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Evolving US Food Safety Regulations and International Competitors: Implementation Dynamics

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ABSTRACT

The 2011 US Food Safety Modernization Act (FSMA) represents a major initiative to improve food safety. The legislation mandates the US Food and Drug Administration (FDA) with developing a regulatory system to implement the Act. Both domestic and foreign firms that wish to supply US consumers with food will face a considerable increase in regulatory costs. Implementation has proved challenging for the FDA leading to delays which increase investment risks for foreign suppliers, particulalry from developing countries. This paper sets out the major FSMA requirements and examines how the regulatory burden may fall on foreign versus US suppliers.

Keywords. competitiveness; food safety; implementation dynamics; international trade, regulatory burden

1 Introduction

The Food Safety Modernization Act (FSMA), signed by President Obama, on 4 January 2011, has been touted as the most significant update of US food safety laws since 1930s. The FSMA charges the United States Food and Drug Administration (FDA) with protecting Americans against food-borne diseases and illness. The FSMA sets out a wide ranging set of tasks, some with deadlines, which must be accomplished by the FDA to implement the Act. These have proved challenging for the FDA to accomplish leaving food companies, including foreign suppliers, with little clarity as to what a FSMA-based regulatory regime will entail or the investments it may require. After almost five years since the new Act became law, and important deadlines likely missed, the implementation dynamics of the FSMA warrants an examination to determine the implications for international supply chains, including those originating in the European Union (EU) wishing to move food products into the US.

The spur for a stronger US regulatory regime for food safety arose from high-profile outbreaks of food-borne illness that shook public confidence in the US food supply. For example, evidence of E. coli and Salmonella had been found in domestic and imported foods including spices, peanut butter, cookie dough, spinach, melons, hot peppers, tomatoes and green onions (Carte Pate and Leavitt Partners, 2010). 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 public perception that the food-safety standards of many countries from which imports are sourced are weak or that enforcement is lax. Issues with food quality (e.g. the substitution of horsemeat for beef in processed foods) and food safety are widely reported in the US press and on social media so that exporters having high standards such as the EU are not differentiated in the minds of consumers.

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 US 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 Applications 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). Further, 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 others' deteriorate. Increases in import standards, new procedures and more complex regulations are expected to increase costs disproportionally for firms in developing countries because they have less capacity to deal with the changes (Khorana et al., 2010). On the other hand, for jurisdictions that already have high standards, and thus high costs, such as the EU meeting a second set of similarly high, but different standards, may impose considerable costs on firms and supply chains.

The interaction between regulation and international competitiveness for food safety is complex. Many of the increased costs relate to monitoring activities that are often subsumed in the general administrative costs of a firm – and thus cannot easily be separated out (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 in the food system can be temporary transitional impediments to competitiveness or ongoing constraints that negatively affect trade flows. They are open to political interference through a government's 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 – despite some timetables for implementation having been mandated in the legislation. It is possible, however, to point out potential areas where bottlenecks may exist in the future and/or where the application of the FSMA is likely to violate WTO commitments. Countries with little WTO experience – often developing countries – will have to learn when an importer's regulations can be challenged and how a successful challenge can be mounted. Even for European firms which have long history of international dealings, there can be a costly period of learning-by-doing associated with mounting a challenge to new regulations.

In the next section the main requirements of the FSMA are summarized. This is followed by a discussion of the dynamics of implementing the extensive changes mandated in the legislation governing the FSMA and, in particular, the mismatch between the resources available and the task the regulators have been tasked with. The focus is on those aspects of the FSMA that will affect foreign suppliers and the difficulties the delays in implementation cause for foreign firms. The next section examines the FSMA in the context of the international commitments made by the US at the World Trade Organization (WTO) to determine any areas open to an international challenge. The final sections provides conclusions.

2 The US Food Safety Modernization Act of 2011

The FMSA became law in January 2011 but a considerable grace period for implementation was granted as the FDA and other US regulatory agencies needed to develop new protocols and procedures, train staff and inform both domestic and foreign-origin food supply chain participants what compliance will entail. Under the FSMA 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, newly covered in the Act.

