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# Preliminary Impact Assessment Study: US Food Safety Legislation –Final Report

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## EXECUTIVE SUMMARY

Over the past decade, food safety has become a top of mind issue amongst consumers and legislators in the United States. Incidents involving fresh produce, peanuts, processed foods and meat products have generated considerable concern, prompted the establishment of well funded advocacy groups, lead to a series of high profile court cases, focused media interest on both domestic and imported foods and stimulated legislators to introduce amendments to federal (and state) legislation.

In the current, 111<sup>th</sup> Congress, 19 bills have been introduced that in one way or another deal with food safety. Approximately one half of these are directed at modernizing the federal government's regulatory capacity, particularly that of the Food and Drug Administration (FDA), which is responsible for regulating 80 percent of products (domestic and imported) in the US food chain. Some bills deal specifically with perceived problems with imported products. Others have focused on the fragmented structure and divided jurisdictions of the federal government's food safety system and proposed a single window approach – a new food safety agency. The most comprehensive of the bills reflect a growing Congressional and public consensus that FDA's current reactive approach should be replaced by one that evaluates hazards and risks, emphasizes prevention by food businesses, and focuses inspection resources appropriately in high risk areas.

The most prominent bill in the House of Representatives is HR 2749, "The Food Safety Enhancement Act of 2009". It fits into the comprehensive group. It was introduced on June 8, 2009 by Representative Henry Waxman and is the successor to the "Food and Drug Administration Globalization Act (HR 759)" introduced in January by Representative John Dingell.<sup>1</sup> HR 2749 was amended and approved by a House Energy and Commerce subcommittee on June 10, 2009. The full House Energy and Committee amended and approved HR 2749 on June 17, 2009. The full House approved the bill with some more amendments on July 30<sup>th</sup>.<sup>2</sup> S 510, "FDA Food Safety Modernization Act", is the most prominent and comprehensive bill in the US Senate. It was introduced On March 3<sup>rd</sup> 2009 by Senator Richard Durbin and a bipartisan group of Senators. The Senate began its consideration of the bill on October 22, 2009 and is expected to conclude its work either by year end or early in 2010.

The **objective** of this study was to identify measures under consideration that could have the largest negative impacts on Canadian companies required to meet US Food and Drug Administration food safety requirements, listing the potential problems and their impacts on exporters. The study involved performing comparative analysis of two proposed US food safety bills and in collaboration with other industry experts 1) identifying the most problematic measures; 2) explaining problems that could occur for Canadian exporters; 3) outlining the consequences to these exporters; 4) recommending alternative ways to achieve the US's objectives; and 5) identifying next steps.

**The two most prominent bills were chosen for analysis: HR 2749, "The Food Safety Enhancement Act of 2009" and S 510, "FDA Food Safety Modernization Act".**

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<sup>1</sup> Olsson, Frank, Weeda, Terman, Bode, Matz PC, "Food Safety Legislation in the 111<sup>th</sup> Congress", June 22, 2009.

<sup>2</sup> Becker G, CRS, "Food Safety: Selected Issues and Bills in the 111<sup>th</sup> Congress", August 14, 2009.



Both of the bills analyzed focus only on the jurisdiction of FDA and explicitly exclude those commodities covered by USDA (meat and poultry). Neither bill creates a new food safety agency.

Based on the analysis, **there are six measures that depending on how they are implemented have the potential to negatively affect Canadian exporters.** The consequences of these measures are summarized below. Alternatives, if feasible, are also presented.

| <i>Measure</i>                           | <i>Current Practice &amp; Changes</i>  | <i>Consequences</i>  | <i>Alternatives</i>  |
|--|--|--|--|
| Hazard Analysis                          | <p>The US requires HACCP (Hazard Analysis and Critical Control Points) based systems for facilities processing seafood, juices, and low-acid foods.</p> <p>Within the FDA mandate, Canada requires HACCP only for fish and seafood facilities.</p> <p>Both bills would make HACCP mandatory for all domestic and foreign facilities.</p> | <p>Canadian export facilities must develop and implement HACCP and food defense plans to maintain market access. This has a bottom line impact and will not enhance relative competitiveness. There are no Canadian standards for HACCP trainers or auditors. Biennial or triennial revision of HACCP plans will be burdensome on exporters. Large companies appear to be more likely to have HACCP in place than small companies. It may be necessary to revise provincial government HACCP programs to meet FDA needs. Demand for implementation assistance will increase.</p> | <p>The triennial renewal requirement for HACCP plans in S 510 is the least burdensome option.</p> <p>Canada should seek recognition in the legislation of the HACCP-based concept (industry developed generic programs) as well as site-specific HACCP systems.</p> <p>Generic HACCP-based programs recognized by the competent authorities in exporting countries should only be required to be updated every 5 years</p> |
| Fresh Produce & Other Raw Ag Commodities | <p>Currently, the FDA has guidelines, not regulations, for the fresh produce sector.</p> <p>Both bills would put in place mandatory scientific and risk based standards for the fresh produce sector (growing, harvesting, processing, packing, transporting &amp; holding).</p>   | <p>The measure (both bills) should stimulate the uptake of the CHC’s CanadaGAP and CPMA’s Repack/Wholesale Food Safety programs. It may require changes to CFIA recognition programs for the national OFFS and PFFS programs. Both bills would increase the cost to export. While the House bill is focused on fresh produce, the FDA is allowed to cover other areas such as lentils and peas. Difficulties in having these commodities put in place HACCP plans at the farm level could result in loss of market access.</p>   | <p>Include foreign government recognized, HACCP-based, 3<sup>rd</sup> party certified food safety schemes within the scope of the legislation.</p>   |
| Risk Based Inspection                    | <p>FDA currently inspects only a small proportion of the facilities under its jurisdiction (about 7,000) of which an even smaller proportion are foreign. Much of its inspection activity is reactive not proactive (risk-based).</p> <p>Both bills require the inspection of foreign facilities exporting to the</p>                    | <p>Based on current registrations, about 14,700 Canadian facilities would now require inspection. Inspection costs would vary by facility products and complexity. Costs would also vary by the source of the inspection (US government, Canadian government or third party).</p> <p>There are implications for the Canadian government if non-registered</p>  | <p>Canada supports a risk-based inspection in principle, but will want to be sure that any frequencies eventually mandated by U.S. legislation or regulation can be scientifically justified as an effective and</p>   |



|                               |   |  |   |
|-------------------------------|---|--|---|
|                               | <p>US. Frequency would vary by risk categories (which will be defined at a later date) between 6 months and 5 years.</p>  | <p>establishments seek regular inspections.</p> <p>If accredited third parties are involved then these services are currently in short supply in Canada (and in the United States) and will be subject to an initial spike in demand as firms move to meet the requirements by the implementation deadlines.</p> <p>Clarification of Categories 1 and 2 was requested.</p>   | <p>efficient way to manage risk. Canada should propose that the legislation stop short of mandating the frequency of inspections, and instead require regulators to develop and implement a risk-based schedule based on sound science. Canada should offer to work closely with the U.S. on the development of a science-based system.</p> |
| Certification & Accreditation | <p>Certification is an accepted practice in international trade and Codex has developed guidelines governing it. There is uncertainty as to whether or not FDA currently has the authority to enter into certification agreement with exporting countries.</p>  | <p>Both bills authorize the Secretary to require certification of imports under certain conditions where either the exporting country’s food safety system or the exporting facility’s food safety system has not met certain requirements. There is uncertainty in both bills about what products would require certification and whether or not Canadian exports would be subject to certification. Industry requests clarification.</p>   | <p>Canada should seek to ensure that products of national food safety systems recognized as equivalent to the new US requirements will not require certification.</p>   |
| Import Regime                 | <p>FDA is currently empowered to refuse entry to any food import that “appears” to be adulterated, misbranded or otherwise in violation of the law. It requires importers to provide prior notification for each shipment. It has established an electronic database (OASIS) which inspectors use to identify risk and select shipments for inspection. However, it has only 450 inspectors for over 300 ports of entry and in practice inspects approximately 1% of shipments.</p> <p>Both bills would tighten import controls through either verification or certification systems. These could involve foreign governments (or third parties).</p> <p>Importers would be required to verify supplier activities.</p> <p>The Senate bill provides for</p> | <p>Both bills allow for expedited imports. Both increase the cost of exporting and thicken the border. Some Canadian firms may withdraw from the US market if the benefit of market access does not exceed the cost of these measures. Food processors identified the Foreign Supplier Verification Program as having the potential to be a very problematic measure, increasing costs and being discriminatory to foreign food. Other participants suggested that under the Senate bill, facilities have to meet certain requirements and that this is just echoing this. It was suggested that Canada may have similar provisions in place. The Senate bill would give FDA additional authority to review food safety systems of importing countries to ensure overseas regulators are controlling risks. It would provide FDA the authority to enter into equivalency agreements. This would be positive for Canadian exporters. However, care must be exercised when defining equivalency.</p> | <p>Canada should ensure that FDA has the authority to enter into equivalency agreements as is proposed in S 510.</p>  |



|              |   |  |  |
|--------------|---|--|--|
|              | entering into equivalency agreements.   |  |  |
| Traceability | <p>FDA currently requires one-step forward/one-step back traceability from facilities that manufacture, process, pack, transport, distribute, receive, hold, or import food (but exempt farms and restaurants from some or all of the requirements).</p> <p>The House bill would establish a “full pedigree” traceability requirement for all facilities except retail and foodservice and exempt farms in some situations.</p> <p>The Senate bill would require traceability for the fresh produce supply chain.</p> | <p>The full traceability requirement goes well beyond the current one-step forward one-step back system and may be infeasible. Industry expressed support for a unique identifier number based on international standards (GS1).</p> <p>Canada’s traceability initiative is focused on livestock/meat. Extending the effort to all commodities would greatly increase the scope and the cost and effort required. If US industry programs are selected, then Canadian exporters will have to harmonize existing programs with the US programs.</p> <p>This measure will increase the cost associated with exporting (and the cost of doing business for US domestic firms).</p> <p>Concerns were raised about the timeframe for implementation and traceability beyond the case level for produce. It was also noted that traceability does not enhance food safety.</p> | <p>Limit the new traceability requirements to one – forward one-back and to encourage the US to drop the traceability requirements completely in the event that analysis indicates significant problems.</p> <p>Use international standards as basis for FDA regulations concerning unique identifiers, nomenclature, etc.</p> <p>Limit traceability in the produce sector to the case not the item level.</p> |



## 1. PROJECT DETAILS

The **overall goal** of this project is to provide insight regarding the impact of proposed US food safety legislation, in particular amendments to the Food and Drug Act, on Canadian exporters. This insight would allow Canada to develop its strategy with respect to the US legislation and to propose alternative measures.

The specific **objective** of this study was to identify measures under consideration that could have the largest negative impacts on Canadian companies required to meet US Food and Drug Administration food safety requirements, listing the potential problems and their impacts on Canadian exporters.

The **scope of this study** covered the following:

- Performing comparative analysis of two proposed US food safety bills (HR 2749 – Food Safety Enhancement Act of 2009 as approved by the House of Representatives on 31 July 2009 and S 510 FDA Modernization Act)
- In collaboration with other industry experts 1) identifying the most problematic measures; 2) explaining problems that could occur for Canadian exporters; 3) outlining the consequences to these exporters; and 4) recommending alternative ways to achieve the US's objectives
- Preparation of an interim/draft report
- Preparation of a final report after receiving feedback from AAFC and other departments

The **data and information required** was collected by the consulting team via primary and secondary research. The secondary research involves gathering relevant information on the proposed legislation from government web sites, industry news releases, trade publications, etc. The primary research involves discussions with industry stakeholder groups.

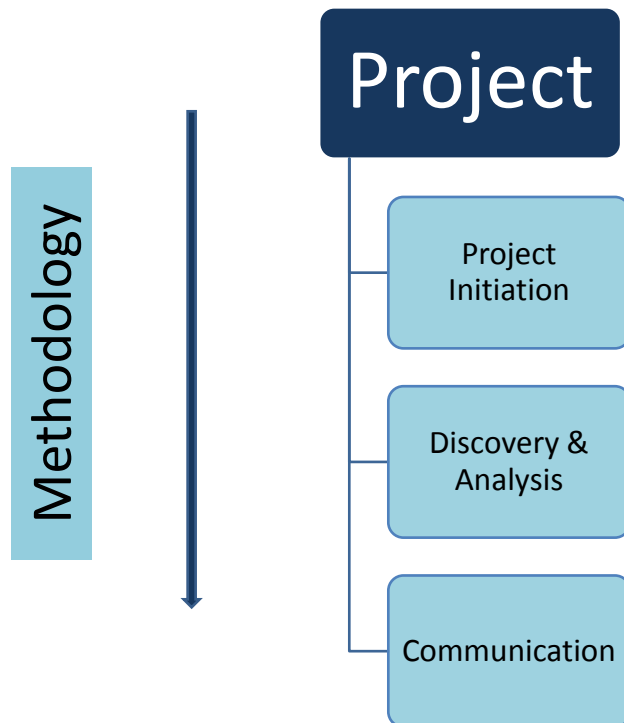
The **deliverables** are shown below along with the associated time line:

- Initial meeting between consulting team and project coordination team (August 28, 2009)
- Work plan (submitted September 10, 2009)
- Preparation and submission of interim/draft report after completion of analysis (submitted September 23, 2009)
- Meeting between consulting team and project coordination team to discuss interim report (held September 25, 2009)
- Preparation and submission of final report (amended to October 19, 2009)

The **methodology** consisted of the following components: project initiation, discovery and analysis, and communication. In the project initiation component, the consulting team and project coordination team met via conference call to discuss the project and determine which two proposals to analyze. In the discovery and analysis component, the chosen proposals are compared and then -- in collaboration with other industry experts -- the consulting team: 1) identified the most problematic measures; 2) explained problems that could occur for Canadian exporters; 3) outlined the consequences to these companies;



and 4) recommended alternative ways to achieve the US's objectives. The communication component involved an interim/draft report, meeting to discuss interim/draft report, and a final report.



