to continue; keep up; preserve (a state of affairs, activity, etc.)” and as “preserve or provide for the preservation of (a building, machine, road, etc.)”. It gives the definition of the verb “update” as “make more modern or up-to-date, especially by replacing old material, methods, etc. or including new material” and “provide (a person) with the latest information about something”. A preventive control plan requires more than maintenance, it must be periodically reviewed to ensure that it is up-to-date and it must be updated when changes in inputs, processes, end products, etc. are made to ensure that it remains effective.

The Coalition recommends that s 84(1) be amended by including the concept of “updating”. The amended wording would then read:

84 (1) A licence holder or operator must prepare, keep, ~~and maintain~~ and update a written preventive control plan that meets the requirements of section 87 for any activity that they conduct in respect of a food or food animal that is identified in their licence.

ss. 84(2) to (4) – Exceptions - These subsections set out exceptions to the requirement to have a preventive control plan for food to be exported, for game animals and for licence holders with sales of food that are less \$30,000 per annum who are not either applying for an export certificate or whose licenced activities include “food animals, meat products, fish, dairy products, eggs, processed egg products and processed fruit or vegetable products”. As stated in our 2015 comments and in our comments above on Part 3 – Licenses “all participants in the supply chain that **import, export or sell or convey food interprovincially** should not only be covered by the regulations but identified within the regulatory regime with a license”. This concept applies equally to the requirement to have a written preventive control plan.

With respect to 84(2), exporters of food or a prescribed food commodity should, in principle, be required to have a preventive control plan not just those requiring an export certificate or exporting a fish or meat product. Food exported from Canada should meet the food safety requirements of the regulations, even if it is not required to meet all the labelling or quality requirements of the regulations. Unsafe food exports could seriously damage the reputation of Canadian food products in either or both the domestic and international markets.

With respect to 84(3) very small food businesses, if they are licence holders they should have a preventive control plan.

With respect to 84(4), ss. 1(1) defines a “game animal” as a “wild animal that is a food animal ... that is hunted under licence issued by a province”. By definition a “game animal” cannot be “slaughtered” although it may be processed. If it is processed then for those post-mortem activities, a preventive control plan should be required.

The Coalition recommends that 84(2), 84(3) and 84(4) be deleted.

s. 85 – Growers or harvesters of fresh fruits or vegetables - The Coalition’s comments on Part 3 – Licences has already recommended that growers and/or harvesters of fresh fruits and vegetables that are to be sent or conveyed from one province to another or to be exported should be licenced.

The Coalition recommends that if the requirements for licencing extended to these growers and harvesters, then s. 85 can be deleted.

If that recommendation is not accepted, then the Coalition recommends that s. 85 be amended to make it consistent with the Coalition’s proposed rewording of 84(1). The amended wording would then read:

Growers or harvesters of fresh fruits or vegetables

85 Any person who grows or harvests fresh fruits or vegetables must prepare, keep, and maintain and update a written preventive control plan that meets the requirements of section 87 for any activity that they conduct in respect of those fresh fruits or vegetables if the fresh fruits are vegetables *are to be sent or conveyed from one province to another or to be exported.*

~~**(a) to be exported and a certificate or other document referred to in section 48 of the Act will be sought in respect of the fresh fruits or vegetables; or**~~

~~**(b) and the person’s gross sales that are derived from food are more than \$30,000 for the previous 12 months.**~~

s. 87(1)(c)(i) – Content of preventive control plan – As noted above with respect to the definition of “control measure” (s. 42), the revision of the long-standing objectives of a control measure to exclude the concept of “reduction to an acceptable level” is not acceptable. The reference to only “prevention” or “elimination” is not consistent with the current definitions in the *Codex General Principles for Food*

Hygiene and its HACCP Annex, in the rules under the *US Food Safety Modernization Act* and in the ISO 22000:2005, the international standard for food safety management systems. Further, as of April 2017, there are discussions underway in both the Codex Committee on Food Hygiene and the ISO subcommittee responsible for revising ISO 22000:2005 to revise the definition of “control measure” to delete the word “eliminate”. The logic of this proposal is that given advances in testing methodologies it has become increasingly difficult to attain “zero” presence of a biological, chemical or physical contaminant. The Coalition has recommended that the definition of “control measure” in s. 42 be amended.

