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The New Food Safety Regime in the US: How Will It Affect Canadian Competitiveness

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Abstract

The Food Safety Modernization Act (FSMA) which was signed into law in January, 2011 represents a major initiative to improve food safety in the US. The legislation mandates the US Food and Drug Administration with developing a regulatory system to implement the Act. 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 firms, both domestic and foreign, that wish to supply US consumers with food will face a considerable increase in regulatory costs. This paper outlines the major requirements of the FSMA and suggests how the regulatory burden may fall on foreign versus US domestic suppliers. Areas where Canadian firms may be disadvantaged relative to US firms are outlined. Opportunities that may arise from the FSMA for Canadian agri-food firms are discussed, as are the areas where the FSMA may not conform with the international trade commitments of the United States.

Keywords: competitiveness, food safety, regulatory burden, SPS

1.0 Introduction

The United States Food and Drug Administration's (FDA) Food Safety Modernization Act (FSMA), signed by President Barak Obama, on 4th January 2011, has been touted as the most significant update of US food safety laws since the 1930s. The FSMA mandates the FDA to protect the American public against food-borne diseases and illness. The spur for a stronger regulatory regime for food safety arose from high-profile outbreaks of food-borne illness that shook public confidence in the US food supply over the last few years. For instance, evidence of *E. coli* and *Salmonella* have been found in domestic and imported foods including spices, peanut butter, cookie dough, spinach, melons, hot peppers, tomatoes and green onions. The new regulations focus on better arming the FDA to protect consumers against food-borne problems associated with 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 over 150 countries, and there is a widely held perception that the food-safety standards of many countries from which imports are sourced are weak or that enforcement is 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 FSMA focuses on preventing food related problems rather than mitigating them. The Act covers about 80 percent of all food consumed within the US, with the exception of meat, poultry and dairy, which is regulated separately by the U.S Department of Agriculture. The Bill also includes exemptions for small food companies and farms.

Governments have the obligation and the right to take actions to protect their citizens from harm – including those that may arise from food consumption. A failure in the food safety system can be one of the most politically damaging events for policy makers. It does not matter whether the failure originated within the domestic market or outside the country, domestic politicians are likely held accountable by their citizens. As a result, ensuring the safety of the food supply is an area of policy making where sovereignty is closely guarded (Kerr and Hobbs, 2010). Given improved detection technologies and changing risk environments, periodic changes to food safety regulatory regimes can be expected. Regulatory changes are likely to increase the costs for firms involved in food supply chains. If those cost increases fall disproportionately upon some participants in agri-food supply chains their competitiveness can be expected to deteriorate. The commitments made under the World Trade Organization's (WTO) Agreement on the Application of Sanitary and Phytosanitary Measures (SPS), however, stipulates that changes in regulations should not impose costs in such a way that they disadvantage foreign producers relative to domestic producers (Isaac, 2007). Thus, increases in costs that apply equally to US and foreign firms should not adversely affect competitiveness. Further, internationally, even if all foreign firms are treated the same, the ability of firms and supply chains to adapt to the new requirements may differ so that the relative competitiveness of some country's firms will improve while other's deteriorate.

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 51.4 percent of export market share in agri-food and seafood products in 2009 (AAFC, n.d.). Similarly, Canada is the largest market for U.S agricultural goods. About 6,000 truckloads of fresh produce from the

US are delivered to Canadian grocery stores every day (CBC, n.d.). Hence, it may well be that the FSMA could adversely affect the competitiveness of US-origin supply chains in the Canadian market; and or Canadian-origin supply chains in the US market.

The interaction between regulation and international competitiveness in relation to food safety is complex. Many of the increased costs relate to monitoring activities and are often subsumed in the general administrative costs of a firm – and thus cannot easily be identified (Hobbs and Young, 2000). They represent calls on the time of individuals. Bottlenecks may materialize in the process of meeting a new standard – lack of certified facilities, delays in regulators putting in place sufficient staff to undertake new aspects of their regulatory oversight, the need to train staff in testing laboratories, etc. These bottlenecks can be temporary transitional impediments to competitiveness or ongoing constraints that negatively affect trade flows. They are open to political interference through the budgetary process and, hence, are susceptible to capture by those who seek economic protection. In many cases it is not yet possible to fully assess the FSMA's effect on competitiveness because the administrative details have yet to be worked out by the FDA. Thus, all that can be done here is to point out potential areas where bottlenecks may exist in the future and/or where the application of the FSMA are likely to violate WTO commitments.