The following consultation process was to be used to validate and expand upon the findings of the initial analysis.

- A conference call was held with AAFC's industry working group on food safety legislation. This provided an opportunity to bring key players at the relevant industry associations up to speed on the initial findings, collect their initial feedback, and determine what subsectors (processed food, fruits and vegetables, grains etc.) should be the focus of more detailed consultation with industry experts
- Follow-up calls with individual industry associations or groups of industry associations (by subsector) were organized to discuss specific issues in more detail.

## 2. FOOD SAFETY INITIATIVES IN THE US

### 2.1 The Situation

Food safety systems protect consumers' health and safety, meet international trade obligations with respect to risk based food control systems, and provide food with attributes demanded by consumers. <sup>3</sup> **Globalization and changes in consumer preferences make the development and implementation of effective food safety systems more challenging today.** The expansion of multinational companies, trade agreements, and better transportation and logistics allow the consumption of a greater variety and more exotic foods. Growing income, education levels, and ethnic diversity have increased consumer demands for convenient, diverse and health food. <sup>4</sup> However, the growth in ready to consume products and food prepared away from home increases food safety issues. Greater nutritional awareness increases the consumption of fruits and vegetables, which can have food safety problems. The significant increase in the variety and origination of products offered increases consumer choice but also has implications for food safety. Better accessibility to foreign produced food and changes in consumer demand have resulted in the growth of imported foods, which increases the risk of food safety issues. Also complicating food safety are the discoveries of new pathogens and wide-spread ingredient fraud in some countries and changes in the technology used throughout the supply chain and in detection. <sup>5</sup>

In the US:

- In terms of US per capita food availability, lbs per capita of fresh fruit has increased from 116.5 in 1990 to 126.2 in 2007. Per capita availability of fresh vegetables has increased from 175 lbs in 1990 to 202.2 lbs in 2007. <sup>6</sup>
- In 2008, consumers spent 1,165 B US on food, with 48.5% being spent on food away from home. <sup>7</sup>
- In 2004, 16% of US food consumption was from imports (by weight) compared to an average of 13.4% from 1991 to 1995. <sup>8</sup>
- US imports of food have increased from \$41 B US in 1998 to \$78 B US in 2007. Growing demand for consumer ready foods such as meat seafood, processed foods, and fresh fruits and vegetables was responsible for most of this growth.

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<sup>3</sup> FAO, "Assuring Food Safety and Quality: Guidelines for Strengthening National Food Control Systems", 2003.

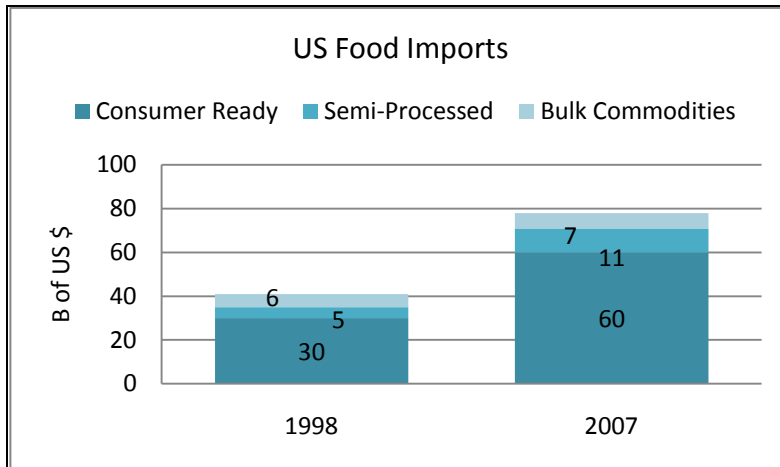
<sup>4</sup> Brooks N, J Buxby and A Regimi, "Globalization and Evolving Preferences Drive US Food Import Growth", Journal of Food Distribution Research, March 2009.

<sup>5</sup> FAO, "Assuring Food Safety and Quality: Guidelines for Strengthening National Food Control Systems" and US FDA, "Food Protection Plan", November 2007.

<sup>6</sup> <http://www.ers.usda.gov/Data/FoodConsumption/FoodAvailQueryable.aspx#midForm>

<sup>7</sup> [http://www.ers.usda.gov/Briefing/CPIFoodAndExpenditures/Data/Expenditures\\_tables/table10.htm](http://www.ers.usda.gov/Briefing/CPIFoodAndExpenditures/Data/Expenditures_tables/table10.htm)

<sup>8</sup> ERS, USDA, "Food Safety and Imports: An Analysis of FDA Food-Related Import Refusal Reports", September 2008.



- Trade agreements and proximity influence import patterns. For example, grain, meat and milk are sourced primarily from Canada and Mexico while fresh fruits and vegetables are sourced from Canada, Mexico and countries in Central and South America. Products such as dried, frozen and processed fruits and vegetables can travel further and can be sourced from Asian countries such as China, Thailand, Vietnam, and India. Free Trade Agreements between the US and Australia and Chile have resulted in growing imports.<sup>9</sup>
- Multinationals are establishing operations in lower cost less developed countries and then exporting output to the US and other countries. US commodities are also being exported to low cost countries for re-packaging in consumer ready products and then re-exported to the US.<sup>10</sup>

The US Centers for Disease Control estimates that each year 76 M Americans contract a food borne illness, with 323,000 being hospitalized, and 5,200 dying.<sup>11</sup> Although the US food supply has become safer over time, improvement seems to have stalled.<sup>12</sup>

“After decades of steady progress, the safety of the nation’s food supply has not improved over the past three years, the government reported Thursday. And, it said, in the case of **salmonella**, the dangerous bacteria recently found in peanuts and pistachios, infections may be creeping upward. The report, from the **Centers for Disease Control and Prevention**, demonstrates that the nation’s **food safety** system, created when most foods were grown, prepared and consumed locally, needs a thorough overhaul to regulate an increasingly global food industry, top government health officials said Thursday. “The system needs to be modernized to address the challenges and changes of the globalization of the food supply and rapid distribution chains,” said Dr. David Acheson, associate commissioner for foods at the **Food and Drug Administration**. “F.D.A. needs to do more inspections.” Dr. Stephen F. Sundlof, director of the agency’s food center, agreed. “As supply chains get longer and longer,” Dr. Sundlof said, “there’s more opportunity to introduce contaminants that have a public health effect.””  
<http://www.nytimes.com/2009/04/10/health/policy/10food.html?sq=food%20safety&st=cse&scp=8&pagewanted=print>

Analysis by the US Centers for Disease Control found that the most common sources of food poisoning in the US in 2006 were poultry and produce.<sup>13</sup> Recent outbreaks of foodborne illness have resulted from contaminated peanut butter (500 illness and 8 deaths), pot pies, spinach<sup>14</sup> and raw cookie dough<sup>15</sup>.

<sup>9</sup> ERS, USDA, “Food Safety and Imports: An Analysis of FDA Food-Related Import Refusal Reports”, September 2008.  
<sup>10</sup> ERS, USDA, “Food Safety and Imports: An Analysis of FDA Food-Related Import Refusal Reports”, September 2008.  
<sup>11</sup> <http://www.cdc.gov/ncidod/eid/vol5no5/meadG.htm>  
<sup>12</sup> <http://www.nytimes.com/2009/05/11/health/11food.html?pagewanted=print>  
<sup>13</sup> New York Times, “Report Finds Poultry is Top Outbreak Source”, June 12, 2009.



From 1998 to 2004, the types of products most often refused entry into the US by FDA inspectors were vegetables (21%), seafood (20%), and fruit (12%). (Meat, poultry and processed egg products are inspected by USDA and thus not included in the FDA refusal statistics.) Almost two-thirds of the violations were because of adulteration (safety and package integrity issues) while one-third were because of misbranding (or lack of proper label).<sup>16</sup>

The cost associated with foodborne illness is significant. USDA has estimated that the annual cost of Salmonella in the US is \$2.6 B US. The cost of Shiga Toxin-producing E.coli O157 (STEC O157) is estimated to be \$478 M US.<sup>17</sup> These estimates cover the cost of medical treatment, lost productivity, and premature death. **There are also significant costs to industry from foodborne illness arising from recalls, reduced consumer demand, and consumer concern.** The following box discusses Canadian estimates of the economic cost of foodborne illness.

“The annual impact of foodborne illness on the Canadian economy, specifically illness caused by *E. coli* O157:H7, is significant. A study conducted by the Guelph, Ontario-based George Morris Centre examined yearly costs associated with foodborne illness related to *E. coli* O157:H7 in Canada. The estimate is \$29.6 million.

This is based on, and includes, costs for the following:

- Health care, including visiting a family physician and/or the hospital emergency department, hospitalization due to Hemolytic Uremic Syndrome (HUS - requires dialysis and potential treatment for kidney failure), medication, and ongoing dialysis;
- Productivity loss;
- Premature death.

In addition to the above costs, the impact of controlling the prevalence of this organism in our environment has been estimated to be in excess of \$33 million. This estimate is based on:

- Food recalls;
- Declining consumer demand for affected food products;
- Consumer concern regarding product safety. “

<http://www.fightecoli.com/?lang=en&pageID=3-1>

## 2.2 Initiatives

**The Food and Drug Administration (FDA), Food Safety and Inspection Service (FSIS), and the Environmental Protection Agency (EPA) are the major agencies responsible for regulating food and food ingredients at the federal level in the US.** As the following table indicates, the FDA is responsible for all imported food except for meat, poultry, and processed egg products. FSIS is responsible for both domestic and imported meat, poultry, and processed egg product.<sup>18</sup> FDA regulated food includes the following: “food and food additives for man or animals, dietary supplements and dietary ingredients, infant formula, beverages (including alcoholic beverages and bottled water), fruits and vegetables, fish and seafood, dairy products and shell eggs, raw agricultural commodities for use as food or components of food, canned foods, live food animals, bakery goods, snack food, and candy”<sup>19</sup>

<sup>14</sup> Flex News, “Salmonella Outbreak to Spur US Food Safety Reforms”, January 28, 2009.

<sup>15</sup> ABC News, “3 Kinds of E. Coli Linked to Nestle's Cookie Dough”, July 9, 2009

<sup>16</sup> Brooks N, J Buxby and A Regimi, “Globalization and Evolving Preferences Drive US Food Import Growth”, Journal of Food Distribution Research, March 2009.

<sup>17</sup> <http://www.ers.usda.gov/data/foodborneillness/>

<sup>18</sup> Buzby J, L Unnevehr, and D Roberts, “Food Safety and Imports: An Analysis of FDA Food-Related Import Refusal Reports”, September 2008.

<sup>19</sup> FDA, “Registration of Food Facilities, Overview and Background”, October 2003.

| <i>Food</i>   | <i>Responsible Agency</i>   |
|---|---|
| Domestic and imported meat, poultry, and processed egg products (excludes exotic meats)   | Food Safety and Inspection Agency (FSIS) – part of USDA                                     |
| “All domestic and imported food marketed in interstate commerce” plus exotic and game meats, food additives, veterinary drugs, animal feed, and products with 2% cooked meat or poultry or 3% raw meat or poultry | Food and Drug Administration (FDA) – part of Department of Health and Human Services (DHHS) |
| Pesticide licensing and residue tolerance   | Environmental Protection Agency<br>Enforcement by FSIS and FDA                              |

Buzby J, L Unnevehr, and D Roberts, “Food Safety and Imports: An Analysis of FDA Food-Related Import Refusal Reports”, September 2008.

While new legislation is being debated, the previous and current Administrations continue to move forward with specific initiatives.

President Bush established the **Interagency Working Group (WG) on Import Safety** on July 18, 2007. According to the WG, *“To adapt to a rapidly growing and changing global economy, the US government must develop new import-safety strategies that expand and emphasize a cost-effective, risk based approach. Such an approach identifies risks at the points they are most likely to occur, and then targets the response to minimize the likelihood that unsafe products reach US consumers.”* The accompanying plan recognized that the import safety chain includes both foreign and domestic public and private sector businesses/entities involved in the import life cycle and that the entire chain must work together to prevent unsafe imports.<sup>20</sup>

**The Food and Drug Administration (FDA) introduced its Food Protection Plan** in November of 2007. This plan applies to 1) animal and human food; 2) imported and domestically produced products; and 3) food safety (unintentional contamination) and food defense (deliberate contamination). The FDA’s plan is based on three core elements: prevention (build in safety), intervention (test and inspect based on risk) and response (react rapidly and communicate effectively). The principles underlying the plan are 1) focus on risk over a product’s life cycle; 2) target resources to maximize risk reduction; 3) address contamination (unintentional and intentional); and 4) science and modern technology.<sup>21</sup>

**FDA Guidance for Industry - Voluntary Third-Party Certification Programs for Foods and Feeds** in January 2009. This guidance document and the subsequent pilot project involving aquaculture responds to the increased demands on suppliers, both domestic and foreign, by US retailers and food for independent third party certification to food safety and other standards and the impact that this is having through the supply chain. It indicates that the US "government supports voluntary certification programs as one way to help ensure products meet U.S. safety and security standards and to allow Federal agencies to target their resources more effectively". The guidance sets out general attributes of a certification program, the proposed approach to recognition and the opportunities that recognition might create for foreign suppliers vis-a-vis inspection, etc.<sup>22</sup>

<sup>20</sup> Interagency Working Group on Import Safety, “Action Plan for Import Safety”, November 2007.

<sup>21</sup> FDA, “Food Protection Plan”, November 2007.