The Coalition recommends that 87(1)(c)(i) be amended consistent with the new definition of control measure in s. 42. The amended wording would then read either:

(i) a description of the biological, chemical and physical hazards that are identified under section 44 as presenting a risk of contamination of a food, of the control measures that are used to prevent or eliminate those hazards or reduce them to an acceptable level and of the evidence that shows that the control measures are effective,

OR

(i) a description of the biological, chemical and physical hazards that are identified under section 44 as presenting a risk of contamination of a food, of the control measures that are used to prevent ~~or eliminate~~ those hazards or reduce them to an acceptable level and of the evidence that shows that the control measures are effective,

s. 87(1)(c)(i) to (vii) – Content of preventive control plan - The requirements listed in 87(1)(c) **do not** reflect industry expectations for an effective food safety system. They do not include important steps and/or elements included in:

- the Codex Alimentarius Commission HACCP methodology;
- the Agency’s current approaches as set out in the Food Safety Enhancement Program (FSEP) and the Quality Management Program (QMP);
- the federal-provincial-territorial National Food Safety Recognition Programs for On-Farm and Post-Farm Food Safety Programs;
- international standards such as ISO 22000:2005;
- the Global Food Safety Initiative benchmarking requirements; or
- the food safety plan requirements under the *US Food Safety Modernization Act*.

In our 2015 submission, the Coalition recommended that the requirements for a preventive control plan be substantially revised.

Therefore, the Coalition recommends the following replacement for the proposed wording of 87(1)(c):

(i) the names and respective competencies of the persons responsible for developing, maintaining and updating the preventive control plan;

(ii) a description of the biological, chemical and physical hazards that are determined under section 44 to present a risk of contamination of the food;

(iii) a description of the hazard analysis undertaken or adapted to identify the control measures required to control the hazards determined in subparagraph (ii) ;

(iv) a description of the control measures, including critical control points where required, identified in subparagraph (ii);

(v) the evidence that shows that the control measures are effective;

(vi) the procedures for the monitoring of control measures, including critical control points, where applicable;

(vii) the procedures for corrective actions;

(viii) the procedures for treatments and other identified processes (s. 45 and s. 46);

(ix) the competencies and qualifications determined under s. 73;

(x) the supplier assurance program [see comments above s. 70 to s. 72]

(xi) the procedure for complaints (s. 81)

(xii) the procedures for recall (s. 82)

(xiii) the procedure for traceability (s. 88)

(xiv) the procedure for updating and maintaining the hazard analysis and the preventive control plan;

(xv) the procedures, including verification activities, the analysis of verification activities, internal audit and management review, to verify that the implementation of the preventive control plan results in compliance with the Act and these Regulations; and,

(xvi) documents that substantiate that the preventive control plan has been implemented with respect to subparagraphs (c)(i) to (xv).

PART 5 – TRACEABILITY

s. 88 to s. 90 – Traceability requirements – The Coalition notes that these sections of the proposed regulations are basically the same as those in the 2015 draft. Since forwarding our comments on that draft, the Coalition has had the opportunity to rethink its comments, particularly with respect to sub-section 88(2). The Coalition’s other concerns about this Part remain unchanged.

s. 88(1)– Documents - Consistent with its recommendations on licensing (see Part 3 above), the Coalition notes that the preamble in ss. 88(1) could be greatly reduced if those recommendations were accepted, in particular the requirement that persons who grow or harvest fresh fruits or vegetables that are exported or shipped inter-provincially be licensed.

88(1)(a) –Documents - requirement for “lot code” – The Coalition notes that the draft *Interpretive Guidance on Part 5* includes a definition of “lot code”. This definition responds to our 2015 comments on the need for a flexible definition. **The Coalition recommends that the definition of “lot code” be included s. 1(1):**

lot code means any code that can be used to identify a defined quantity of food.

s. 88(2) – Documents – retail sale – Members of the Coalition have raised concerns about the exclusion of restaurants or other similar enterprises from the traceability requirements. These concerns include:

- According to Agriculture and Agri-Food Canada, Canadian consumers have, since 1982, consistently spent about 34% of their annual household food and non-alcoholic beverage expenditures at restaurants and the other 66% at retail stores;
- Institutional food service operations (e.g. retirement homes, nursing homes, hospitals, educational establishments, etc.) often cater to the populations most vulnerable to food borne diseases;
- Retail and food service operations of all sizes and types, share similar challenges in maintaining traceability systems;
- Tracking outbreaks from consumers through their food suppliers to the source of the outbreak is important, no matter which channel the food moved from production, through processing, distribution and handling to final marketing.