- *The foreign supplier verification program*: The FDA has been given the power to require import certification that attests that imported 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 located must also provide assurances that their products are not adulterated or misbranded. The FDA is to provide new regulations to define the required verification methods. Food processors, and in many cases farmers, will have to learn about and understand these verification methods if they wish to continue exporting to the US or to expand into the US market. 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 US Department of Homeland Security and US Department of Agriculture, are to devise regulations that prevent food companies from knowingly including illegal additives, chemicals or other substances in their food products. Even firms operating in countries that have mandatory HACCP systems, such as the EU, will have to ensure both that their current systems meet FSMA protocols (i.e. HACCP systems may vary across countries) and have their activities in this area verified.
- *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 is supposed to increase. Those facilities designated as 'High Risk' must be inspected every three years. Those designated as 'Low Risk' must be inspected within seven years. Both foreign and domestic facilities must be inspected. By 2011, the FDA was mandated to inspect no fewer than 600 foreign facilities and inspections of foreign food facilities were then to double each year over the next five years. When fully implemented, inspection of foreign facilities must take place twice a year. Thus, food processing facilities in the EU must prepare for inspections twice a year. Further, in an effort to improve food safety oversight, FDA offices are to be established in at least five foreign countries that export food to the US. The EU is unlikely to be high on the list of areas to have an FDA office as food safety issues are more prominent in some developing countries. As a result, the ability to deal with a food safety issue may be delayed relative to firms in countries that have a FDA office. The FDA will have the authority to review the current food safety practices of countries that wish to supply the US market – and the foreign governments must prepare the required information and cooperate with the FDA if it wishes to maintain and expand food product exports to the US. The US 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*: Science-based mandatory standards for producing and harvesting fresh produce are to be established by the FDA. Thus, farmers in EU and other foreign countries may have to alter their production methods to be able to access the US market. Further, for some specified vegetables and fruits as well as produce which are designated as being 'High Risk' – designated raw agricultural commodities – the FDA is to 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 are to be developed to deal with outbreaks of food-borne illness by Health and Human Services, in consultation with the Department of

Homeland Security. Retailers in the US will have frontline responsibility for pro-actively alerting customers regarding product recalls.

- *Effective traceability*: In coordination with the fruit and vegetable industries, the FDA is to create a new method of effectively tracking and tracing fresh produce.
- *Laboratory accreditation*: By early 2013, the FDA was mandated to develop a mechanism to accredit laboratories for 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 were supposed to be required to be accredited to conduct any regulatory testing by mid-2013. Foreign governments must weigh the costs of having their own certified laboratories or relying on certified foreign laboratories. This may be a difficult choice for the EU Commission and other foreign governments. With perishable food products, the time that testing takes is important to prevent deterioration of shipment's quality.
- *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. National governments in the EU must decide which form of institution will provide the most effective certification for its food supply chains.
- *Mandatory registration*: A new twice yearly registration procedure is to be put in place and firms must attain compliance with updated requirements or risk suspension. Food facility registrations will need to be renewed every two years. The FDA has the ability to suspend a registration meaning it would be impossible 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 are to be developed by the FDA. Shippers (including those using ships, motor vehicles, railway goods wagons or aircraft), receivers, and others engaged in transportation of food will be required to implement the practices. If these differ from existing EU regulations, firms may find it costly to satisfy both sets of sanitary practices.
- *Pre-screening to expedite imports*: The FDA is to enable 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. Firms in foreign countries must decide whether they wish to participate in pre-screening programs. EU firms, given their existing high standards, may have an advantage in qualifying for pre-screening relative to firms in developing countries.
- *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.

Taken together this represents a massive undertaking for the FDA and it has struggled to implement it. It requires a large number of specially qualified personnel to develop the wide ranging array of regulations and to engage in the ongoing monitoring programs. The FDA has struggled to find sufficient personnel. While US$1.4 billion was budgeted for implementation, it has proved insufficient.

The regulation exempts small US 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 future, food related problems are linked to small scale producers (Superville and Jalonick, 2011). The exemption does not apply to small scale foreign suppliers, including those in the EU. This will disadvantage firms attempting to develop niche markets in the US.

3 The Dynamics of Implementing the FSMA

Given the agenda set out in the FSMA outlined above it is obvious that the task faced by the FDA is enormous. Developing the regulatory systems for food is a complex task requiring expertise from a host of disciplines from those with a basis in science to social scientists that understand compliance costs and the role of incentives to those with legal training to others with a specialization in education. It takes time. The FDA is struggling with implementation. A speech by Michael Taylor, Deputy Commissioner for Foods and Veterinary Medicines, FDA to the World Food Safety and Security Forum hosted at the Milan EXPO in September 2015 is instructive. Mr. Taylor (2015) stated:

> One of the biggest food safety challenges we all face, however, is how to provide the level of verification that is needed for food safety and consumer confidence in a world of expanding scale and diversity of international trade in food, coupled with always finite and often scarce resources available for food safety. …

> Systems recognition is based on a rigorous assessment by FDA that another country has a food safety system that is comparable to ours in its capacity and effectiveness in assuring good food safety outcomes. …
>
> So far we have entered into a systems recognition agreement with New Zealand … We are in late stages of assessments and development of mutual recognition agreements with Australia and Canada, and we have begun the assessment dialogue with our counterparts at the European Commission.