<sup>22</sup> FDA, “Guidance for Industry - Voluntary Third-Party Certification Programs for Foods and Feeds”, January 2009



In March 2009, **President Obama established a new Food Safety Working Group** to provide advice on food safety regulation, compliance, and coordination. The group’s guiding principles are the prevention of harm to consumers; that good data and analysis are necessary for effective food safety; and that outbreaks should be quickly identified, traced and stopped.<sup>23</sup> The Working Group’s initiatives and progress on implementing these initiatives are shown below.<sup>24</sup>

| <i>Initiative</i>  | <i>Progress</i>   |
|--|---|
| Preventing salmonella contamination in eggs and poultry products   | July 7, 2009 FDA publishes the final rule on <b>Prevention of Salmonella Enteritidis in Shell Eggs</b> . It requires preventive measures during the production of shell eggs in poultry houses and requires subsequent refrigeration during storage and transportation.   |
| Reducing E.coli 0157:H7 in beef, leafy greens, melons, and tomatoes  | July 31, 2009 USDA and FDA announced the issuance of guidance for routine sampling of bench trim for E. coli as well as draft guidance to minimize or eliminate contamination in tomatoes, melons, and leafy greens   |
| Building a national tracing and response system through the development of a tracing system, improving state capacity, etc | November 3, 2009 – FDA and USDA announced public consultations (December 2009 – March 2010) to stimulate and focus a discussion about mechanisms to enhance product tracing systems for food intended for humans and animals. This discussion will help FDA and FSIS determine what short and long term steps the two agencies should take to enhance the current tracing system. |
| Improving the organization of food safety responsibilities at the federal government level                                 | October 5, 2009 USDA announced that Leanne Skelton, Chief of the Fresh Products Branch will join FDA for a six month period to develop new food safety rules  |

The FDA opened its **Reportable Food Registry Electronic Portal** in September 2009. “The requirements apply to any person who has to submit registration information to the FDA for a food facility that manufactures, processes, packs, or holds food for human or animal consumption in the United States. These people are termed responsible parties. A responsible party:

1. Must investigate the cause of the adulteration if the adulteration of food may have originated with the responsible party
2. Must submit initial information; followed by supplemental reports
3. Must work with the FDA authorities to follow up as needed

A responsible party is not required to report if it found the problem before the food was shipped, and corrected the problem or destroyed the food.”<sup>25</sup>

**Nearly 20 food safety bills have been introduced into the 111<sup>th</sup> Congress, approximately half of which deal with substantive changes to the US approach to food safety. Most of these focus on changes to the Federal Food Drug and Cosmetics Act and on modernizing the Food and Drug Administration’s approach to regulating food safety.**

<sup>23</sup> President’s Food Safety Working Group, “Food Safety Working Group: Key Findings”, July 2009.

<sup>24</sup> President’s Food Safety Working Group, “President’s Food Safety Working Group: Delivering Results”, July 2009; USDA, “Agriculture Secretary Vilsack, Health, and Human Services Secretary Sebelius Announce New Strategies to Keep America’s Food Supply Safe”, July 31, 2009; and USDA, “USDA Joins FDA Efforts on New Food Safety Regulations”, October 5, 2009.

<sup>25</sup> FDA, “FDA Opens the Reportable Food Registry Electronic Portal for Industry Food Facilities Now Required to Report Potentially Dangerous Products”, September 8, 2009.



**The most prominent bill in the House of Representatives is HR 2749, “The Food Safety Enhancement Act of 2009”**, which was introduced on June 8, 2009 by Representative Henry Waxman. This bill is the successor to the “Food and Drug Administration Globalization Act (HR 759)” introduced in January by Representative John Dingell.<sup>26</sup> HR 2749, the revised version of HR 759, was amended and approved by a House Energy and Commerce subcommittee on June 10, 2009. The full House Energy and Committee amended and approved HR 2749 on June 17, 2009. The full House approved the bill with some more amendments on July 30, 2009.<sup>27</sup>

**S 510, “FDA Food Safety Modernization Act”**, is the most prominent bill in the US Senate. It was introduced on March 3, 2009 by Senator Richard Durbin and a bipartisan group of Senators. The Senate began its consideration of the bill on October 22, 2009 and is expected to conclude its work either by year end or early in 2010. A conference between the two houses would follow to arrive at a common bill.

Besides HR 2749 and S 510 other comprehensive bills were:<sup>28</sup>

- HR 875 – Representative DeLauro proposed a bill creating a new independent Food Safety Administration to operate comprehensive food safety program but not including FSIS’s meat and poultry program. The agency would remain in HHS but be separate from FDA.
- HR 1332 – Representative Costa – similar to Durbin’s Senate bill

*In the House, the House Energy and Commerce committee is responsible for FDA issues while the House Ag committee is responsible for USDA’s meat and poultry inspection. In the Senate, FDA issues are looked after the Committee on Health, Education, Labour and Pensions. The committee on agriculture looks after meat and poultry inspection by the USDA. The House and Senate Appropriation Committee’s agricultural subcommittee is responsible for funding and oversight of both FDA and USDA.*

**The bills selected for analysis were HR 2749, “The Food Safety Enhancement Act of 2009”, and S 510, “FDA Food Safety Modernization Act”**. These two bills are analyzed in the following chapter.

<sup>26</sup> Olsson, Frank, Weeda, Terman, Bode, Matz PC, “Food Safety Legislation in the 111<sup>th</sup> Congress”, June 22, 2009.

<sup>27</sup> Becker G, CRS, “Food Safety: Selected Issues and Bills in the 111<sup>th</sup> Congress”, August 14, 2009.

<sup>28</sup> Becker G, CRS, “Food Safety: Selected Issues and Bills in the 111<sup>th</sup> Congress”, August 14, 2009.



### 3. COMPARISON OF PROPOSALS

This section provides our comparison of HR 2749, “The Food Safety Enhancement Act of 2009”, and S 510, “FDA Food Safety Modernization Act” using secondary research and input from discussions with industry working groups.

**Both of the bills analyzed focus only on the jurisdiction of FDA and explicitly exclude those commodities covered by USDA (meat and poultry).** Neither bill creates a new food safety agency.

HR 2749 and S 510 propose major and comprehensive changes to the existing legislation. As a consequence, the measures proposed are in many cases tightly interrelated and the impact on food businesses, domestic or foreign, will be cumulative. All facilities, for example, will have to register, implement a HACCP-based food safety system and a traceability system, be subject to inspection, etc. If foreign, the facility will also be subject to additional requirements such as importer verification and/or certification.

However, the two bills are not identical and have significant differences in approach and content. For example, the House bill, HR 2749, “The Food Safety Enhancement Act of 2009”, tends to be more prescriptive, providing detailed actions for the Secretary to follow. For example, with respect to “facility registration”, the House bill includes more detailed processes and provides for exemptions. In the matter of “risk based inspection” the House bill sets out three categories to the Senate’s two and prescribes more detailed reporting. Under “performance standards”, the Senate bill sets out a simple requirement for the Secretary to evaluate relevant data every two years and, when appropriate, to issue contaminant-specific and science-based guidance, action levels or regulations. HR 2749 goes into significant detail about the process the Secretary is to follow, the requirements for publication, sampling protocols, etc. Similar differences in detail and the depth of the prescription are evidenced in other areas such as traceability, product testing and food defense.

#### 3.1 Identification of Potentially Most Problematic Measures

Based on our analysis of the bills, we grouped the issues covered by the bills into three categories. Category 1 measures are those that, have the potential to negatively affect Canadian exporters. Category 2 measures are those that may have implications. Category 3 measures do not have implications for Canada.

**We identified 14 measures that have the potential to negatively affect Canadian exporters. The full scope of their impact, however, cannot be determined at this time as this depends on how they are implemented.** These Category 1 measures are shown in the following table. The table also indicates in which section of the House or Senate bill the issue is dealt with.



| <i>Category 1 – Known to be Important</i> |                          |                        |
|---|--------------------------|------------------------|
| Measure                                   | HR 2749                  | S 510                  |
| Facility Registration                     | 101                      | 102                    |
| Hazard Analysis and Preventive Controls   | 102                      | 103, 106, 113          |
| Performance Standards                     | 103                      | 104                    |
| Fresh Produce & Other Raw Ag Commodities  | 104                      | 105                    |
| Risk-based Inspection                     | 105                      | 201                    |
| Traceability                              | 107                      | 204                    |
| Certification & Accreditation             | 109                      | 303/308                |
| Import regime                             | 113, 204, 205, 206, 136, | 301, 302, 303, 304,305 |
| Notification & Recall, etc                | 111                      | 206                    |
| Reportable Food Registry                  | 112                      |                        |
| COOL                                      | 202                      |                        |
| Foreign Inspectorate                      | 208                      | 307, 309               |
| Extraterritoriality                       | 213                      |                        |
| Transportation sanitation                 |                          | 112                    |

The following table indicates the following 13 measures that may have implications for Canada.

| <i>Category 2 – May have Implications</i>      |                              |       |
|--|------------------------------|-------|
| Measure  | HR 2749                      | S 510 |
| Access to Records                              | 106                          | 101   |
| Re-inspection & Recall Fees                    | 108                          | 107   |
| Testing & Lab Accreditation                    | 110                          | 202   |
| Infant Formula                                 | 114                          |       |
| Procedures for seizure                         | 131                          |       |
| Administrative Detention                       | 132                          | 207   |
| Restricted Movement                            | 133                          |       |
| Penalties                                      | 134 – criminal, 135 – civil, |       |
| False or misleading reporting to FDA           | 210                          |       |
| Subpoena                                       | 211                          |       |
| National agriculture and food defense strategy |                              | 108   |
| Salmonella Final Rule for processed eggs       |                              | 111   |

There are also some measures that appear to have no implications for Canada. These Category 3 issues are shown below. These deal primarily with matters of domestic policy or administration and range from improvements to the US surveillance capacity to providing authority for FDA to charge fees for export certificates and assistance to foreign governments to improve their capacity in food safety regulation.



| <i>Category 3 – Unlikely to have Implications</i>      |         |       |
|--|---------|-------|
| Measure  | HR 2749 | S 510 |
| Surveillance   | 121     | 205   |
| Public Education and advisory system                   | 122     |       |
| Research   | 123     | 108   |
| Decontamination and disposal standards and plans       |         | 208   |
| Food substances generally recognized as safe           | 201     |       |
| Exportation certificate fees                           | 203     |       |
| FDA Field Laboratories                                 | 209     |       |
| Whistleblower protections                              | 212     |       |
| Support for training institutes                        | 214     |       |
| Bisphenol A in food and beverage containers            | 215     |       |
| Lead content labeling – ceramic tableware and cookware | 216     |       |
| Food and Agriculture Coordinating Councils             |         | 109   |
| Building domestic capacity                             |         | 110   |
| Building capacity of foreign governments               |         | 306   |
| Funding for food safety                                |         | 401   |

**Discussions with industry** allowed the consultants to further refine the list of most potentially problematic measures. The following groups participated in discussions: grains, oilseeds, and pulses; food processors; horticulture; and importers and exporters. Some groups such as the millers and the seafood sector were unable to participate within the timeframe allowed for the completion of this report and thus there may be issues that were not identified. All groups indicated that based on clarifications and further consideration they might revise their list of problematic measures. The importer and exporter group wished to highlight the integrated nature of supply chains in North America and throughout the globe and to emphasize that a thicker border and changes in the playing field have significant consequences.

The “Hazard Analysis and Preventive Controls” and the “Traceability” measures were identified as having the potential to be problematic by all the industry groups. The “Certification and Accreditation” measure was viewed as being problematic by the grains, oilseeds, and pulses; food processors; and horticulture groups. These groups also requested further clarification on the “Performance Standards” measure. The horticulture group noted that depending on the acceptance of industry programs, the “Fresh Produce & Other Raw Ag” measure could potentially be a problem. The food processors and horticulture sectors had concerns about the “Import Regime” measure.

## 3.2 Analysis of Measure with the Greatest Potential to Impact Canadian Exporters

This section provides a side-by-side comparison of the most problematic measures (Category 1 issues). The discussion of each measure explains the problems that could occur for Canadian exporters; outlines the consequences to exporters (or regulators); and where possible suggests alternatives to achieve US objectives.

### 3.2.1 Facility Registration

Currently the US requires domestic and foreign firms to register (The Public Health Security and Bioterrorism Preparedness and Response Act of 2002, aka Bioterrorism Act) “if they manufacture, process, pack, or hold food for human or animal consumption in the US”. Farms, restaurants, retailers and some others are exempt from registration. Importers cannot take delivery of product if the foreign facility is unregistered. Under the current regulations, firms do not have to renew their registration and there is no cost to register. As of July 15, 2009, 382,866 facilities had registered with 41% being domestic US facilities. Canadian facilities represented 4% of total facilities, behind Japan, China and Mexico.<sup>29</sup>

#### Registration of Food Facilities under Bioterrorism Act (July 15, 2009)

|        | # Registrants | Share |
|--------|---------------|-------|
| US     | 156,493       | 41%   |
| Japan  | 24,164        | 6%    |
| China  | 21,794        | 6%    |
| Mexico | 17,731        | 5%    |
| Canada | 14,731        | 4%    |
| Italy  | 14,723        | 4%    |
| France | 13,607        | 4%    |
| Other  | 119,623       | 31%   |
| Total  | 382,866       |       |

The bills are compared in the following table.

HR 2749 (House) requires domestic and foreign facilities (including US importing agents) to register annually; pay a fee of \$500 (adjusted for inflation) per facility up to a maximum of \$175,000 per company; report changes in information within 30 days; file information electronically; and have a unique facility identifier. Certain farms (not those that pack or hold food grown or raised on farms owned by others) are exempt.

<sup>29</sup> <http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/RegistrationofFoodFacilities/ucm175995.htm>  
SJT Solutions, Monachus Consulting & Sally Rutherford Consultants | November 13, 2009

The Senate bill (S 510) requires food facilities to register biennially. The bill provides a simplified renewal process. No fees are to be assessed for registration. These costs will be covered through new FDA appropriations.

Problems and Consequences

Domestic and foreign facilities are already required to register under the Bioterrorism Act which amended the Federal Food Drug and Cosmetics Act. Consequently, the impact of this measure will be additional time and costs related to gathering and submitting the additional information. Because the House bill requires annual registration and the payment of a fee, it would result in greater compliance costs than the Senate bill. Both bills would add to the cost and difficulty of shipping to the US. Overall, the measure would thicken the border.