2.0 The US Food Safety Modernization Act of 2011

The FMSA became law in January 2011 but there will be a considerable grace period as the FDA and other US regulatory agencies must develop new protocols and procedures, train staff and inform both domestic and foreign-origin food supply chain participants what compliance will entail. Under the new US\$1.4 billion bill, the FDA will have new prevention-focused tools and a clear regulatory framework to help make substantial improvements in their approach to food safety (FDA, n.d.). The following are the key policy changes in the new FSMA that may have potential implications for those trading foodstuffs into or out of the US. It should be remembered that the FSMA does not regulate meat, poultry and dairy products. Alcoholic beverages, dietary supplements, and seafood are, however, now covered in the Act.

- *The foreign supplier verification program:* The FDA has been given the power to require import certification for imports that attests that the food was produced in compliance with US laws and regulations. US importers will be required to verify the activities of their foreign suppliers, ensuring their suppliers produce foods that comply with: 1) hazard analysis and preventative controls (HACCP); or, 2) with production and harvesting standards. A foreign supplier must also provide assurances that their products are not adulterated or misbranded. The FDA will provide new regulations by the end of 2011 to define the required verification methods. The FDA will determine requirements based on the known risks associated with the food or its geographic origin. Food without proper foreign supplier verification and importing food without a verification program in place may result in import prohibitions or criminal prosecution. 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 gives the FDA the power to directly order a mandatory food recall or to seize and detain food if there is a reasonable probability that the product is adulterated or misbranded and could cause serious adverse health consequences. Previously, recalls were voluntary with the decision lying with the firm. It is hoped that the threat of FDA action will induce more firms to undertake voluntary recalls expeditiously.
- *Shut down of production:* The FMSA gives the FDA the ability to temporarily shut down a food production facility if a possible health risk is suspected. The FDA is granted expanded access to food production facility records. It may formally request access to a firm's records if there is reason to suspect 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 of the passage of the FMSA. Both foreign and domestic facilities must be inspected. In 2011, the FDA is mandated to inspect no fewer than 600 foreign facilities and inspections of foreign food facilities must double each year for the next five years. When fully implemented, inspection of foreign facilities must take place twice a year. Further, in an effort to improve food safety oversight, FDA offices must be established in at least five foreign countries that export food to the US. The FDA will have the authority to review the current food safety practices of countries that wish to supply the US market. The Secretary of Health and Human Services is tasked with working with foreign governments to streamline the inspection of foreign facilities.
- *Standards for on-farm production and harvesting:* Nationwide science-based mandatory standards for producing and harvesting fresh produce will be established by the FDA. Further, for some specified vegetables and fruits as well as produce which are designated as being 'High Risk' – designated raw agricultural commodities – the FDA will publish safety guidelines. The Act also requires the FDA to identify the most significant food threats – food-borne contaminants and diseases – every two years.
- *Post-harvest supply chains:* Specific response and recovery procedures will be developed to deal with outbreaks of food-borne illness by Health and Human Services, in consultation with the Department of Homeland Security. Grocery stores will have frontline 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. The goal is to increase the number of laboratories that qualify. Foreign laboratories are eligible for participation if they achieve the model standards. Laboratories will be required to be accredited to conduct any regulatory testing by mid-2013.

- *Third-party auditors:* The FSMA requires that the FDA establish a means to recognize accreditation bodies and third-party auditors. Third-parties can be a foreign government, a private firm or a non-government organization (NGO). 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. The FDA will have the ability to suspend a registration meaning that no one would be able to import food into the US from such facility. A suspended US facility would not be able to export.
- *Agriculture and food products transportation:* Regulations regarding sanitary practices in transportation must be developed by the FDA. Shippers, carriers by motor vehicle or rail vehicle, receivers, and other persons engaged in transportation of food will be required to implement the practices.
- *Pre-screening to expedite imports:* The FDA will provide a voluntary qualified importer program for firms desiring expedited import procedures for food. Importing firms participating in this program are required to have certifications from an accredited third-party auditor. High risk foods or foods from high risk countries, at FDA's discretion, may have additional requirements specified.
- *The burden of costs and incentives:* The FDA may collect fees to offset importer re-inspection related costs and for administering the qualified importer program. Firms that require re-inspection or recall may be subject to a fee established by the FDA.