As outlined above the FSMA mandates a system for foreign supplier verification. As yet, this system does not exist. The FDA has taken five years to develop a system for recognition agreements, which are only a step in the process of establishing regulatory thresholds for market access. As indicated in the quote above it has only concluded one recognition agreement with two formally in process of development. These are all with countries with high levels of food safety. Discussions have just begun with the EU – a major trading partner with high food safety standards. In a world where in excess of 150 countries supply the US with food, FDA compliance with the FSMA appears painfully slow. No developing countries are yet in the set of countries where the process has even begun. Where does this leave firms in the EU or other countries where nothing has been concluded. What investments in food safety should they make? The lack of progress increases the level of risk associated with engaging in supplying food products to the US. This slowness in progress on just this one facet of the FDA's responsibilities encompassed in the FSMA underlines the scale of the implementation process – the FDA is likely doing the best it can given the available resources.

> In his testimony regarding resourcing implementation of the FSMA before the US Congress in 2014 Mr. Taylor stated:
>
> The determination that we have all made to improve the safety of our food supply requires two fundamental steps. The first was to give FDA the mandate and tools to modernize the food safety system, and I applaud you for doing that via the enactment of FSMA. The second is to give FDA the capacity to carry out the numerous changes embodied in the law. It is that challenge that we must continue to address. Simply put, we cannot achieve our objective of a safer food supply without a significant increase in resources….
>
> Without adequate funding, FDA will be unable to adequately fulfill its oversight responsibilities. This includes implementing the Foreign Supplier Verification Program, which requires new staff and skills to audit and verify the adequacy of the importer's verification plan; conducting more foreign inspections; working more closely on food safety with foreign governments to leverage their efforts; and improving our data and import systems to facilitate prompt entry of foods that meet our safety standards. … But we cannot meet this need without the resources it takes to build the new import system.

Simply put, the FDA is under resourced relative to its new responsibility leading to considerable delays in implementation with the result that the regulatory future is opaque, the international trade environments is riskier and investment in exporting food products to the US inhibited. Thus, the dynamics of implementation add an additional dimension to the new food systems required of foreign suppliers in the FSMA. The implications of this implementation dynamic will be incorporated in the assessment of the FSMA for foreign suppliers in what follows. The absence of details regarding even the rough outlines of the new regulatory system means that assessments of, for example, the potential increase in costs associated with compliance means that even the most basic planning cannot be undertaken by existing exporting firms from the EU or potential exporting firms that can identify markets of interest in the US.

4 What are the implications of the FSMA for food exporters to the US?

It is not possible to provide a complete assessment of the effect of the FSMA on the competitiveness of the foreign origin supply chains because full implementation will likely be considerably delayed – 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 of imported food to be fully implemented (Sawka and Kerr, 2010). Much of what ultimately affects exporters' competitiveness will arise from future regulations developed by the FDA. Exporters need to remain vigilant as the new US regulatory environment pertaining to food safety unfolds.

Exporters of agri-food produce and products to the US and US domestic importers will eventually be subject to much closer scrutiny of their food safety controls under the FSMA. This applies equally to all foreign suppliers of the US, including those from jurisdictions with high food safety standards such as the EU. The legislation has raised the bar for entry of agri-food products into the US by imposing additional minimum requirements. Importing firms will be accountable for food safety due to the new importer verification requirements and this, in turn, implies that foreign suppliers will be directly responsible for complying with the new regulations when they are eventually developed. As with their US counterparts, EU suppliers will have to comply with registration requirements, increased FDA requests for access to records, undertake hazard analysis in ways specified by the FDA, implement preventive controls and performance standards, put in place product tracking systems and engage in increased recordkeeping activities. While these processes are already done by firms in the EU to meet domestic standards, there is no assurance that these will be sufficient for compliance with US requirements. The US is devising regulations both for domestic production and management of supply chains as well as those for more than 150 countries. There is no assurance that these will be compatible with those that already exist in the EU.

Mitigation strategies for intentional adulteration must be put in place by firms but, as yet, these have not been developed. All these can raise the cost of sourcing in the EU and other foreign countries if the process of obtaining a verification certificate proves costly, lengthy or complex. While costs will undoubtedly rise, they will also rise for US firms. It may well be that firms in advanced markets like the EU may be better able to meet US standards than firms located in developing countries – something that could provide them with a competitive advantage. Without details, however, the required assessments cannot be undertaken to allow any new avenues of increased competitiveness to be planned for.

The FDA will henceforth require imported food to be certified to ensure compliance with US laws. This will require exporting firms in the EU 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 US 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 is to, but has not yet provided 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. Until the regulations are developed investments in these systems must be held in abeyance. Those wishing to export to the US will also need to provide training for employees or hire skilled workers to undertake verification and testing procedures. If products have to be transported to some other place for testing additional transportation costs will be incurred.

