

Legislative and Regulatory Changes An Industry Perspective

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Unparalleled Change

Canada

- ✓ CFIA importer licensing
- CFIA licensing service standard and user fee
- ✓ CFIA legislative modernization
- CFIA regulatory modernization
- CFIA inspection modernization
- H.C. Bill C-38
- H.C. Food Act

United States

- ✓ Food Safety Modernization Act-FSMA



Canada-U.S. Perimeter Initiative

- ✓ Regulatory Cooperation Council
- ✓ Beyond the Border Initiative

Importer Licensing



Importer Licensing

Traditional Approach

- Entity/individual to be licensed identified in regulation
- Import process complex-numerous business models make it difficult to uniquely identify an entity or individual
- Non-resident importers – 40% of U.S. exporters are non-resident Canadian importers, 30% of Canadian companies non-resident importers to the U.S.

Alternative Approach

- Importer and foreign exporter would decide which of the parties is responsible & liable for food safety and product compliance
- Required by regulation for responsible party to be identified to CFIA
- Importer or foreign exporter would be required to be licensed
- If foreign exporter identified as the responsible party – non resident importer
- Clearly defined eligibility criteria for “food safety” non resident importer [perhaps increased demonstration of food safety assurance]
- Non-resident importer would pay the cost for CFIA audits in foreign country
- Documentation would be made available to CFIA upon request, within specified timeframe
- Inter-government agreement to enforce non compliance of non-resident importer
- Concept of non-resident importer posting a bond as leverage for compliance
- Modeled after CRA and CBSA regulatory framework for duties and taxes with non-resident importers

Importer Licensing-Devil in the Hows

Notify CFIA of Unsafe Food

- Considerable understanding gained through product safety notification requirements under CPSA
- When does a company “become aware of” unsafe food ?
 - Division of a multi-national in a foreign country has knowledge of an unsafe food but the Canadian subsidiary doesn’t, is that “becoming aware” ?
 - What is criteria for deeming a food ? Is it a single consumer complaint ?
- Who within the company “becomes aware” ?
- Expectations for international food safety monitoring and surveillance ?
- Who within a company must report ?

Importer Licensing-Devil in the Hows

Notify CFIA of Unsafe Food Cont'd

- When does 24 hour timeframe start ? How would weekends and civic holidays treated ? International time zones ?
- What series of events does notification trigger ?



CFIA Legislative Renewal

CFIA Legislative Renewal

- Consolidation of *Agricultural Products Act*, *Meat Inspection Act*, *Fish Inspection Act*, *Consumer Packaging and Labelling Act*
- Increased consistency of policy development, inspection and enforcement decisions; reduce cost to industry
- Improve certification of exports for international market access
- Creation of an appeal mechanism
- Extend the requirement for use of best practices and modern food safety approaches across food categories
- Extend potential for licensing and registration regimes across all food categories
- Common licensing and registration regimes
- Increased authority for food traceability

CFIA Legislative Renewal

Considerations of Interest

- Definition of “*prepare*” incorporated
- Provision for administrative monetary penalties
- New prohibitions
 - General prohibition on importing anything the sale of which would be a contravention of the FDA
 - Prohibition on selling a recalled product
 - Prohibition on importing, exporting, or sending or conveying a food commodity from one province to another contrary to the regulations, or without a registration or license if required

CFIA Legislative Renewal

Considerations of Interest Con't

- New authority to disclose personal information and confidential business information with the public or person[s] or government in situations of risk of injury or health or recall
- Incorporation of documents by reference into regulations [Canada organic standard] that can be updated without requirement for regulatory amendment



U.S. Food Safety Modernization Act

U.S. Food Safety Modernization Act

- ❖ Foreign manufacturers registration with US FDA
- ❖ US importers required to import from registered foreign suppliers & verify food safety compliance of products
- Canadian manufacturers required to register with FDA every second year [2011].
- Canadian manufacturers must implement HACCP food safety risk assessment and management system and prerequisite food safety practices for market access [2012].
- Canadian non-resident importers require to have presence in the U.S. and employee[s]

U.S. Food Safety Modernization Act

- By 2013 US importers must have process to ensure that all imported food is produced in a compliance with the preventive control requirements, the produce safety standards, and other U.S. laws and regulations [2013].
- Certification that imported food is produced in compliance with U.S. laws and regulations [2011].
- Importers required to disclose to FDA if the food offered for import was refused by any other country as part of the prior notice requirements [2011].

U.S. Food Safety Modernization Act

- New regulations to require that shippers, carriers by motor vehicle or rail vehicle, receivers, and other persons engaged in transportation of food to use sanitary practices [2013].
- Re-inspection fees [\$224/hr. domestic; \$335/hr. foreign] [October 2011].
- New requirements for food tracking and traceability
- Potential for 3rd private party audit verification or other governmental verification



Canada-U.S. Perimeter Initiative

Canada-U.S. Perimeter Initiative

Regulatory Cooperation Council

- Develop common approaches to food safety-minimize the need for routine food safety surveillance inspection activities in each other's country
- Establish mutual reliance on jointly acceptable food safety laboratory recognition criteria, test results and methodologies to ensure that food safety laboratory testing conducted in one country is acceptable to regulators in both countries
- Further align crop protection product [e.g. pesticide] approvals and establishment of maximum pesticide residue limits/tolerances in both countries.

Canada-U.S. Perimeter Initiative

Beyond the Border Initiative

- U.S. and Canada to conduct joint assessments and audits of plant, animal and food-safety systems in third countries
 - By Dec. 2012, develop assessment processes and joint site-visit plans for commodities of common interest from third countries and address how to incorporate the findings into risk management decisions & develop mechanism to share results of assessments when conducted separately.
 - By Dec. 2012 develop joint methodologies for food safety system assessment including audit criteria for conducting audits

Canada-U.S. Perimeter Initiative

Beyond the Border Initiative Con't

- U.S. and Canada to conduct joint assessments and audits of plant, animal and food-safety systems in third countries
 - By December 2012 develop joint audit plans to pilot the evaluation of foreign food safety inspection systems in third countries
 - By December 2012 develop a protocol for what information from audits can be shared and how findings from site visits will be used in risk-management decisions

Questions ?

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