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THE FDA'S FOOD SAFETY MODERNIZATION ACT AND ITS ECONOMIC IMPLICATIONS

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The 111th Congress enacted the FDA (Food and Drug Administration) Food Safety Modernization Act (FSMA) which was signed into law by President Obama on January 4, 2011. This is the first comprehensive reform of FDA food safety policy since the Federal Food, Drug, and Cosmetic Act was enacted in 1938, although the food safety programs of the U.S. Department of Agriculture's FSIS (Food Safety and Inspection Service) and EPA (Environmental Protection Agency) had been modified in the interim.

This article begins with a synopsis of the major provisions of the FSMA. A side-by-side comparison of the new and old legislation can be found in Knutson and Ribera (2011). The article then emphasizes the potential economic impacts on the agrifood industry, the issues not addressed by the new law, and several of its intended and unintended consequences.

Synopsis of the FSMA

The most important policy change contained in the FSMA is that it authorizes and mandates that the FDA pursue a science-based and a risk-based food safety policy. Policies based on science incorporate considerations of the level of risk in designing a regulatory framework. Such an approach recognizes that resource limitations require identification of the greatest risks and that those resources should be focused on the greatest opportunities and benefits to reduce risk. In 2010, the National Academy of Sciences gave strong endorsement for the need to adopt a risk based approach to food safety. Arguably, while FDA has pursued elements of a science and risk-based approach, this mandate gives FDA authority to implement this approach.

The major FSMA strategy for implementing a science- and risk-based approach to food safety policy is the mandate for the use of Hazard Analysis Critical Control Point (HACCP) procedures. The FSMA requires the development and implementation of HACCP plans for food-handling facilities including on-farm packing and holding facilities. The HACCP plan must include identifying: (1) reasonable foreseeable hazards, including those that may be introduced as a result of terrorism; (2) preventive controls and control points to minimize, prevent, or control hazards; (3) means of monitoring the effectiveness of preventive controls; (4) corrective actions to be taken if controls are found to be ineffective; (5) means of monitoring and verifying the adequacy of controls, including maintaining two-years of monitoring and verification records; and (6) provisions for reanalyzing the HACCP plan every three years. FDA is required to issue benchmark performance standards to serve as a guide for controlling processing risk and determining food safety. In the rulemaking process, the FSMA requires FDA to set forth the on-farm packing, holding, manufacturing, and processing activities that are proposed to be covered by the HACCP requirements.

To provide an up-to-date enforcement registry, all food handling facilities are required to register with the FDA every two years and cannot be sold in interstate commerce without being registered. The power to cancel registration then becomes a tool for enforcing the law. FDA is given the power to investigate a facility if it believes that there is a reasonable probability that use or exposure to a food item handled in the facility will cause serious adverse health consequences or death to humans or animals.

FDA's authority to regulate farms has been an issue since its creation in 1938 (Burrows 2008). As a result of this controversy, FDA's regulation of farms has been limited to guidelines recommending production, harvesting, and handling Good Agricultural Practices (GAPs). Under the FSMA, on-farm produce handling, holding, and packing

operations are treated as a food facility which is required to develop and implement a HACCP plan. This requires that produce farms establish science-based minimum standards for safe production and harvesting of fruits and vegetables that are raw commodities, to minimize the risk of serious adverse health consequences or death.

While the law does not use the HACCP verbiage, probably because it is very controversial with farmers, FSMA reads like a HACCP plan that must be developed and implemented by produce farms. For imported products the FSMA appears to shift the responsibility for enforcement of its science-based food safety measures from FDA to importers. It does this by requiring that importers perform risk-based foreign supplier verification analyses to assure that imported foods are produced in compliance with HACCP procedures and are not adulterated or misbranded.

Realizing the potential adverse implications for small businesses, the Congress added a number of exemptions near the closing of the 2010 lame-duck session. The nature and implications of these exemptions will be discussed below.

Economic Issues and Impacts

Several economic issues are raised by the FSMA. Some of these issues are matters of definition, which are required to be studied and addressed in the process of FDA implementation. For example, FDA is required to determine size definitions for small or very small businesses.