The legislation requires the FDA to develop 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 many exporting countries will have to expand and investments in new laboratories will likely be warranted. If the new testing procedures differ from existing methods in the EU new investments may also be required. This is a clear area for potential bottlenecks. Delays in developing the accreditation program increase the likelihood of delays for export supply chains. In many cases, 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 firms will be able to ship to the US 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. In short, a great deal of uncertainty exists.

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 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.

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 firms that may be excluded from audited supply chains given the fixed costs of auditing.

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.

The FSMA mandates the use of US recognized HACCP by foreign firms. While HACCP is widely used, 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, EU firms may have to alter their practices and be forced to simultaneously use a domestic 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 outside the US. Further, a system for certification and audit of the HACCP systems used by firms wishing to export to the US will have to be established. The more that the EU Commission and the European Food Safety Authority can negotiate for EU mechanisms to be granted equivalence to those being developed in the US, the less costly will be compliance for EU exporters. This should be a priority in discussions with the US.

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 product's history with its eventual distribution is a daunting task, particularly in developing countries. The US has been a laggard in traceability initiatives (Brocklebank et al., 2008) relative to, for example, the European Union. While traceability is simple in concept – and thus politically popular – it is difficult and costly in practice. Thus, mandating traceability in the US may result in considerable costs being lumbered onto both US industries and international suppliers. Again, given the extensive use of traceability systems in the EU, this is an obvious area where EU authorities should push for the granting of equivalence.

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 (Loppacher and Kerr, 2005). If there is a softening of the traceability requirement, exporters to the US should be vigilant to ensure that such changes are not made in ways that disadvantage foreign suppliers.

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 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 rigor with which inspections are undertaken (Bruce and Kerr, 1986; Kerr, et al., 1986). 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 a facility will again be able to begin exporting to the US. Those charged with protecting the market from unsafe food have little interest in when exports can actually resume. The 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 an insightful lesson (Loppacher and Kerr, 2005).

The FDA must 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 suppliers in the EU. Again, establishing such standards for a wide variety of products will require a considerable resource commitment by the FDA. As yet, there appears to be little progress toward implementation in this area. It is clearly an area where the ambitions of legislators outstrip the capacity of the regulator.

The requirements for transporting food may require investments in new shipping equipment and other related facilities. While this may represent a considerable expense for foreign firms, the same costs will be borne by US firms. To reach the new transportation standards may be much more difficult for suppliers from developing countries relative to those in the EU given the generally poor state of infrastructure in many of those countries.

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 also 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 personnel will be more prone to make mistakes – mistakes that can be costly for exporting firms. Delays in implementation play havoc with the investment that will have to be made for EU firms to continue to access the US market. 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 rolled out over the next few years.

5 The FSMA and international trade commitments

The FSMA provisions fall largely 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 Favored 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 commitments 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 a presumption that foreign facilities are riskier than US facilities – in fact EU facilities may represent less risk given stringent EU regulations. Inspections will, however, still have to be undertaken. 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 in the EU represent a greater food safety risk than domestic facilities to the satisfaction of a WTO Disputes Panel. This provision of the FSMA could be challenged at the WTO.

A potential source of inconsistency of the regulation with WTO rules is the exemption of small scale US producers from HACCP requirements. This exemption has not been extended to foreign small scale 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 may be small.

As the FDA develops 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 by EU authorities 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 EU 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 foreign food meets scientifically-based food safety requirements – as they do in the EU – they should not be excluded from the US market based on the production or harvesting methods used. Mandating the use of an exclusive US HACCP standards might also be considered a PPM.

6 Conclusion

The FSMA represents a major attempt at strengthening the safety of food consumed in the US. While one might question the efficacy of the changes in delivering greater food safety, the intent is clear. Once implemented, it could increase the trust of US consumers in EU food products leading to opportunities for market expansion. 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 US and foreign firms will have to bear that cost if they wish to continue to supply the US market.

The effect on competiveness 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 EU and other 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 has yet to develop a host of new FSMA regulations. These must be assessed as to whether they discriminate in favour of US supply chains.

It is also clear that the costs of the FSMA will fall on US exporters. Import competing firms outside the US that compete in the international market will not be lumbered with these costs. Thus, the competitiveness of US exporters should decrease. Some EU firms should be able to capitalize on this opportunity.

The FSMA appears to be a major undertaking with a very large responsibility placed on the FDA. Bottlenecks to exporting are bound to appear which will be very frustrating for EU firms. Private industry in EU should avail themselves of any opportunities provided by the FDA to have input into the implementation of the FSMA and EU authorities need to proactively monitor implementation to ensure it complies with US international obligations at the WTO. Food systems can adapt to major regulatory changes but the dynamic forces arising in the process of implementation can complicate adjustment and increase its costs.

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