Both domestic and foreign facilities are treated equivalently.

Alternatives

**Of the two legislative proposals, the Senate’s requirements would be the least burdensome.**

**Facility Registration**

| Sec | HR 2749   | Sec | S 510   |
|-----|---|-----|---|
| 101 | <p><b>Summary: Section 101. Changes in Registration of Food Facilities.</b></p> <p>Section 101 amends section 415 of the FFDCa to require annual facility registration.</p> <p>Registrants are required to provide additional information pertaining to the facility, including contact information, the primary purpose and business activity of the facility, all trade names under which the facility conducts business related to food, and for foreign facilities, the United States agent for the facility.</p> <p>The registrant is required to notify the Secretary of any change in the submitted information no later than 30 days after the date of such change.</p> <p>A “facility” is defined to include any factory, warehouse, or establishment (including a factory, warehouse, or establishment of an importer) that manufactures, processes, packs, or holds food. Facilities do not include farms; private residences of individuals; restaurants; other retail food establishments; nonprofit food establishments in which food is prepared for or served directly to the consumer; or fishing vessels.</p> | 102 | <p><b>Summary: Section 102. Registration of Food Facilities</b></p> <p>Expands current registration requirements for food facilities by requiring all food facilities to register and renew registration biennially.</p> <p>Grants FDA authority to adjust food registration categories.</p> <p>Gives the Secretary authority to suspend facility registration if there is a reasonable probability that food from the facility will cause serious adverse health consequences or death to humans or animals.</p> |



|  |   |  |  |
|--|---|--|--|
|  | <p>The Secretary is authorized to suspend the registration of a facility for a violation of the Act that could result in serious adverse health consequences or death.</p> <p>The Secretary is also granted authority to cancel a registration that the Secretary determines was not updated or otherwise contains false, incomplete, or inaccurate information, or if the required registration fee has not been paid within 30 days after the due date. However, an order to suspend or cancel a registration shall not be delegated to any officer or employee other than the Commissioner, the Principal Deputy Commissioner, Associate Commissioner for Regulatory Affairs, or the Director for the Center for Food Safety and Applied Nutrition.</p> <p>The Secretary is required to provide a report to Congress annually detailing the number and type of facilities registered under this section.</p> <p>Section 101 requires the Secretary to assess and collect an annual fee of \$500 for the registration of a facility under section 415 of the FFDCA. The fee shall be collected and available to defray the costs of food safety activities (activities related to compliance by facilities registered under section 415 with the requirements of this Act relating to food). The registration fee shall not exceed \$175,000 for an individual company. The Secretary is required to hold a public meeting to allow stakeholders to provide input into how the fee revenue will be allocated.</p> <p>[Note: additional provisions at s.204 – commercial importers, s.205 – customs brokers]</p> |  |  |
|--|---|--|--|

### 3.2.2 Hazard Analysis, Risk-Based Preventative Controls, Food Safety Plan & Finished Product Testing

The internationally accepted approach to food safety management for all segments of the food supply chain incorporates the Codex Alimentarius Commission’s HACCP (Hazard Analysis and Critical Control Points) principles. Regulatory requirements for food businesses to use HACCP or HACCP-based systems vary by country and by commodity.

Currently, the FDA only requires HACCP systems for facilities processing seafood, juices and low-acid canned foods. Canada currently requires mandatory HACCP only for fish/seafood facilities – not for the others covered by the FDA mandate. In addition, meat and poultry processors in both countries are covered by mandatory HACCP requirements.



Outside these regulated industries, the implementation of HACCP or HACCP-based food safety management systems is variable. Major food processors have in many cases voluntarily implemented HACCP systems. An increasing, but limited number of food industry SME's are also implementing HACCP. In Canada, registrations to any of the private standards involve a small number of companies. For example, only 34 firms have been registered to the provincial government HACCP Advantage programs, all in Ontario. The registrations to other HACCP or food safety schemes offered by certification bodies are also modest in comparison to the 14,700 firms noted above: BNQ (21), QMI-SAI Global (15), NSF International (126), BRC (26), and SQF (38).

The treatment of the Hazard analysis measure in the two bills is compared in the following table.

The House bill requires mandatory HACCP and preventive controls for all domestic and foreign facilities. The requirement would come into effect within 18 months for large firms and within 2 or 3 years for small and medium sized enterprises (SMEs) depending on size. The written plans would have to be kept for two years and updated every 2 years or when changes are made to inputs, processes, etc. Facilities would also have to implement a written food defense plan to protect against intentional contamination. Supplier verification activities related to ingredients and to products remaining under the facility's control are also required. This bill also requires certain high risk facilities to submit final product test results.

For "high risk" (Category 1) facilities, the House bill, subject to a pilot project, requires submission of final product test results "documenting the presence of contaminants in food posing a risk of severe adverse health consequences or death" independent of the requirements for recall and notification.

The Senate bill requires mandatory HACCP and preventive controls for all domestic and foreign facilities. Records are to be kept for two years. The written plan is to be updated at least every three years or when changes in processes or practices occur.

Both bills require FDA to issue regulations setting out science-based standards for the food safety plans and include provisions requiring facilities to take intentional contamination into account in their hazard analyses or develop food defense plans.

### Problems and Consequences

**Both of these bills have significant potential implications for Canadian exporters.** If they do not currently have them, Canadian facilities must develop and implement food safety (HACCP) and food defense plans relatively quickly to maintain access to the US market. This will have a **bottom line impact** and will not increase their relative competitiveness.

Depending on the content of the new FDA regulations, guidance documents and other measures, it may be necessary to **revise provincial government HACCP programs and industry HACCP and HACCP-based food safety schemes to meet the new requirements.**

Biennial or triennial revision of HACCP plans will be burdensome on exporters.



The demand by Canadian SME's that are not currently registered establishments (under Canadian regulation) for federal/provincial funding to implement food safety management systems will increase significantly.

Discussions with the **grains, oilseed and pulse** sector identified the requirements for HACCP Based Plans as problematic. Although large companies have HACCP in place, not all facilities in the industry have implemented HACCP. These facilities would be required to implement HACCP if they wanted to maintain access to the US market. Concerns were raised about the availability of qualified resources to implement, certify and audit HACCP and the cost of implementation.<sup>30</sup>

According to the **food processing** group consulted, not all facilities exporting to the US have HACCP plans in place. Smaller operations are less likely to have these plans in place. Concern was raised about whether the equivalency between FSEP and US HACCP requirements would continue and whether at the higher level of the Canadian and US food safety systems equivalence Canada would fall behind.

Discussions with the importer/exporter group also identified concerns over the measures related to HACCP. It was noted that there are no government standards for HACCP trainers and certifiers. Clarification is required.

The implications of the final product testing proposals in HR 2749 are unclear and will be subject to a pilot project and a two year implementation timeframe. When implemented, all Category 1 facilities that identify finished product that poses a risk for adverse health consequence or death would have to submit these results to FDA. Such test results, in all facilities would be available for review during inspections.

Both domestic and foreign facilities are treated equivalently.

### Alternatives

The triennial renewal requirement for HACCP plans in S 510 is the least burdensome option.

**Canada should seek recognition in the legislation of the HACCP-based concept (industry developed generic program) as well as site-specific HACCP systems. HACCP-based programs recognized by the competent authorities in exporting countries should only be required to be updated every 5 years (unless there are significant changes) in line with the approach used by international benchmarking schemes (e.g. GlobalGAP and GFSI).**

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<sup>30</sup> Further work should involve consultation with the Canadian Grain Commission because this organization manages several certification programs.



**Hazard Analysis Preventive Controls & Finished Product Test Results**

| Sec | HR 2749  | Sec | S 510  |
|-----|--|-----|--|
| 102 | <p><b>Section 102. Hazard Analysis, Risk-Based Preventive Controls, Food Safety Plan, and Finished Product Test Results from Category 1 Facilities.</b></p> <p>Section 102 requires the owner, operator, or agent of a facility to develop and implement a written food safety plan.</p> <p>As part of this food safety plan, the owner, operator, or agent shall conduct a hazard analysis; identify, implement, and validate effective preventive controls; monitor preventive controls; institute corrective actions when monitoring shows that preventive controls have not been properly implemented or were ineffective; conduct verification activities; maintain records of monitoring, corrective action, and verification; and reanalyze for hazards. The food safety plan shall also include a description of the facility's procedures for recordkeeping; recall; trace back; supply chain safety; and science-based performance standards. When developing food safety plans under Section 102, facilities should evaluate whether there are hazards that could affect the safety, sanitation or wholesomeness of the food manufactured, processed, packed, transported, or held by the facility.</p> <p>The requirements of this section shall take effect 18 months after the date of enactment. Small businesses and very small businesses will have 2 years and 3 years, respectively, to comply.</p> <p>Section 102 also requires certain high-risk facilities to submit finished product test results documenting the presence of contaminants in food posing a risk of severe adverse health consequences or death. Before requiring the reporting of such test results, the Secretary must conduct 2 or more pilot projects and a study to evaluate the feasibility of such a reporting system.</p> <p>Section 102 requires facilities to implement a written food defense plan to protect against intentionally introduced contaminants.</p> | 103 | <p><b>Section 103. Hazard Analysis and Risk-Based Preventative Controls –</b></p> <p>Requires all registered facilities to identify known or reasonably foreseeable hazards and implement preventive controls to significantly minimize or prevent those identified hazards.</p> <p>Each owner or operator is required to have a written plan describing their hazard analysis and preventative controls, which shall be made available to FDA upon request.</p> <p>Failure to comply with this section is a prohibited act under the FDCA.</p> <p>The provision provides flexible compliance timeframes for small and very small businesses, and deems facilities in compliance with existing seafood, juice, and low-acid canned foods regulations to be in compliance with this section.</p> <p><b>Sec. 106. Intentional Adulteration –</b></p> <p>Requires FDA, working with DHS and USDA, to conduct vulnerability assessments and issue regulations to protect against the intentional adulteration of food.</p> <p><b>Sec. 113. Food Allergy and Anaphylaxis Management for Children –</b></p> <p>Directs HHS, in consultation with the Department of Education, to develop voluntary food allergy management guidelines to manage the risk of food allergy and anaphylaxis in schools or early childhood education programs. Provides for non-renewable food allergy management incentive grants for up to two years to assist local educational agencies (LEAs) with adoption and implementation of the voluntary food allergy management guidelines.</p> |



### 3.2.3 Performance Standards

In the context of food safety, performance standards are a quantitative measure of a substance or containment that are used to benchmark whether or not a food is safe, or to clearly establish what is or is not acceptable. They include, for example, maximum residue levels (MRLs) for pesticides, veterinary drugs or other chemicals or levels of specific microbial pathogens or a standard that defines the acceptable outcome of a process in reducing a pathogenic contamination. Performance standards can be international standards, set for example by Codex or by the OIE, or they may be national standards.

Currently, the FDA is only authorized to issue standards for tolerances for pesticides and drug residues. USDA has issued two performance standards for the verification of microbial safety of meat and poultry.

Canada, with the exception of the listeria policy, does not have federal performance standards. Canadian meat and poultry processors currently meet US performance standards. The subject of performance standards has begun amongst the federal, provincial and territorial governments and is raised in the draft FPT National Strategy for Safe Food.

The treatment of the performance standards measure in the two bills is compared in the following table.

#### Problems and Consequences

**Both bills would put in place new requirements. The secretary will have to establish new standards for the most significant food-borne contaminants. If the FDA approach follows the pattern set by USDA with respect to E.coli and Salmonella, then mandatory testing at key process steps will be required.**

Testing and the required expertise will increase costs for facilities that are impacted.

Both domestic and foreign facilities are treated equivalently.

#### Alternatives

It is suggested that governments (FPT) engage industry groups affected by the proposed legislation in a dialogue about performance standards at the earliest opportunity.

Canada should work proactively with the US to ensure that any new standards considered (in either country) are risk and science based, practical to implement and do not unnecessarily impact on trade.



**Performance Standards**

| Sec        | HR 2749  | Sec        | S 510   |
|------------|--|------------|---|
| <b>103</b> | <p><b>Section 103. Performance Standards.</b></p> <p>Section 103 requires the Secretary to, not less frequently than every 2 years, identify the most significant foodborne contaminants and the most significant resulting hazards. The Secretary shall issue science-based performance standards to minimize to an acceptable level, prevent, or eliminate the occurrence of such hazards.</p> <p>Section 103 also requires the Secretary to publish in the Federal Register a list of foodborne contaminants that have the greatest adverse impact on public health. In determining whether a particular foodborne contaminant should be added to such list, the Secretary is required to consider the number and severity of illnesses and the number of deaths associated with the foods associated with such contaminants.</p> | <b>104</b> | <p><b>Section 104. Performance Standards –</b></p> <p>Requires FDA, not less than every 2 years, to determine the most significant food-borne contaminants and, when appropriate to reduce the risk of serious illness or death, prevent adulteration, or prevent the spread of communicable disease, to issue science-based guidance documents, action levels, and/or regulations to prevent adulteration.</p> <p>Performance standards cannot be facility-specific.</p> |

**3.2.4 Fresh Produce and Other Raw Agricultural Commodities**

Currently, the fresh produce sector is covered by FDA guidance, not regulations. The FDA guidance document which focuses on microbial hazards (i.e. is not HACCP-based) is under revision. In July 2009, FDA issued new guidance documents for leafy greens, tomatoes and melons. USDA AMS offers a GAP certification program based on the generic FDA guidance. California and Arizona have leafy greens marketing agreements covering GAPS and packing practices. These are recognized by CFIA. They also are not HACCP-based. In September 2009, USDA AMS announced a round of consultations in October on a national leafy greens marketing agreement based on the structure of California agreement and focusing primarily on microbial controls. The detailed requirements and audit metrics of the proposed national agreement would only be developed after the agreement is established and some regional variations could be permitted.