The Coalition recommends that s. 88(2) be amended and the reference “restaurants or other similar enterprises” be deleted. This position is consistent with the Coalition’s Principle #1 –“Food safety is a shared responsibility of all participants in the supply chain”. The amended text of 88(2) would then read:

Documents — retail sale

88 (2) Any person who sells a food at retail, including food service enterprises and restaurants, ~~other than a restaurant or other similar enterprise that sells the food as a meal or snack,~~ must prepare and keep documents that set out the information specified in paragraphs (1)(a) and (c) to (e).

89 (1)(a) - Production of Documents - The Coalition recognizes that the proposed regulation has been amended by the insertion of **89(1)(a)(ii)** to provide the Minister with some flexibility when a longer time period is appropriate (e.g. when a serious risk is not evident or when more time is needed to provide records). This amendment is a welcome one. Coalition members have noted that in a global economy,

and especially considering widely distributed products or ingredients from one lot can be used in many different products, pulling all records in less than 24 hours could be very difficult.

89 (1)(b) - Production of Documents - Coalition members have noted that the requirement for a “single file” is restrictive and, in some cases may not be achievable. **The Coalition recommends that 89(1)(b) be amended to add Ministerial flexibility to this requirement. The amended text would then read:**

- (b) (i) if provided electronically, in a single file and in plain text that can be imported into and manipulated by standard commercial software; or**
- (ii) any other number of files that is specified by the Minister.**

Part 6 – Commodity-specific Requirements

s. 118 – Definition of “on-farm food safety program” – The Coalition is concerned that the definition of an “on-farm food safety program” is restricted to “a program that relates to food animals”. This does not reflect the very broad use of on-farm food safety programs across primary agriculture in Canada (e.g. grains and oilseeds, mushrooms, fruits and vegetables, herbs and spices, food animals, etc.), in the *National Food Safety Recognition Program* administered by the Agency for the federal, provincial and territorial governments and in the Agency’s *Private Certification Policy (Food Safety)*. The definition in the 2011 *On-Farm Food Safety Recognition Program Federal-Provincial-Territorial Protocol Document* is:

On-farm food safety program – a systematic, HACCP-based approach to promote the production of safe products at the farm level; represented by a set of production practices, including control measures, a producer manual and a management manual

The approach and outcomes identified in the above definition results in the primary producer having what is in essence a well-developed preventive control plan, as required by the proposed regulations. There is one important difference, as noted in our discussion under s. 44(1) – *Identification, analysis, prevention and elimination of hazards*. On-farm and other similar food safety programs are “HACCP-based”. The farm or establishment does not undertake a “site-specific” hazard analysis as currently required by s. 44(1). It adapts the production practices identified by the generic hazard analysis undertaken by those responsible for the program and reviewed for technical soundness under the Agency’s *Food Safety Recognition Program*. The definition in s. 118 does not clearly indicate who is responsible for the hazard analysis, the farm or the program.

The Coalition believes that the definition in s. 118 should be moved to s. 1(1) and be amended to be generic and essentially consistent with the definition now in use in the *Food Safety Recognition Program*. Its usage in Division 6 should be restricted to “food animals”. The amended text for the generic food safety program definition and the on-farm food safety program definition would then read

on-farm food safety program means a program , assessed by the Agency as meeting the Category I criteria set out in the document entitled *Private Certification Policy (Food Safety)*, prepared by the Agency and published on its website, as amended from time to time , that relates to a food or food commodity animals that is operated on a farm or at a similar place at an establishment and under which hazards relating to the safety of the food or food commodity meat products or products that may be derived from these the food animals commodity are identified, analyzed and controlled.

AND

on-farm food safety program means a food safety program operated on a farm

- s. 155(c) - Trichinella spp. — pork
- s. 163(1)(d) - Required Information (birds)
- s. 163(1)(h) – Required Information (equines)

These sections require a primary producer to have in place an on-farm food safety program or to identify the name of any such program that is in place on the production unit for the food animal in question. **The Coalition is uncertain as to the Agency’s true intent, however, we support the requirement for an on-farm food safety program, which as noted above is essentially the same as having in place a written preventive control plan.**

Part 7 - Recognition of Foreign Systems

s. 168 (1) - Recognition of inspection system - The Coalition is concerned that the provisions in the proposed regulations concerning recognition of foreign systems is restricted to “meat products or shellfish”. It would appear not to encompass the 2016 agreement between Health Canada, CFIA and the US Food and Drug Administration on food safety systems recognition. **The Coalition would like to know under what authority the Canada/US agreement was made and is governed? Part 7 could be amended to cover “inspection systems for meat products and shellfish” and “food safety systems”. This would clarify and strengthen the role of the Canada/US food safety systems recognition agreement and any future agreements that Canada might enter into.**