The regulation exempts small producers from recordkeeping and hazard analysis requirements. Small scale producers are defined to cover a category of producers who sell directly to distributors and whose annual sales are less than US\$500,000. This exemption may be revoked if, in the future, food related problems are linked to small scale producers (Superville and Jalonick, 2011).

3.0 Implications for the Competitiveness of the Canadian Agri-food Sector

It is not possible to provide a complete assessment of the effect of the FSMA on the competitiveness of the Canadian agrifood 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 – for example, it took years for the much less ambitious and simpler US country of origin labelling (COOL) of imported food to be fully implemented (Sawka and Kerr, 2010). Much of what ultimately effects Canadian competitiveness will arise from the future regulations developed by the FDA and other US government agencies. Still, the main areas where Canadian competitiveness could be affected can be identified. Canadian agri-food firms need to remain vigilant as the full extent of the new US regulatory environment pertaining to food safety unfolds.

Exporters of agri-food produce and products to the US and U.S domestic importers will be subject to much closer scrutiny of their food safety controls under the new FSMA. This applies equally to all foreign suppliers of the US. 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 by firms. All these can raise the cost of exporting to US and foreign supplier verification can deter U.S importers from sourcing in Canada if the process of obtaining a verification certificate is costly, lengthy and 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 exporters of some products might have a competitive advantage over competing exporters in the US market and see trade expand.

A preliminary impact assessment of the FSMA by Thompson and Rutherford (2009) found that all participating groups of Canadian agri-food exporters identified the ‘hazard analysis and preventive controls’ and ‘traceability measures’ as areas of concern. Grains, oilseeds and pulse exporters, processed food and horticulture exporter groups particularly identified ‘certification and accreditation’ measures as areas they considered problematic. Further clarification on the ‘performance standards’ measure was also sought by these groups. A horticulture exporter group noted that depending on the acceptance of current Canadian industry practices, the standards established by the FDA for production of fresh produce and other raw agricultural products could be a potential problem.

The FDA will henceforth require imported food to be certified to ensure compliance with U.S. laws. This will require exporting firms to identify the appropriate US laws and then to make the changes necessary to come into compliance. Subsequently, certification will have to be arranged. If the firm fails to obtain certification, exports may be disrupted until the problem is identified and rectified. Entry into the U.S. may be delayed until certification is obtained. Certification may be delayed due to a shortage of certifiers. In case of perishable products, such as fresh fruits and vegetables, a delay in obtaining certification can lead to deterioration in the quality of the products awaiting export. The FDA will provide regulations regarding how a firm can verify that food has not been adulterated or misbranded. In this case, the exporting industry may incur additional cost if they have to install equipment for verification of food safety, such as equipment for testing for contamination or chemical residues. The industry will also need to provide training to employees or hire skilled workers to undertake verification and testing procedures. If products have to be transported to some other place for testing, then additional transportation costs will be incurred.

The legislation requires the FDA to develop a program for accrediting testing laboratories within two years of its passing. 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 and investments in new laboratories likely warranted. This is a clear area for potential bottlenecks. 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. Similarly, the training/upgrading of staff skills will have to await the release of the FDA accreditation standards. What is not clear is how the ability to export will be affected in the time between the date of the FDA establishing a program and the time it takes to comply. Accreditation will take time, particularly if facilities have to be upgraded or staff retrained. Putting in place an accreditation program itself will require either evaluation by FDA personnel or the development of third party certification institutions. FDA personnel are likely to be stretched by the demand for certification leading to queuing delays. Alternatively, the establishment of a third party system will require the development of a regulatory regime to oversee that industry. It is not clear whether Canadian firms will be able to export while constraints on the accreditation of laboratories exist. Further, those laboratories that manage to garner accreditation early in the process may be able to extract rents in terms of testing fees while laboratory capacity constraints exist. Thus, a great deal of uncertainty exists for Canadian agri-food exporters.

A similar problem relates to the establishment of a third party audit system. The intent of the new audit system is to ensure that all parties in food supply chains are conforming 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 the expansion of existing accredited third party auditing firms and/or the establishment and accreditation of new third party audit firms. Again, there is considerable potential for bottlenecks to develop. Until the FDA program is rolled out, a full evaluation is not possible.

This auditing of firms for compliance with US laws and regulations all along the supply chain may provide an incentive for transaction cost reducing vertical integration – a reduction in monitoring costs through a reduced number of audits (Hobbs and Kerr, 1992). Even if full vertical integration is not the result, the requirement for auditing may work to the detriment of small Canadian firms that may be excluded from audited supply chains given the fixed costs of auditing.