The treatment of the fresh produce measure in the two bills is compared in the following table.

The House bill would put into place mandatory scientific and risk based standards for the fresh produce sector (growing, harvesting, processing, packing, sorting, transporting & holding) and these would have to be put in place within 3 years. Biological, chemical and physical hazards are covered. The results would be similar to a HACCP-based approach as utilized in the Canadian and many other food safety schemes for fresh produce production and handling. The FDA is to issue science-based standards with some flexibility for local conditions in US states or in other countries. The scope is limited to fruit,



vegetables, nuts and fungi but may be extended (e.g. could cover lentils, peas, etc).<sup>31</sup> Enforcement will occur through audit/certification or inspection. The bill provides some flexibility for small farms.

The Senate bill would put in place mandatory scientific and risk based standards for the fresh produce sector (growing, harvesting, processing, packing, sorting, transporting & holding).

### Problems and Consequences

The existing voluntary US requirements (e.g. FDA guidance documents and California Leafy Greens GAPs) have been criticized in the AMS hearings<sup>32</sup> as being too onerous for small farmers, contrary to organic practices and resulting in the dismantling of a number of environmental best management practices and new requirements that run counter to wildlife diversity goals. The costs of implementation have also been described as burdensome<sup>33</sup>.

Testimony at the National Leafy Greens Marketing Agreement hearings by AMS officials indicates that USDA proposes to undertake inspections on farms and in handling facilities using its own staff.<sup>34</sup>

The measure (both bills) could stimulate the uptake of the CHC's CanadaGAP and CPMA's Repack/Wholesale Food Safety programs. These programs may require revision to meet the new FDA requirements. Changes may also be necessary to the CFIA recognition programs for the national OFFS and PFFS programs if these are used as an integral part of the establishment of equivalence.

### **Both bills would increase the cost to export.**

**While the House bill is focused on fresh produce, the definition of other raw agricultural commodity permits the FDA to cover other areas, such as lentils and peas, if such standards are necessary to minimize the risk to human or animal health.**

Discussion with the grain, oilseed and pulse sector clarified that the House bill does not name pulse crops as being potential candidates for inclusion in the fresh produce and other raw agricultural commodity provision. The analysis only raises the potential for inclusion. **Future proposals** to include these commodities would draw considerable comment from the domestic industry. If implemented, such a requirement would drive demand for the Canada Grains Council's on-farm food safety program and for the Canadian Grain Commission's HACCP certification program for facilities which would create an additional cost burden for producers and companies.

Both domestic and foreign facilities are treated equivalently.

<sup>31</sup> The measures allows for the possibility of adding other raw agricultural commodities at a later date. Presumably this would only occur if a problem with a specific commodity occurred. Pulse crops are not named as being potential additions.

<sup>32</sup> [www.ams.usda.gov/AMSV1.0/ams.fetchTemplateData.do?template=TemplateA&navID=Proposed-](http://www.ams.usda.gov/AMSV1.0/ams.fetchTemplateData.do?template=TemplateA&navID=Proposed-LeafyGreensMarketingAgreement&rightNav1=Proposed-LeafyGreensMarketingAgreement&topNav=&leftNav=&page=LeafyGreensProposal&resultType=&acct=fvmktord)

[LeafyGreensMarketingAgreement&rightNav1=Proposed-](http://www.ams.usda.gov/AMSV1.0/ams.fetchTemplateData.do?template=TemplateA&navID=Proposed-LeafyGreensMarketingAgreement&rightNav1=Proposed-LeafyGreensMarketingAgreement&topNav=&leftNav=&page=LeafyGreensProposal&resultType=&acct=fvmktord)

[LeafyGreensMarketingAgreement&topNav=&leftNav=&page=LeafyGreensProposal&resultType=&acct=fvmktord](http://www.ams.usda.gov/AMSV1.0/ams.fetchTemplateData.do?template=TemplateA&navID=Proposed-LeafyGreensMarketingAgreement&rightNav1=Proposed-LeafyGreensMarketingAgreement&topNav=&leftNav=&page=LeafyGreensProposal&resultType=&acct=fvmktord)

<sup>33</sup> Hardesty, Shermain D. and Kusunose, Yoko *Growers' Compliance Costs for the Leafy Greens Marketing Agreement and Other Food Safety Programs*, September 2009

<sup>34</sup> [www.ams.usda.gov/AMSV1.0/getfile?dDocName=STELPRDC5080328](http://www.ams.usda.gov/AMSV1.0/getfile?dDocName=STELPRDC5080328)

Industry has requested clarification on this measure.

Alternatives

Canada should seek recognition in the legislation for national HACCP-based industry programs recognized by the competent authorities in exporting countries (e.g. CHC’s CanadaGAP and CPMA’s Repack/Wholesale Food Safety Program) as equivalent to the “science based standards”. With respect to audit/inspection, Canada should seek recognition in the legislation of different options, including direct government inspection, audit by third parties accredited by competent authorities in exporting countries, etc.

**Fresh Produce and Other Raw Agricultural Commodities**

| Sec        | HR 2749  | Sec        | S 510  |
|------------|--|------------|--|
| <b>104</b> | <p><b>Section 104. Safety Standards for Fresh Produce and Certain Other Raw Agricultural Commodities.</b><br/>(Definition of “other raw agricultural commodity” - “any food in its raw or natural state ...”)</p> <p>Section 104 requires the Secretary, in coordination with the Secretary of Agriculture, to establish by regulation science-based standards for the safe growing, harvesting, packing, sorting, transporting, and holding of raw agricultural commodities for which the Secretary has determined that such standards minimize the risk of serious adverse health consequences or death to humans or animals. The Secretary shall provide a reasonable period of time for compliance, taking into account the needs of small business for additional time to comply.</p> <p>Section 104 requires the Secretary, in issuing the regulations under this section, to take into consideration, consistent with ensuring enforceable public health protection, the impact of any regulations issued under this section on small-scale and diversified farms, and on wildlife habitat, conservation practices, water-shed protection efforts, and organic production methods. The Secretary is permitted to provide for coordination with other entities and provide for recognition through guidance of other existing publicly available procedures, processes, and practices that the Secretary determines to be equivalent to the goals established under this section.</p> <p>Section 104 requires the Secretary to update the guidance document entitled “Guidance for Industry: Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables.”</p> | <b>105</b> | <p><b>Section 105. Standards for Produce Safety –</b></p> <p>Gives FDA the authority to set commodity specific standards for the safety of fresh produce. States may apply for variances from the standards due to local growing conditions.</p> |



### 3.2.5 Risk Based Inspection

Both proposals have measures that would require FDA to establish inspection schedules for all facilities (domestic or foreign) based on risk. Based on the current facility registrations (see 3.2.1) FDA has responsibility to inspect about 156,000 US facilities. Recent estimates<sup>35</sup> suggest that FDA visits only 7,000 establishments per year with most of these inspections targeted at “high risk” facilities. As a result most others would see an inspector, not more than once every 10 years (on average) and perhaps never.

As noted above, there are about 226,000 foreign facilities currently registered, of which 14,700 are in Canada. Most of these Canadian facilities are not currently inspected by CFIA or by provincial inspectors. Some, but not all, will have food safety (e.g. HACCP or HACCP-based) plans in place and some will have food defense plans in place. Many will be subject to supplier audits either directly by their customers (e.g. retailers or manufacturers) or indirectly through third party auditors.

The measures are compared in the following table.

Under the House bill, high risk facilities would be (randomly) inspected at least every 6 to 12 months. Low risk facilities would be inspected (randomly) every 18 months to three years while facilities that hold food would be inspected (randomly) at least every five years. The Secretary must issue a notice regarding the ranking of facilities in terms of risk and solicit input prior to implementing this measure. Foreign facilities would be inspected by “an agency or representative of a country”.

Under the Senate bill, high risk facilities would be inspected annually. Other facilities would be inspected at least every four years.

#### Problems and Consequences

Both bills require the inspection of Canadian facilities exporting to the US. Frequency would be determined by risk, which will be defined at a later date.

Inspections would likely follow a two stage process, the first stage of which might be conducted remotely or both stages could take place on site. Stage one would involve a review of the written food safety and food defense plans. Stage two would be an on-site inspection of the facility to determine if the written plan had been effectively implemented. Depending on the nature of the facility, the inspections could take from a minimum of 1 day to several or more days. The proposed inspections would be random, but likely with prior, but perhaps limited, notice. The costs to facilities outside of the US would depend on the approaches taken in implementing this measure. Inspections might be carried out by FDA inspectors or by third party inspectors or by Canadian government inspectors. If plants are already being inspected by CFIA, it is likely that there would be no or limited incremental costs. For

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<sup>35</sup> Becker, Geoffrey S. , Food Safety: Selected Issues and Bills in the 111<sup>th</sup> Congress (Congressional Research Service, 14 August 2009) p. 14

those not currently inspected, the costs could include time spent (USDA AMS currently uses a \$92US/hour charge for its GAP audits) and travel costs.

There are implications for the Canadian government in terms of inspection of 14,000 plus facilities (non-registered establishments) not currently subject to regular inspections.

**If accredited third parties are involved then** these services are currently in short supply in Canada (and in the United States) and will be subject to an initial spike in demand as firms move to meet the requirements by the implementation deadlines.

The **food processors** raised liability as an important aspect of risk-based inspection. More information is required about which manufacturing and processing facilities would be deemed high-risk. Canada’s capacity to undertake equivalent inspections/audits on all exporting facilities was also raised.

Both domestic and foreign facilities are treated equivalently.

Industry has requested clarification as to the definitions of the Risk Categories (1 and 2).

Alternatives

Canada supports a risk-based inspection in principle, but will want to be sure that any frequencies eventually mandated by U.S. legislation or regulation can be scientifically justified as an effective and efficient way to manage risk. It is essential that finite resources for food safety be expended for maximum possible benefit. In keeping with this, Canada should propose that the legislation stop short of mandating the frequency of inspections, and instead require regulators to develop and implement a risk-based schedule based on sound science. Canada should offer to work closely with the U.S. on the development of a science-based system and emphasize that giving the Secretary flexibility in this area will help ensure maximum value for resources expended. [Note: This measure is closely linked to 3.2.7 – Accreditation & Certification and to 3.2.8 Import Regime.]

**Risk Based Inspection**

| <i>Sec</i> | <i>HR 2749</i>  | <i>Sec</i> | <i>S 510</i>  |
|------------|---|------------|---|
| <b>105</b> | <p><b>Section 105. Risk-based Inspection Schedule.</b></p> <p>Section 105 requires that each facility registered under section 415 be inspected by the Secretary, by a federal, state, or local official in the case of a domestic facility, or by an agency or representative of a country in the case of a foreign facility, according to a risk-based schedule. The risk-based schedule shall be implemented not later than 18 months after enactment and shall provide for a frequency of inspections commensurate with the risk presented by the facility and shall be based on the following categories and inspection frequencies:</p> <ul style="list-style-type: none"> <li>• Category 1 (high-risk) -- the Secretary shall</li> </ul> | <b>201</b> | <p><b>Sec. 201. Targeting Inspection Resources</b></p> <p>Requires FDA to allocate food inspection resources according to the risk profile of the facility and other important criteria.</p> <p>Requires FDA to increase the frequency of inspections at all facilities, with high-risk facilities inspected annually and other facilities inspected at least once every four years.</p> <p>Requires FDA to submit an annual report to Congress regarding the frequency of, and costs associated with, inspections.</p> |



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|  | <p>randomly inspect a category 1 food facility at least every 6 to 12 months.</p> <ul style="list-style-type: none"> <li>• Category 2 (low-risk) -- the Secretary shall randomly inspect a category 2 facility at least every 18 months to 3 years.</li> <li>• Category 3 (facility that holds food) -- the Secretary shall randomly inspect a category 3 facility at least every 5 years.</li> </ul> <p>Prior to implementing this schedule, the Secretary must issue a notice in the Federal Register detailing the basis for ranking facilities and provide for a 60 day comment period and a public meeting to obtain input. The Secretary must undergo a similar process when the Secretary proposes to change its process for assessing high risk facilities.</p> <p>Section 105 requires the Secretary to provide an annual report to Congress on the number of facilities inspected and the costs of implementing the risk-based inspection schedule for the preceding 12 months. In the third year after enactment, the Secretary is also required to submit to Congress a report describing recommendations on the risk-based inspection schedule, including recommendations for adjustments to the timing of the schedule. In making recommendations to change the inspection schedule, the Secretary shall consider the nature of the food products being processed, stored, or transported; the manner in which food products are processed, stored, or transported; the inherent likelihood that the products will contribute to the risk of foodborne illness; the best available evidence concerning reported illnesses associated with the foods processed, stored, held, or transported in the category of facilities; and the overall record of compliance with food safety law among facilities in the category, including compliance with applicable performance standards and the frequency of recalls.</p> <p>Six months after submitting the Third-Year Report, the Secretary may implement the adjustments to the inspection schedule recommended in the Third Year Report with respect to Category 2 and Category 3 facilities only. The new inspection schedule and a justification for the changes must be published in the Federal Register.</p> |  |  |
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### 3.2.6 Traceability

The treatment of the traceability measure in the two bills is compared in the following table.



Current FDA regulations require persons who manufacture, process, pack, transport, distribute, receive, hold, or import food to establish and maintain records identifying the immediate previous source of all food received, as well as the immediate subsequent recipient of all food released. **This is a one-step forward/one-step back system.** The regulations also set out the information that must be established and maintained, how long it must be maintained, and how quickly it must be available to FDA when FDA has a reasonable belief that an article of food is adulterated and presents a threat of serious adverse health consequences or death to humans or animals. The regulations exclude farms and restaurants from some or all of the requirements.

