THE NEW FOOD SAFETY REGIME IN THE US: HOW WILL IT AFFECT CANADIAN COMPETITIVENESS?

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The Food Safety Modernization Act (FSMA) signed into law by President Obama in January, 2011 provides a legislative framework for a major overhaul of the US food safety system. The FSMA charges the US Food and Drug Administration (FDA) with implementing the Act and reforming food regulations. As yet, the full effect of the Act cannot be evaluated because the regulatory requirements are yet to be developed. There is little doubt, however, that those, both domestic and foreign, that wish to supply US consumers with food will face a considerable increase in regulatory costs. This policy brief outlines the major requirements of the FSMA. Areas where Canadian firm may be disadvantaged relative to US firms are outlined.

The catalyst for a more robust regulatory regime for food safety arose from widely publicized outbreaks of food-borne illness that lessened to a considerable degree consumers' faith in the US food supply in recent years. For instance, evidence of E. coli and Salmonella have been found in a variety of domestic and imported foods including spices, peanut butter, cookie dough, spinach, melons, hot peppers, tomatoes and green onions. The new regulations focus on enhancing the ability of the FDA to proactively intervene against food-borne risks associated with both domestic and imported food. Imports became a particular concern after widely publicised problems with food imported from China in 2007 (Liu et al., 2009).

The US imports food from approximately 150 countries, and among the American public and politicians there is a perception that foreign food-safety standards are lax. Imported food constitutes 15 percent of the US food supply, including 80 percent of the seafood and approximately 60 percent of the fresh produce that is consumed (Superville and Jalonick, 2011). The Act covers 80 percent of food consumed within the US. The major exceptions are meat, poultry and dairy products, which are under the regulatory authority of the U.S Department of Agriculture. The FSMA also includes exemptions for small food companies and farms.

The US is by far Canada's largest trading partner, accounting for approximately three quarters of Canada's exports and two thirds of imports in 2009 (Statistics Canada, n.d.). The US is also Canada's largest agricultural export market, constituting approximately 50 percent of export market share in agri-food and seafood products in 2009 (AAFC, n.d). Canada is also the largest market for U.S agricultural exports. Hence, it may well be that the FSMA could adversely affect the competitiveness of US-origin supply chains in the Canadian market.

The FMSA became law in January 2011, but will come into effect only with a lag as the FDA must develop new protocols and procedures, train staff and inform both domestic and foreign-origin food supply chain participants what compliance will entail. The key policy changes in the new FSMA with trade implications are:

- *The foreign supplier verification program*: The FDA has been given the power to require certification that imports have been produced in compliance with US laws and regulations. US importers will be required to verify that their foreign suppliers comply with: 1) hazard analysis and preventative controls (HACCP); or, 2) with production and harvesting standards. The FDA will provide new regulations by the end of 2011 to define the required verification methods. Food production facilities must inform the FDA, in writing, of all identified hazardous practices that exist along their supply chains and their plans to implement preventive measures. The FDA, along with the Department of Homeland Security

and Department of Agriculture, will issue regulations that prevent food companies from knowingly including illegal additives, chemicals or other substances in their food products.

- *Mandatory food recalls*: The FMSA now gives the FDA the power to directly order a mandatory food recall or to seize and detain products. Previously, recalls were voluntary.

- *Shut down of production*: The FMSA also gives the FDA the ability to temporarily shut down a food production facility if a possible health risk is suspected. The FDA may now formally request access to a firm's records if it suspects a potential public health risk or for tracking purposes.

- *The frequency of inspection*: The frequency of inspections by the FDA will increase. Those facilities designated as 'High Risk' must be inspected every three years. Those designated as being 'Low Risk' must be inspected within seven years. Both foreign and domestic facilities must be inspected. When fully implemented, inspection of foreign facilities must take place twice a year. The FDA can now review the food safety practices of countries that wish to supply the US market.

- *Standards for on-farm production and harvesting*: Nationwide science-based mandatory standards for producing and harvesting fresh produce will be established by the FDA.

- *Post-harvest supply chains*: Specific response and recovery procedures will be developed to deal with outbreaks of food-borne illness. Grocery stores are responsible for pro-actively alerting customers regarding product recalls.

- *Effective traceability*: In coordination with the fruit and vegetable industries, the FDA will create a new method of effectively tracking and tracing fresh produce.

- *Laboratory accreditation*: By early 2013, the FDA must develop a mechanism to accredit laboratories for the purposes of food safety testing. The mechanism is to have model standards that include sampling and analytical procedures, internal quality controls and training for individuals carrying out the collection of a sample and subsequent analysis. Foreign laboratories are eligible for participation.

- *Third-party auditors*: They must establish a means to recognize accreditation bodies and third-party auditors. Third-party audit certifications will be used to ensure that an imported product complies with US laws and regulations.

- *Mandatory registration*: A new twice yearly registration procedure will be put in place and firms in the food industry must attain compliance with updated requirements or risk suspension. Food facility registrations will need to be renewed every two years.

- *Agriculture and food products transportation*: Mandatory regulations regarding sanitary practices in transportation must be developed by the FDA.