Canadian exporting firms must also register with the FDA. Registrations will have to be renewed twice a year. This requirement may work against intermittent or opportunistic exporters that currently exploit international market arbitrage rather than engaging in sustained exporting. As they cannot predict when arbitrage opportunities will arise they may choose not to consistently register. Similar requirements that arose from post-9/11 Homeland Security initiatives, however, may not have been particularly onerous (Kerr, 2004).

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. Resources constraint issues may again come to the fore as there will be

the need for US recognized HACCP trainers and certifiers which currently do not exist in Canada. Further, a system for certification and audit of the HACCP systems used by Canadian exporting firms will have to be established.

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. Canada's official traceability initiative is centred on livestock and meat, while some other industries are putting traceability systems in place. The US has been a laggard in traceability initiatives (Brocklebank et al., 2008). While traceability is simple in concept – and thus politically popular – it is difficult and costly in practice. In the European Union where traceability has been officially promoted, and to some extent mandated, the efficacy of the systems put in place have not proved particularly robust. Thus, mandating traceability in the FSMA may prove to be operationally problematic with considerable costs lumbered onto both US domestic industries and international suppliers. One can expect considerable 'push back' from the domestic industry in the US if the post-BSE – *bovine spongiform encephalopathy* – experience with the US beef industry is at all representative. If there is a softening of the traceability requirement, Canada should be vigilant that such changes are not made in ways that disadvantage foreign suppliers. The study by Thompson and Rutherford (2009) found that a group identified as importers/exporters viewed the proposed FSMA traceability measures as very problematic and unlikely to enhance food safety.

It is not clear whether the FDA's mandate to require recall of products can extend to foreign suppliers. At the very least, suspect foreign products will now be open to seizure and detention. Given the provisions for mandatory registration, foreign suppliers that did not comply with a FDA mandatory recall would likely quickly have its registration cancelled effectively ending its ability to export. Hence, one is likely to observe compliance with recall requests.

The inspection of foreign facilities mandated in the FSMA is an enormous task given the number of countries that currently supply food products to 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. Inspections add new facets to exporting including inconsistency among inspectors, opportunities for corruption and political interference in the rigour with which inspections are undertaken. Inspections were a contentious issue in the Canada-US Free Trade Agreement negotiations (Bruce and Kerr, 1986; Kerr, et al., 1986). The expansion of US inspections into the NAFTA marketplace would seem to represent a potential backward step in North American market integration.

The FSMA gives the right to the FDA to shut down a facility if it suspects a food safety risk. Beyond the questions raised regarding the legitimacy of extraterritoriality, this is not a particularly contentious issue. The contentious issue may become, however, under what circumstances will a facility be able to begin exporting to the US again. Those charged with protecting the market from unsafe food have little interest in when exports can actually resume. The recent Canadian experience with the ability of US-based interest groups to delay the re-

opening of the US border in the wake of the discovery of BSE in Canada and the subsequent border closure provides a powerful lesson (Loppacher and Kerr, 2005).

The FDA will establish production and harvesting standards for fresh produce. Agronomic conditions vary greatly and can be localized to a considerable degree. Thus, standards established for US conditions may not be optimal for production and harvesting in all circumstances. As a result, exports may be denied market access or compliance costs may be higher for foreign suppliers. Again, establishing such standards for a wide variety of products will require a considerable resource commitment by the FDA – and the possibility of delays.

The requirements for transporting food may require investments in new trucks and other shipping related facilities. While this may represent a considerable expense for Canadian firms, the same costs will be borne by US firms given the integrated nature of the North American market. To reach the new transportation standards may be much more difficult for suppliers from developing countries given the generally poor state of infrastructure in many of those countries. As a result, Canadian exporters may find that they have gained a competitive advantage.

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. There is unlikely a pool of such individuals for the FDA to draw upon so compromises will have to be made either on the quality of the people implementing the program or in the timelines. Less than fully trained people will be more prone to make mistakes – mistakes that will be costly for exporting firms. Delays in implementation play havoc with the investment that will have to be made to continue to access the US market. As yet, the full effect of the FSMA for Canadian competitiveness is far from transparent. Canadian firms that wish to export to the US will have to be vigilant as there will be a host of FDA regulations that will be rolling out over the next few years.