In Canada, CFIA has published recall guidance documents for various segments of the supply chain (manufacturers, distributors, retailers, importers, etc). These set out best practices for tracing. These guidelines are currently being revised. In 2003-2004, the food supply chain and governments collaborated on the development of the Canadian Food Traceability Data Standard (CFTDS) or Can-Trace standard. It was published in December 2004 and revised in August 2006. Now administered by GS1 Canada, the standard sets out the data requirements for a one-step forward, one-step back traceability system. The Can-Trace standard has had a major influence on international standards development including ISO 22005:2007, the GS1 implementation guide for traceability of fresh fruits and vegetables and the North American Produce Traceability Initiative.

The House bill would require the development of a mandatory tracing system for domestic and imported food that identifies each person who grows, produces, manufacturers, processes, packs, transports, holds or sells such food in as short a timeframe as practicable, but in no longer than 2 business days. The regulations would be preceded by analysis of the technology and methodologies; analysis of the costs and benefits; feasibility of the technology; public input; and pilot projects. Farms only selling directly to consumers, a restaurant, or a grocery store are exempt. Otherwise, farms will have to record and retain for 6 months records of all sales. Restaurants and food retailers must document the farms sourced from. Food from a fishing vessel is exempt until it is sold by the vessel. For the grain<sup>36</sup> sector, the tracing system begins at the first elevator/warehouse. The Secretary may exempt food if full traceability is not necessary to protect public health and in this case must have in place one-forward one-back tracing.

The House bill also permits the FDA in consultation with USDA to establish regulations concerning common nomenclature for food. Various nomenclature schemes already exist and work is underway in some sectors (e.g. produce) to develop an international nomenclature. Development of a national scheme by the US would create new burdens on exporters.

The Senate bill would require the development of a tracking and tracing system for fruits and vegetables. A pilot project would be completed. Small business needs would be taken into account.

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<sup>36</sup> “Grains or similarly handled commodity’ means wheat, corn, grain sorghum, barley, oats, rice, wild rice, rye, soybeans, legumes, sugar cane, sugar beets, sunflower seed, rapeseed, canola, safflower, flaxseed, mustard seed, cambe, sesame seed, camelina, cottonseed, cocoa beans, grass hay, and honey. The term may include any other commodity as determined by the Secretary in coordination with the Secretary of Agriculture.”

### Problems and Consequences

The traceability measure has considerable momentum outside of Congress and the development of the final systems will take into account industry views. It is likely that industry developed programs would become the norm. **While the House bill covers all food, the Senate bill only covers fruits and vegetables.**

In the produce sector, the Produce Marketing Association and United Fresh Produce Association argue that traceability must be industry driven. It has a Produce Traceability Initiative underway with the active support of the Canadian Produce Marketing Association and the endorsement of the Food Marketing Institute and many of its retail members<sup>37</sup>. This initiative is one-step forward, one-step back to the case level at the backdoor of the retail or foodservice facility.

FMI in collaboration with GS1, the Grocery Manufacturers Association and the National Grocers Association have launched (September 2009) a new Rapid Recall Exchange<sup>38</sup> to enhance the effectiveness of voluntary recalls. A similar initiative has also been announced in Canada (November 2009) by GS1 Canada, CCGD, CFGI, FCPC and the Retail Council of Canada (RCC).

In the grains sector where inputs are sourced from many suppliers and where co-mingling is a standard procedure, the NGFA believes that the House measure is “**onerous and unachievable**”.<sup>39</sup>

**The House bill’s full traceability requirement goes beyond the current one-step forward, one-step back system and may be infeasible/problematic.** It would require a facility “to maintain the *full pedigree* of the origin and previous history of the product ...[and] link that history with the subsequent distribution of the product”.<sup>40</sup> The House bill does have provisions to reduce traceability to one-step forward and one-step back if full traceability is not required for the protection of the public.

The House’s requirement for a unique identifier could be problematic unless it is based on international standards (e.g. GS1).

Canada’s traceability initiative is currently focused on livestock/meat. Extending this initiative to all commodities would greatly increase the scope, the cost and the effort required.

If US industry programs are selected, then Canadian exporters will have to **harmonize existing programs with the US programs.**

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<sup>37</sup> [www.producetraceability.org](http://www.producetraceability.org)

<sup>38</sup> [www.rapidrecallexchange.org](http://www.rapidrecallexchange.org)

<sup>39</sup> NGFA, “Food and Feed Safety”.

<sup>40</sup> Pape and Ross of TraceGains suggest that most companies can not meet the current one-up, one-down requirements as required by the BioTerrorism Record Keeping Act of 2002. Full pedigree traceability which increases visibility along the supply chain could result in disintermediation in the supply chain and this would limit support for full traceability. These experts also suggest that the House bill is much more explicit about what is required compared to BioTerrorism Record Keeping Act which is relatively ambiguous. (<http://www.qualitydigest.com/inside/fda-compliance-article/food-safety-policies-add-confusion.html>)



Traceability for the grain sector begins at the first elevator. However, farms are expected to keep records of where they sold their products. HACCP has product recall plans which would allow companies to trace one step forward and one step back. Some companies may not be able to trace one-step forward and one-back.

Concerns were raised by the food processors about the implementation timeframe for HACCP and traceability – too short.

Concerns were raised by the produce sector about the implementation of traceability beyond the case level (i.e. item level traceability within the chain is impractical) and about the importance of using international standards.

The importer/exporter group viewed the traceability measures as very problematic and unlikely to enhance food safety. It is not possible to execute full pedigree traceability. Canadian industry has been very successful at implementing one-step forward and one-step back traceability and should work with US counterparts to develop the US one forward and one back system.

**Some Canadian sectors have implemented or are implementing traceability initiatives because of market needs so legislation requiring traceability, depending on what type was required, would not increase costs or thicken the border for these sectors. For other sectors, however, the traceability measure will increase the cost associated with exporting (and the cost of doing business for US domestic firms). The border will thicken for these companies.**

Both domestic and foreign facilities are treated equivalently.

Industry requests clarification of the role of international standards in the proposed US requirements for traceability and nomenclature.

Alternatives

**Canada should seek to limit the new requirements to** one –forward one-back and to encourage the US to drop the traceability requirements completely in the event that analysis indicates low-risk and significant implementation problems. In the produce sector, traceability should be at the case level not at the item level.

Canada should seek a legislative commitment to use international standards (e.g. GS1) in traceability and collaboration by the US in developing international standards vis-à-vis nomenclature of foods.

Note: Government and industry should review the questions on traceability systems published in the Federal Register by FDA and USDA on November 3, 2009.

**Traceability**

| Sec | HR 2749                            | Sec | S 510  |
|-----|------------------------------------|-----|--|
| 107 | Section 107. Traceability of Food. | 204 | Section 204. Enhancing Traceback and Recordkeeping – |



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| <p>Section 107 requires the Secretary to establish, by regulation, a tracing system for food that is located in the United States or is for import into the United States.</p> <p>Before issuing a proposed regulation, the Secretary shall conduct information gathering to (1) identify technologies and methodologies for tracing to enable each person who produces, manufactures, processes, packs, transports, or holds a food to maintain the full pedigree of the origin and previous distribution history of the food, link that history with the subsequent distribution of the food, establish and maintain a system for tracing the food that is interoperable with the systems established and maintained by other such persons, and to use a unique identifier; and (2) to the extent practicable, assess the costs and benefits associated with the adoption of such technologies, the feasibility of such technologies for different sectors for the food industry, and whether such technologies are compatible with the requirements of this subsection.</p> <p>Section 107 requires the Secretary to take into account information obtained through this information gathering process, and to conduct at least 2 public meetings and one or more pilot projects. The Secretary shall consult with the Secretary of Agriculture in conducting pilot projects with respect to farms.</p> <p>After completing this public input process, the Secretary shall issue regulations establishing a tracing system that enables the Secretary to identify each person who grows, produces, manufacturers, processes, packs, transports, holds or sells such food in as short a timeframe as practicable, but in no longer than 2 business days.</p> <p>The Secretary may include in such regulation: the establishment and maintenance of lot numbers; a standardized format for pedigree information; and the use of a common nomenclature for food. In issuing such regulation that will impact farms, the Secretary must coordinate with the Secretary of Agriculture and take into account the impact of the regulations on farms.</p> <p>Food produced on a farm and sold directly to a consumer, restaurant, or grocery store is exempt from the tracing system requirements, although restaurants and grocery stores must keep records documenting the farm that was the source of the food. If food is produced through the use of a</p> | <p>Requires FDA, in coordination with the produce industry, to establish a pilot project to test and evaluate new methods for rapidly and effectively tracking and tracing fruits and vegetables.</p> <p>Ensures methods are appropriate for small businesses.</p> <p>Requires FDA, after completion of the pilot project, to establish standards for the types of information, information format, and timeframes for submission of food records to aid the Secretary in rapidly performing trace back activities in the event of a food-borne illness outbreak.</p> |
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|  | <p>fishing vessel, the food is exempt from the requirements of this section until the food is sold by the fishing vessel. Any tracing system with respect to grains must be limited to enabling the Secretary to identify persons who handled the grains from the initial warehouse that held the grain to the ultimate consumer. The Secretary is also granted authority to exempt a food from the tracing system requirements if the Secretary determines application of these requirements is not necessary to protect the public health. For a food so exempted, each person who produces, manufactures, processes, packs, transports, or holds such food is required to maintain records to identify the immediate previous sources of such food and its ingredients and the immediate subsequent recipients of such food.</p> |  |  |
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### 3.2.7 Certification & Accreditation

Certification is an accepted practice in international trade and Codex has developed guidelines governing it.

*Certification is the procedure by which official certification bodies and officially recognized bodies provide written or equivalent assurance that foods or food control systems conform to requirements. Certification of food may be, as appropriate, based on a range of inspection activities which may include continuous on-line inspection, auditing of quality assurance systems, and examination of finished products.<sup>41</sup>*

The treatment of the certification and accreditation measure in the two bills is compared in the following table.

The House bill provides authority for certification for some imported foods. Certification would be required for a particular country or region if it would assist in determining admittance; for a certain food type that could pose a significant risk; or for imports from a country where there is a certification agreement in place. A qualified certifying entity would be required and could be an agency or government representative, an individual, or entity recognized by the Secretary or a Secretary recognized accreditation body. Regulations are to be issued to prevent conflicts of interest problems.

The Senate bill provides authority for certification for high risk imports. If an import does not have the required certification, it may be refused entry.

<sup>41</sup> Codex Alimentarius Commission, Guidelines for the Design, Operation, Assessment and Accreditation of Food Import and Export Inspection and Certification Systems CAC/GL 26-1997



Problems and Consequences

**There is uncertainty in both bills about what products would require certification and whether or not Canada would be a targeted country.** If we assume that the Canadian system is recognized by the Secretary as being equivalent and that high risk facilities are subject to the levels of inspection, etc required by the Act, then it is unlikely that high risk Canadian exports would be subject to certification.

This measure applies only to imported products and foreign facilities.

Industry requests clarification concerning which imported products would be categorized as “high risk” and might, therefore, require certification.

Alternatives

**Canada should seek to ensure that products of national food safety systems recognized as equivalent to the new US requirements will not require certification.** [Note: This measure is closely related to 3.2.5 – Risk Based Inspection and 3.2.10 – Import Regime.]

**Certification & Accreditation**

| Sec | HR 2749  | Sec     | S 510  |
|-----|--|---------|--|
| 109 | <p><b>Section 109. Certification and Accreditation.</b></p> <p>Section 109 establishes that certain imported foods be accompanied by a certification that the food complies with specified requirements of the Federal Food, Drug, and Cosmetic Act. The Secretary shall require certification for food imported from a particular country or region if certification would assist the Secretary in determining whether to refuse to admit such article; for a type of food that could pose a significant risk to health, certification would assist the Secretary in determining whether such article poses such risk; or for an article imported from a particular country, there is an agreement between the Secretary and the government of such country providing for such certification. Certifications under this section must be provided by a “qualified certifying entity.” A qualified certifying entity may be an agency or a representative of the government of the country from which the article originated, an individual or entity determined by the Secretary, or an accredited body recognized by the Secretary. The Secretary is required to issue regulations to ensure that any qualified certifying entity and its auditors are free from conflicts of interest.</p> | 303/308 | <p><b>Sec 303. Authority to Require Import Certifications for Food –</b></p> <p>Allows FDA to require certification or other assurance of safety for high-risk food imports. FDA may refuse admission of a food import lacking required certification.</p> |



### 3.2.8 Import Regime

FDA is currently empowered to refuse entry to any food import that “appears” to be adulterated, misbranded or otherwise in violation of the law. It requires importers to provide prior notification for each shipment and has established an electronic database (OASIS) which inspectors use to identify risk and select shipments for inspection. However, FDA has only 450 inspectors for over 300 ports of entry and in practice inspects approximately 1% of imported food shipments.

The following table describes the import measures in the bills.

The House bill would establish a **Safe and Secure Food Importation Program** which facilitates importation if *all facilities in the supply chain* comply with guidelines developed by the Secretary in consultation with Customs and Border Protection and taking into account other relevant federal programs.

The Senate bill would establish a **Foreign Supplier Verification Program** that requires importers to verify supplier activities (e.g. food safety plan, food defense plan, traceability, etc). It would be illegal to import food without having such a program in place. The Senate bill allows for expedited entry under the **Voluntary Qualified Import Program** if the product’s supply chain activities exceed minimum standards.

#### Problems and Consequences

These measures either create an opportunity for US importers to more quickly move products across the border (House bill) by verifying that their suppliers meet the new requirements or mandates a new requirement (Senate bill) obliging importers undertake this verification. In the House scenario, importers will respond using market pressure to ensure verification. In the Senate scenario, they will have no choice but to verify. In either case, the burden will be shifted to the exporting facility to demonstrate that they are in full compliance and the options for this could involve either government inspection or third party audits.

Importers may also be subject to pressure from their customers (e.g. retailers, food service distributors, manufacturers, etc) to impose requirements over and above the legislated requirements or to ensure that verification is more frequent than the mandated inspection frequencies. This could pressure exporting facilities into implementing either private standards schemes, such as those benchmarked by the Global Food Safety Initiative, or requirement proprietary to the customer.