- *Pre-screening to expedite imports*: The FDA will provide a voluntary qualified importer program for firms desiring expedited import procedures for food.

- *The burden of costs and incentives*: The FDA may collect fees to offset importer re-inspection related costs. Firms that require re-inspection or recall may be subject to a fee established by the FDA.

It is not possible to provide a complete assessment of the effect of the FSMA on the competitiveness of the Canadian agri-food sector because full implementation will only be achieved over the next two or three years – and this is assuming the FDA can actually achieve the targets for the development of systems, procedures and trained personnel set out in the legislation. The latter cannot be assumed. Canadian agri-food firms need to remain vigilant as the full extent of the new US regulatory environment pertaining to food safety unfolds.

Food exporters to the US will be subject to much closer scrutiny of their food safety controls. The legislation has raised the bar for entry of agri-food products into the US by imposing additional minimum requirements. Importers are now accountable for food safety due to the new importer verification requirements and this, in turn, implies that Canadian agri-food exporters will have to be directly responsible for the safety of their products. As with their US counterparts, Canadian agri-food exporters will have to comply with registration requirements, increased US FDA requests for access to records, undertake hazard analysis, implement preventive controls and performance standards, put in place product tracking systems and engage in increased recordkeeping activities. Mitigation strategies for intentional adulteration must be developed within firms. All these can raise the cost of exporting and foreign supplier verification can deter U.S importers from sourcing in Canada if the process of obtaining a verification certificate is costly, lengthy or complex. While costs will undoubtedly rise, they will also rise for US firms. It may well be that Canadian firms may be more able than firms from other nations, particularly firms located in developing countries, in meeting US standards. As a result, despite the increase in costs, Canadian exports of some products might expand.

The legislation requires the development of a program for accrediting testing laboratories. Given the wide ranging increase in monitoring embedded in the FSMA there is likely to be an increased demand for food safety related testing. Existing laboratories in Canada will have to expand. Certification will involve both evaluation of laboratory infrastructure and the training of laboratory staff. Investments in expanded and new laboratories will have to await the release of the new FDA accreditation program and what the process will entail. This is a clear area for potential bottlenecks.

A similar problem relates to the third party audit system. The intent of the new audit system is to ensure that all parties in food supply chains conform to US laws. It is not clear how onerous such audits will be for firms along the supply chains. The costs involved could be substantial. In any case, this will be a major undertaking and require expansion of the third party industry. Again, there is considerable potential for bottlenecks to develop.

The FSMA mandates the use of US recognized HACCP by foreign firms. While HACCP is widely used in Canada, there is no international harmonization of HACCP systems (Kerr,

2000). If the FDA insists on the use of HACCP systems that comply with US standards, Canadian firms may have to alter their practices, or be forced to simultaneously use a Canadian system and a US system. Further, a system for certification and audit of the HACCP systems used by Canadian exporting firms will be required.

The FSMA requires traceability of imported food products. For many industries, and particularly for fresh produce, where inputs are sourced from many suppliers, maintaining the complete information on the place of origin and supply chain movements of a product and linking a products history with its eventual distribution is a daunting task.

The inspection of foreign facilities mandated in the FSMA is an enormous task given the number of countries that currently supply the US and the complexity of international supply chains. All foreign facilities are to be inspected every two years. As yet, there is no indication who will be undertaking the inspections. Whether it is FDA personnel or third parties that will undertake the inspections, it will require a large number of trained inspectors.

In general, the FSMA sets out a very ambitious agenda for the FDA under very short timelines. While it is hard to judge if the resources made available to the FDA will be sufficient for it to undertake what it has been charged with, it will require considerable numbers of trained and relatively specialized people.

The FSMA provisions fall under the commitments that the US has made under the WTO's SPS agreement. Central to those commitments is the Principle of Non-discrimination. There are two elements of Non-discrimination – *Most Favoured Nation* and *National Treatment*. National Treatment is what is applicable in the case of the FSMA. National Treatment commits a country not to impose SPS-based regulations that treat foreign suppliers differently than domestic suppliers. The FSMA would appear to have the potential to violate US National Treatment commitments. As the regulations develop they should be carefully monitored by Canadian firms to ensure they do not impose greater costs on Canadian firms than US firms.

The FSMA represents a major attempt at strengthening the safety of food consumed by US consumers. While one might question the efficacy of the changes in delivering greater food safety, the intent is clear. What is not clear, as yet, is what regulatory compliance will cost. It would appear that it will be a considerable burden for agri-food supply chains. Both domestic and foreign firms will have to bear that cost.

The FSMA appears to be a major undertaking with a very large responsibility placed on the FDA. It would seem that bottlenecks to exporting are bound to appear which will be very frustrating for Canadian firms. It is important for Canadian firms and Canadian policy makers to work hard to ensure that temporary bottlenecks do not become permanent inhibitors of trade. The Canadian government needs to understand industry concerns and use any mechanisms – including those in the NAFTA – to initiate consultations with the US.

Given the likely lags in implementation, North American food markets are likely to exhibit considerable disequilibrium over the near term. Trade flows will be affected. As the

implementation programs of the FSMA become more transparent, more sophisticated analysis into its effect on Canadian competitiveness in the US market can be undertaken.

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