4.0 The FSMA and International Trade Commitments

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 violate US National Treatment provisions in a number of ways.

The requirement that foreign facilities be inspected twice a year when 'High Risk' facilities in the US are only inspected once every three years and US 'Low Risk' facilities will be inspected within seven years is clearly discriminatory. There is an egocentric presumption that foreign facilities are riskier than US facilities. Given that inspections will likely impose considerable costs, this provision endows US producers with a competitive advantage over foreign suppliers. Countries can impose higher standards if there is scientific evidence or evidence of an increased risk. It is unlikely that the US could prove that foreign facilities

represent a greater food safety risk than domestic facilities to the satisfaction of a WTO Disputes Panel. This provision could be challenged at the WTO.

A potential source of inconsistency of the regulation with WTO rules is the exemption of small scale producers from HACCP requirements. This exemption has not been extended to foreign suppliers. From a food safety perspective, this exemption is hard to understand. Scientifically, there is no evidence attributing food-borne complications to large scale supply chains or imported products. It does recognize the disproportionate burden HACCP and traceability would place on small agri-food companies and farms. That the exemption has not been extended to foreign suppliers could be challenged as a violation of National Treatment at the WTO. The exemption in the US is, however, only for firms supplying locally (however defined). Hence, the trade effects on Canadian exporters may be small.

As the FDA sets out its regulations, there may be other areas where National Treatment is violated. In particular, the requirements for inspection, certification, tracing and auditing should be monitored carefully for requirements that are stricter for foreign suppliers than domestic firms. The FDA is also allowed to impose fees to recover the costs of inspections, etc. These fees could be charged in ways that could discriminate against foreign suppliers.

The FDA is to develop production and harvesting standards for fresh produce. If foreign firms are judged to not be complying with these standards, they will not be allowed to export to the US. Trade barriers are not allowed to be put in place on the basis of production and processing methods (PPMs). If Canadian food meets scientifically-based food safety requirements, they should not be excluded from the US market based on the production or harvesting methods used. Mandating the use of US HACCP standards might also be considered a PPM.

Under the provisions of the NAFTA, Canada and Mexico are supposed to be consulted when there is a major regulatory change (McLachlan et al., 1988). One wonders to what degree Canadian (and Mexican) authorities have been consulted regarding the FSMA and how much they will be consulted by the FDA as it develops its implementing regulations. Unfortunately, as with a number of the *regulatory cooperation and coordination* aspects of the NAFTA, one suspects that the operationalization of this provision has never achieved the negotiators intent (Kerr, 2006).

5.0 Conclusion

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 supply chains in the food industry. Both domestic and foreign firms will have to bear that cost if they wish to continue to supply the US food market.

The effects on competitiveness is a relative concept. If costs were borne equally by all suppliers of food to the US market there would be no change in competitiveness. If the burden

falls unequally, this will lead to changes in competitiveness. If costs fall unequally on foreign suppliers then they will lose markets to US suppliers. Except in a few cases – inspections and small scale producers – as yet there is little evidence of overt discrimination against foreign suppliers. It is, however, early days as the FDA must develop a host of new regulations pertaining to the FSMA. These must be assessed as to whether they discriminate in favour of US supply chains.

Even if costs rise, competitiveness may improve if Canadian firms can more easily comply with the FSMA than other foreign suppliers. Some provisions of the FSMA are likely to prove to be very onerous for supply chains originating in developing countries, much more onerous than for their Canadian competitors. Thus, Canadian firms should be on the lookout for these types of opportunities.

It is also clear that the costs of the FSMA will fall on all US firms – except for those receiving exemptions due to their small size. Firms exporting from the US will thus be lumbered with the costs of complying with the FSMA. Import competing Canadian firms will not incur these costs. Thus, the competitiveness of US exporters should decrease. Canadian firms should be able to capitalize on this opportunity and increase their market shares.

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 the Canadian government to work hard to ensure that temporary bottlenecks do not become permanent inhibitors of trade. Private industry should avail themselves of any opportunities provided by the FDA to have input into the implementation of the FSMA. The Canadian government should consult with Canadian industry to understand their concerns and use any mechanisms – including those in the NAFTA – to undertake formal and informal consultations with the US.

Given the likely lags in implementation, North American food markets will be beset by considerable uncertainty and some turmoil over the near term. Trade flows will be affected. As the implementation programs of the FSMA become less opaque, more sophisticated analysis into its effect on Canadian competitiveness in the US market should be undertaken.

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