The House bill also requires commercial importers of food to register, pay a \$500 fee, and comply with good importing practices. Conditions for suspension are provided. Customs brokers are also required to register. Each facility, importer and broker is required to have a unique identification number and this could create problems unless it is based on international standards (GS1).

The House bill also makes it illegal to submit inaccurate or incomplete information or to not submit information regarding imported food.



The Senate bill would give FDA additional authority to review food safety systems of importing countries to ensure overseas regulators are controlling risks. **It would provide FDA the authority to enter into equivalency agreements. This would be positive for Canadian exporters.**

Food processors identified the **Foreign Supplier Verification Program** as being a very problematic measure. The measure would push responsibility on the US buyer which would pass on the cost to suppliers. Some call participants suggested that this is very discriminatory measure – a “buy American” program. Other participants suggested that under the Senate bill, facilities have to meet certain requirements and that this is just echoing this.

The importer/exporter group noted that while it would be helpful to negotiate equivalency with the US, care must be taken when defining equivalency.

Alternatives

**Canada should ensure that FDA has the authority to enter into equivalency agreements as is proposed in S 510.**

**Canada should seek a legislative option that would permit the competent authorities in exporting countries to establish equivalence of accreditation of third parties that would allow Canada to recognize existing food safety certification schemes (e.g. on-farm, post-farm, provincial government, international standards, etc).** [Note: This measure is closely related to 3.2.5 – Risk Based Inspection and 3.2.7 – Certification and Accreditation.]

**Import Regime**

| Sec | HR 2749  | Sec                 | S 510  |
|-----|--|---------------------|--|
| 113 | <p><b>Section 113. Safe and Secure Food Importation Program.</b></p> <p>Section 113 permits the Secretary to establish by regulation or guidance, in coordination with CBP, a program to facilitate the movement of food through the importation process if the importer of such food verifies that each facility involved in the production, manufacture, processing, packaging, and holding of the food has been determined to be in compliance with food safety and security guidelines developed by the Secretary, in consultation with CBP. The Secretary is required to take into account other relevant federal programs in developing food safety and security guidelines.</p> | 301, 302, 303, 304, | <p><b>Section 301. Foreign Supplier Verification Program</b></p> <p>Requires importers to perform food safety supplier verification activities to mitigate risks in imported foods. Importation of a food by an importer who does not have such a program in place is a prohibited act.</p> <p>Importers required to comply with existing seafood, juice, and low-acid canned foods regulations are deemed to be in compliance with this section</p> <p><b>Section 302. Voluntary Qualified Importer Program</b></p> <p>Allows importers to qualify for expedited review and importation of food if they go above and beyond the minimum standards to ensure the safety of imported food.</p> <p><b>Section 304. Prior Notice of Imported Food Shipments –</b></p> |



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|     |  |  | Requires prior notice for an imported food to include the name of any country that refused entry of the food. |
| 204 | <p><b>Section 204. Registration for Commercial Importers of Food; Fee.</b></p> <p>Section 204 requires all importers of foods to register with FDA annually and to pay a registration fee in the amount of \$500. An importer that is also a registered facility under Section 101 is subject to only one fee. Each registered importer must comply with good importer practices, which the Secretary, in consultation with CBP, must establish through regulation. The good importer practices will specify the measures an importer shall take to ensure imported food is in compliance with the requirements of the Act.</p> <p>The Secretary may suspend an importer’s registration, after notice and opportunity for an informal hearing, if the importer is found in violation of the Federal Food, Drug, and Cosmetic Act, or found to have knowingly or repeatedly made inaccurate or incomplete statements or submissions of information related to the importation of food. The Secretary may cancel an importer’s registration if, after notice, the Secretary determines that the registration was not updated correctly or otherwise contains false, incomplete, or inaccurate information. If the importer’s registration is updated or corrected no later than 7 days after notice is provided, the Secretary shall not cancel the importer’s registration.</p> <p>Section 204 requires the Secretary, in consultation with CBP, to promulgate regulations, within 36 months, required to carry out the requirements of Section 204. In establishing the effective date of the regulation, the Secretary shall consult with CBP, as appropriate, to provide a reasonable period of time for importers of food to comply with good importer practices.</p> |  |   |
| 205 | <p><b>Section 205. Registration for Customs Brokers.</b></p> <p>Section 205 requires all customs brokers with respect to the importation of food to register with the FDA in a form and manner specified by the Secretary and to submit appropriate unique facility</p>  |  |   |



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|-----|--|--|--|
|     | <p>identifiers as a condition of registration. The Secretary may cancel an importer’s registration, after notice to the customs broker and CBP, if the customs broker’s registration is not updated or otherwise contains false, incomplete, or inaccurate information. If the registration is updated or corrected no later than seven days after notice, the Secretary shall not cancel the registration. Section 205 requires the Secretary, in consultation with CBP, to exempt importations for personal use.</p> <p>Section 205 requires every customs broker required to be registered with the Secretary to, upon request of an officer or employee designated by the Secretary, permit such officer or employee at all reasonable times to inspect their facilities and have access to, and to copy and verify, any related records.</p>  |  |  |
| 206 | <p><b>Section 206. Unique Identification Number for Food Facilities, Importers, and Custom Brokers.</b></p> <p>Section 206 requires that a person required to register a facility under section 415 or importers, and custom brokers required to register pursuant to section 801 submit, at the time of registration, a unique facility identifier. The Secretary is authorized, through guidance, to specify the unique numerical identifier system to be used to meet the requirements of Section 206. In developing such guidance, with respect to importers and customs brokers, the Secretary is required to consult with CBP and take into account the utilization of existing unique identification schemes and compatibility with customs automated systems. Section 206 requires the Secretary to refuse admission of an imported food into the U.S. for interstate commerce unless the unique facility identifiers are provided for such article.</p> |  |  |
| 136 | <p><b>Section 136. Improper import entry filings.</b></p> <p>Section 136 makes the submission of information relating to imported food that is inaccurate or incomplete, or the failure to submit information that is required to be submitted related to imported food a prohibited act. Section 136 allows the Secretary to require the submission of documentation or other information for articles of food that are imported or offered for import into the United States. To the extent that the collection of documentation or other information involves</p>   |  |  |



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|--|---|-----|--|
|  | Customs and Border Protection (CBP) efforts or resources, Section 136 requires the Secretary to consult with CBP. |     |  |
|  |   | 305 | <p><b>Section 305. Review of a Regulatory Authority of a Foreign Country</b></p> <p>Gives FDA additional authority to review food safety systems of importing countries to ensure overseas regulators are controlling risks.</p> |

### 3.2.9 Notification & Recall, etc

The treatment of the notification and recall measure in the two bills is compared in the following table.

The House bill requires facilities, importers, brokers and filers to notify the Secretary if they believe food is adulterated or misbranded such that its use could harm human or animal health. The Secretary may request a voluntary recall and under certain conditions order a cease distribution order. After an informal hearing, the Secretary may order a recall. An emergency recall can be ordered for a good subject to a cease distribution order if there are imminent health consequences or death resulting from consumption.

The Senate bill would allow FDA to order mandatory product recalls if the company does not voluntarily recall the product if it could cause serious health consequences to animals or humans.

#### Problems and Consequences

These provisions mirror Canadian requirements. Exporting facilities would be required to notify FDA and their importing agents.

Both domestic and foreign facilities are treated equivalently.

#### Alternatives

**It is suggested that Canada seek amendments requiring US exporters to notify the competent authorities (e.g. CFIA in Canada) and importers in importing countries “if they believe exported food is adulterated or misbranded such that its use could harm human or animal health”.**

#### **Notification & Recall Etc**

| <i>Sec</i> | <i>HR 2749</i>  | <i>Sec</i> | <i>S 510</i>  |
|------------|---|------------|---|
| 111        | <p><b>Section 111. Notification, Nondistribution, and Recall of Adulterated or Misbranded Food.</b></p> <p>Section 111 requires food facilities, importers, customs brokers, and filers that have reason to believe that an article of food is adulterated or</p> | 206        | <p><b>Section 206. Mandatory Recall Authority –</b></p> <p>Gives FDA the authority to order food recalls when firms fail to voluntarily recall products on their own, when a food is adulterated or contains undeclared allergens and will cause serious adverse health</p> |



|   |   |
|---|---|
| <p>misbranded in a manner that presents a reasonable probability that the use or consumption of, or exposure to, the article will cause a threat of serious adverse health consequences or death to humans or animals to notify the Secretary of the identity and location of the article as soon as practicable.</p> <p>The Secretary may request that any person who distributes an article of food that the Secretary has reason to believe is adulterated, misbranded, or otherwise in violation of this Act voluntarily recall such article.</p> <p>The Secretary shall have the authority to issue an order requiring any person who distributes an article of food to immediately cease distribution of such article if the Secretary has reason to believe that the use or consumption of, or exposure to, the article of food may cause serious adverse health consequences or death to humans or animals. The person subject to the order may appeal the order and request an informal hearing. If after providing an opportunity for an informal hearing under subsection (d), the Secretary determines that the order should be amended to include a recall of the article with respect to which the order was issued, the Secretary shall amend the order to require a recall. Only the Secretary or an official designated by the Secretary may order the recall. An official may not be so designated unless the official is the director of the district under this Act in which the article involved is located, or is an official senior to such director.</p> <p>If the Secretary has credible evidence or information that an article of food subject to an order to cease distribution presents an imminent threat of serious health consequences or death to humans or animals, the Secretary may issue an emergency recall order requiring any person who distributes such article to immediately recall such article. An informal hearing shall be granted following the cease distribution and emergency recall. Section 111 requires that an emergency recall order come from the FDA Commissioner, Principal Deputy Commissioner or Associate Commissioner for Regulatory Affairs.</p> | <p>consequences or death to humans or animals. This authority shall only be delegated to the Commissioner of the FDA.</p> |
|---|---|



### 3.2.10 Reportable Food Registry

**The Reportable Food Registry is already in place.**

“On September 27, 2007, the President signed into law the Food and Drug Administration Amendments Act of 2007 (FDAAA). This law amends the Federal Food, Drug, and Cosmetic Act (FD&C Act) by creating a new section 417, Reportable Food Registry. Section 417 requires the Secretary of Health and Human Services (the Secretary) to establish within the Food and Drug Administration (FDA) a Reportable Food Registry. The congressionally-identified purpose of the Reportable Food Registry is to provide a "reliable mechanism to track patterns of adulteration in food [which] would support efforts by the Food and Drug Administration to target limited inspection resources to protect the public health" (Pub. L. 110-085, section 1005(a)(4)). The Secretary has delegated to the Commissioner of the Food and Drug Administration the responsibility for administering the FD&C Act, including section 417. To further the development of the Reportable Food Registry, section 417 of the FD&C Act requires FDA to establish an electronic portal by which instances of reportable food must be submitted to FDA by responsible parties and may be submitted by public health officials. After receipt of reports through the electronic portal, FDA is required to review and assess the information submitted for purposes of identifying reportable food, submitting entries to the Reportable Food Registry, issuing an alert or notification as FDA deems necessary, and exercising other existing food safety authorities under this Act to protect the public health.”<sup>42</sup>

The following table describes the measure in the House bill.

#### Problems and Consequences

**The House bill would add new reporting requirements. This increases the administrative burden.**

Both domestic and foreign facilities are treated equivalently.

#### Alternatives

**None. FDA has already established the food registry.**

#### **Reportable Food Registry**

| <i>Sec</i> | <i>HR 2749</i>  | <i>Sec</i> | <i>S 510</i> |
|------------|---|------------|--------------|
| 112        | <p><b>Section 112. Reportable Food Registry; Exchange of Information.</b></p> <p>Section 112 amends section 417 of the Federal Food, Drug, and Cosmetic Act to require an owner</p> |            |              |

<sup>42</sup> <http://thepacker.com/Soon-to-be-frequently-asked-questions---Reportable-food-registry/FreshTalkBlog.aspx?articleid=833930&authorid=117&feedid=264>



|  |  |  |  |
|--|--|--|--|
|  | <p>of a food facility, farm, or restaurant to submit a report to FDA following a timely review of any reasonably available data and information that indicates that there is a reasonable probability that use of, or exposure to, a particular article of food will cause serious adverse health consequences or death to humans or animals. Section 112 requires the report to also include analytical results from testing of such article and such additional information as the Secretary deems appropriate. Section 112 requires the Secretary to make available other means of reporting for restaurants and other retail food establishments that have limited ability to report via electronic means.</p> <p>Section 112 authorizes the Secretary to share certain confidential information relating to food with any federal agency, state, local, or foreign government, or any person. This information shall not be publicly disclosed.</p> |  |  |
|--|--|--|--|

### 3.2.11 COOL

Country of Origin Labeling is currently required of the following food products: fresh produce, red meats (beef, pork, lamb and goat), chicken, peanuts, macadamia nuts, pecans and ginseng.

The House provisions regarding Country of Origin Labeling are summarized in the following table.

Under the House bill, all processed food labels would be required identify the country in which the final processing occurred and all unprocessed foods must be labeled with the country of origin of the food. Processed foods complying with CBP labeling requirements and unprocessed foods complying with Farm Bill requirements are deemed to be in compliance. The House provisions follows the **principle of last substantial transformation** – so a product processed in the US is a product of the US and a product processed in Canada is a product of Canada.

The Country of Origin labeling requirements implemented under the last US Farm Bill are **fundamentally different then the provisions in the House bill**. Meat processed in the US from an animal that spent any time at all in Canada must be called either product of US and Canada or product of Canada and US (with the order on the label determined by how much time the animal spent in each country. The complexity of complying with the regulations is reducing the demand for Canadian livestock. The Canadian Government has requested a WTO panel regarding COOL as implemented under the Farm Bill because it “imposes unfair and unnecessary costs on integrated North American supply chains, reducing competitiveness in both Canada and the US. COOL has created confusion and uncertainty for livestock industries on both sides of the border.”<sup>43</sup>

<sup>43</sup> Government of Canada, “Canada Requests WTO Panel on US Mandatory Country-of-Origin Labelling”, October 7, 2009. SJT Solutions, Monachus Consulting & Sally Rutherford Consultants | November 13, 2009



Problems and Consequences

This measure would not be problematic for bulk grains and oilseeds moving into the US. The milling sector would have to identify the country of final processing (i.e. Canada). Representatives of the pulse sector expressed concerns related to potential implementation issues.

The produce sector indicated minimal concerns as country of origin labeling is already in place on both sides of the border.

The importer/exporter group views COOL as potentially very problematic.

Alternatives

**This measure is not related to food safety. Canada should seek to have the provisions deleted.**

**COOL**

| Sec        | HR 2749  | Sec | S 510 |
|------------|--|-----|-------|
| <b>202</b> | <p><b>Section 202. Country of Origin Labeling</b></p> <p>Section 202 requires that all processed food labels identify the country in which the final processing occurred. If the label of a processed food is already in compliance with country of origin requirements from the U.S. Customs and Border Protection, the food will be deemed in compliance with this section. All non-processed foods must be labeled with the country of origin of the food. If a non-processed food already lists the country of origin pursuant to farm bill requirements, the food will be deemed in compliance with this section.</p> <p>Section 202(b)(2)(A) requires the Secretary of Health and Human Services (HHS), acting through the Food and Drug Administration (FDA), to promulgate implementing regulations in accordance with Customs and Border Protection (CBP) laws and regulations with respect to country of origin marking to ensure that the country of origin of final processing for FDA purposes is consistent with the country of origin for CBP marking purposes.</p> |     |       |



### 3.2.12 Foreign Inspectorate

The foreign inspection measure of the two bills is compared in the following table.

Under the House bill, FDA would need to establish and maintain a group of inspectors to inspect foreign facilities.

Under the Senate bill, FDA could enter into agreements with foreign governments to facilitate inspection. It also directs the FDA to place staff in at least five countries.

#### Problems and Consequences

**Canadian exporters would be inspected by FDA.**

#### Alternatives

**Canada should ensure equivalency vis-à-vis the new US system for exports.**

#### Foreign Inspectorate

| <i>Sec</i> | <i>HR 2749</i>   | <i>Sec</i> | <i>S 510</i>  |
|------------|--|------------|---|
| 208        | <p><b>Section 208. Dedicated Foreign Inspectorate.</b></p> <p>Section 208 requires the Secretary to establish and maintain inspectors dedicated to inspections of foreign food facilities.</p> | 307, 309   | <p><b>Section 307. Inspection of Foreign Food Facilities –</b></p> <p>Allows FDA to enter into agreements and arrangements with foreign governments to facilitate the inspection of foreign facilities. Refuses entry of food from a foreign facility or country that fails to permit inspection by the United States.</p> <p><b>Section 309. Foreign Offices of the FDA –</b></p> <p>Directs FDA to establish offices in at least five foreign nations to improve the agency’s presence overseas and positively impact the safety of FDA-regulated products.</p> |

### 3.2.13 Extraterritoriality

The House measure regarding extraterritoriality is shown below.

#### Problems and Consequences

**It may have legal implications for national sovereignty.**

Industry requests clarification of the implications for Canadian exporters and suppliers.



Alternatives

None identified.

**Extraterritoriality**

| Sec | HR 2749  | Sec | S 510 |
|-----|--|-----|-------|
| 213 | <p><b>Section 213. Extraterritorial Jurisdiction.</b></p> <p>Section 213 establishes that there is extraterritorial federal jurisdiction over any violation of this Act relating to any article of food intended for import into the United States or if any act in furtherance of the violation was committed in the United States.</p> |     |       |

**3.2.14 Transportation Sanitation**

The Senate bill would require the FDA to regulate the sanitary transportation of food.

Problems and Consequences

As the measure is enabling, more information is required. **The measure has the potential to create problems for non-dedicated fleets.** It could create an advantage for the Canadian Trucking Alliance’s HACCP based program.

Discussion with food processors identified that while trucks are not required to register there may be some ramifications for them in terms of sanitary requirements.

Both domestic and foreign facilities are treated equivalently.

Alternatives

**This measure needs to be monitored during the Senate and conference discussions.**

**Transportation Sanitation**

| Sec | HR 2749 | Sec | S 510   |
|-----|---------|-----|---|
|     |         | 112 | <p><b>Section 112. Sanitary Transportation of Food –</b></p> <p>Requires FDA to promulgate regulations on the sanitary transportation of food</p> |



## 4. CONCLUSIONS

### 4.1 Potentially Challenging Measures

Congress is proposing a major reworking of the US food safety requirements that will have far reaching implications for both domestic food businesses and those that export to the United States. While, the proposals are currently limited to food under the jurisdiction of the Food and Drug Administration, officials in the Obama administration have clearly signaled that they would seek similar changes in the legislation pertaining to products covered by USDA or in the current regulations to ensure a national food safety system.<sup>44</sup>

Based on the analysis, **there are six measures that depending on how they are implemented have the potential to negatively affect Canadian exporters.** The consequences of these measures are summarized in the following table. Alternatives, if feasible, are also presented.

| <i>Measure</i>                           | <i>Current Practice &amp; Changes</i>  | <i>Consequences</i>  | <i>Alternatives</i>  |
|--|--|--|--|
| Hazard Analysis                          | <p>The US requires HACCP (Hazard Analysis and Critical Control Points) based systems for facilities processing seafood, juices, and low-acid foods.</p> <p>Within the FDA mandate, Canada requires HACCP only for fish and seafood facilities.</p> <p>Both bills would make HACCP mandatory for all domestic and foreign facilities.</p> | <p>Canadian export facilities must develop and implement HACCP and food defense plans to maintain market access. This has a bottom line impact and will not enhance relative competitiveness. There are no Canadian standards for HACCP trainers or auditors. Biennial or triennial revision of HACCP plans will be burdensome on exporters. Large companies appear to be more likely to have HACCP in place than small companies. It may be necessary to revise provincial government HACCP programs to meet FDA needs. Demand for implementation assistance will increase.</p> | <p>The triennial renewal requirement for HACCP plans in S 510 is the least burdensome option.</p> <p>Canada should seek recognition in the legislation of the HACCP-based concept (industry developed generic programs) as well as site-specific HACCP systems.</p> <p>Generic HACCP-based programs recognized by the competent authorities in exporting countries should only be required to be updated every 5 years</p> |
| Fresh Produce & Other Raw Ag Commodities | <p>Currently, the FDA has guidelines, not regulations, for the fresh produce sector.</p>   | <p>The measure (both bills) should stimulate the uptake of the CHC's CanadaGAP and CPMA's Repack/Wholesale Food Safety programs. It may require changes to CFIA</p>  | <p>Include foreign government recognized, HACCP-based, 3<sup>rd</sup> party</p>  |

<sup>44</sup> "While the meat and poultry acts have been amended many times, they do not allow us to address the significant risks facing our food supply as effectively and efficiently as possible. These laws should be modernized to allow for improved flexibility and coordination and to enable USDA to move quickly to address the emerging threats to the food supply. ....There are many valuable provisions in H.R. 2749 and we would like to see similar legislation for FSIS." Statement of Jerold R. Mandé, Deputy Under Secretary for Food Safety, USDA, House Agriculture Committee, 16 July 2009, (<http://agriculture.house.gov/testimony/111/h071609/Mande.pdf>)



|                               |   |   |  |
|-------------------------------|---|---|--|
|                               | Both bills would put in place mandatory scientific and risk based standards for the fresh produce sector (growing, harvesting, processing, packing, transporting & holding).  | recognition programs for the national OFFS and PFFS programs. Both bills would increase the cost to export. While the House bill is focused on fresh produce, the FDA is allowed to cover other areas such as lentils and peas. Difficulties in having these commodities put in place HACCP plans at the farm level could result in loss of market access.  | certified food safety schemes within the scope of the legislation.   |
| Risk Based Inspection         | <p>FDA currently inspects only a small proportion of the facilities under its jurisdiction (about 7,000) of which an even smaller proportion are foreign. Much of its inspection activity is reactive not proactive (risk-based).</p> <p>Both bills require the inspection of foreign facilities exporting to the US. Frequency would vary by risk categories (which will be defined at a later date) between 6 months and 5 years.</p> | <p>Based on current registrations, about 14,700 Canadian facilities would now require inspection. Inspection costs would vary by facility products and complexity. Costs would also vary by the source of the inspection (US government, Canadian government or third party).</p> <p>There are implications for the Canadian government if non-registered establishments seek regular inspections.</p> <p>If accredited third parties are involved then these services are currently in short supply in Canada (and in the United States) and will be subject to an initial spike in demand as firms move to meet the requirements by the implementation deadlines.</p> <p>Clarification of Categories 1 and 2 was requested.</p> | Canada supports a risk-based inspection in principle, but will want to be sure that any frequencies eventually mandated by U.S. legislation or regulation can be scientifically justified as an effective and efficient way to manage risk. Canada should propose that the legislation stop short of mandating the frequency of inspections, and instead require regulators to develop and implement a risk-based schedule based on sound science. Canada should offer to work closely with the U.S. on the development of a science-based system. |
| Certification & Accreditation | Certification is an accepted practice in international trade and Codex has developed guidelines governing it. There is uncertainty as to whether or not FDA currently has the authority to enter into certification agreement with exporting countries.   | Both bills authorize the Secretary to require certification of imports under certain conditions where either the exporting country's food safety system or the exporting facility's food safety system has not met certain requirements. There is uncertainty in both bills about what products would require certification and whether or not Canadian exports would be subject to certification. Industry requests clarification.   | Canada should seek to ensure that products of national food safety systems recognized as equivalent to the new US requirements will not require certification.   |
| Import Regime                 | FDA is currently empowered to refuse entry to any food import that "appears" to be adulterated, misbranded or otherwise in violation of the law. It requires importers to provide prior notification for each shipment. It has established an electronic  | Both bills allow for expedited imports. Both increase the cost of exporting and thicken the border. Some Canadian firms may withdraw from the US market if the benefit of market access does not exceed the cost of these measures. Food processors identified the Foreign Supplier Verification Program as having the potential to be a very   | Canada should ensure that FDA has the authority to enter into equivalency agreements as is proposed in S 510.  |



|                     |  |  |  |
|---------------------|--|--|--|
|                     | <p>database (OASIS) which inspectors use to identify risk and select shipments for inspection. However, it has only 450 inspectors for over 300 ports of entry and in practice inspects approximately 1% of shipments.</p> <p>Both bills would tighten import controls through either verification or certification systems. These could involve foreign governments (or third parties).</p> <p>Importers would be required to verify supplier activities.</p> <p>The Senate bill provides for entering into equivalency agreements.</p> | <p>problematic measure, increasing costs and being discriminatory to foreign food. Other participants suggested that under the Senate bill, facilities have to meet certain requirements and that this is just echoing this. It was suggested that Canada may have similar provisions in place. The Senate bill would give FDA additional authority to review food safety systems of importing countries to ensure overseas regulators are controlling risks. It would provide FDA the authority to enter into equivalency agreements. This would be positive for Canadian exporters. However, care must be exercised when defining equivalency.</p>   |  |
| <p>Traceability</p> | <p>FDA currently requires one-step forward/one-step back traceability from facilities that manufacture, process, pack, transport, distribute, receive, hold, or import food (but exempt farms and restaurants from some or all of the requirements).</p> <p>The House bill would establish a “full pedigree” traceability requirement for all facilities except retail and foodservice and exempt farms in some situations.</p> <p>The Senate bill would require traceability for the fresh produce supply chain.</p>                    | <p>The full traceability requirement goes well beyond the current one-step forward one-step back system and may be infeasible. Industry expressed support for a unique identifier number based on international standards (GS1).</p> <p>Canada’s traceability initiative is focused on livestock/meat. Extending the effort to all commodities would greatly increase the scope and the cost and effort required. If US industry programs are selected, then Canadian exporters will have to harmonize existing programs with the US programs.</p> <p>This measure will increase the cost associated with exporting (and the cost of doing business for US domestic firms).</p> <p>Concerns were raised about the timeframe for implementation and traceability beyond the case level for produce. It was also noted that traceability does not enhance food safety.</p> | <p>Limit the new traceability requirements to one – forward one-back and to encourage the US to drop the traceability requirements completely in the event that analysis indicates significant problems.</p> <p>Use international standards as basis for FDA regulations concerning unique identifiers, nomenclature, etc.</p> <p>Limit traceability in the produce sector to the case not the item level.</p> |

## 4.2 Next Steps

There may be sector issues that were not identified. Not all industry representatives were able to participate in discussions with the consultants within the timeframe of this project. Further research should gather input from these groups. One group suggested that a multi-ingredient food should be subject to further examination.



It may be beneficial to reassess the impact of the measures identified in Category 1 in light of the clarifications requested by industry, further details on the reaction of US industry groups to the two bills, and further input from Canadian industry.

It may be beneficial to look at the measures that were not looked at but that could have implications for Canadian exporters (Category 2).

The COOL measure in the House bill should be monitored. It may be beneficial to examine more closely how COOL would be applied to all non-processed foods. For example, what is the current practice in the US, how would it change, and would any difficulties arise?

Further analysis regarding the inspection of facilities could answer such questions as the impact on cost, the preparation time required, and the impact on inspection work being done by industry-led food safety schemes.

It may be beneficial to review the food safety initiatives launched by the FDA and USDA in 2008 and 2009 and briefly described in Section 2.2 to more fully assess the impact of all the proposed and implemented changes in the US food safety system on Canadian exporters.

It would be worthwhile to create a table that compares proposed US measures with existing Canadian measures and with the amendments to the Food and Drug Act proposed in 2008 (Bill C-51). This would require assistance from CFIA.

It would be beneficial to industry to have further discussions regarding the current and future equivalency of the Canadian and US food safety systems.