Other economic issues relate to the costs imposed on the public and the private sectors. These costs frequently have important unintended consequences, the magnitude of which can be influenced by how the law is implemented. Economists with expertise in food, agribusiness, and agriculture can make significant contributions to analyzing such issues and, thereby, assist in designing realistic implementation provisions where the potential consequences can be taken into consideration.

Budget Constraints

The Congressional Budget Office (CBO) scored the FSMA as increasing the cost of FDA food safety regulations by $500 million. The overall estimated $1.4 billion price tag for food safety regulation will likely receive much attention in these times of substantial budget constraints at the federal, state, and local levels. Considering the federal budget constraints and the resolve of the House Republican majority to cut spending, FDA undoubtedly will look for and take advantage of every opportunity to pass as many of the implementation costs as possible to the state and local governments and to the private sector. This is an important point since state and local health officials have been a front line for inspection of food facilities, which appears to be the highest cost component of the FSMA. With state and local governments also being strapped for cash, this pass-down strategy is likely to meet with substantial resistance. With increased authority for accreditation of third-party inspectors and laboratories, FDA will also likely pursue a strategy of passing as many costs as possible to the domestic private sector. Importers will try to pass the costs of compliance verification on to their sources of supply. Foreign governments interested in increasing their country's exports could end up bearing the costs of developing new export-oriented programs.

Costs of Compliance and Market Structure Impacts

The FSMA will place substantial costs on the private sector. These costs will have significant structural impacts and raise food prices. These conclusions are based on economic logic backed by analyses of the impacts of the implementation of virtually identical food policies and programs by FSIS/USDA (United States Department of Agriculture), for similar programs implemented by the Leafy Green Marketing Agreement (LGMA), and by research indicating the impacts of food safety import regulations.

The most revealing and documented studies of private sector cost impacts were associated with the 1997-2000 implementation of HACCP for meat and poultry plants. Complying with the regulations would be expected to impose substantial variable and fixed costs associated with the development and implementation of the required HACCP plan. As a result of the relatively high fixed costs, the average costs were projected to increase at a decreasing rate as the size of plant increased. Therefore, smaller plants would be much more adversely impacted than larger plants.

A series of studies of the costs and benefits of HACCP were published, the most revealing of which are suggested for further reading. The Unnevehr (2000) and Hooker et al. (2002) publications indicate a range of compliance costs of $0.0004 to $0.4351 per pound of meat with most analyses being in the $0.02 to $0.20 per pound cost range. Subsequently, Muth et al. (2007) confirmed the hypothesized structural impacts of the FSIS HACCP policies with the

finding that very small and small meat packing plants were the most likely to exit during the pathogen reduction HACCP implementation period.

Concerns about market concentration extend throughout the food processing and retailing industry. From a market structure perspective, smaller plants represent the competitive fringe of firms that provide important elements of competition in otherwise highly concentrated markets. Therefore, regulatory activity that adversely affects the competitive fringe also can be expected to have adverse effects on competition. As a consequence, the exit of smaller firms not only adversely affects costs, but also affects consumer choice, including product diversity and product prices. In implementing the FSMA, FDA needs to take into consideration the adverse consequences of their regulatory decisions for food industry costs, for the structure of the food industry, for product diversity, and for food price impacts. This is an important area that warrants further study.

Food Facility Size Considerations and Exemptions

To garner the votes needed for passage, the FSMA gives FDA an opportunity to exempt small and very small facilities from certain regulatory requirements. However, the size specifications for a small and a very small business and the specific nature of the exemption will be unclear until the rule making process is completed in about 18 months. To the extent that precedence plays a role, federal government definitions of small businesses varies by agency. FSIS defines a small plant as having between 10 and 500 employees and a very small plant as having fewer than 10 employees or less than $2.5 million sales annually. The Small Business Administration (SBA) defines a small food processor as having less than 500 employees.

Being a small or very small plant appears to give food facilities regulated by the FSMA more time to comply with federal or equivalent state standards, unless the majority of its distributions are through direct marketing. However, from an economic perspective, FDA should be interested in: (1) the type and size distribution of facilities in terms of both numbers and percent of facilities and products; (2) related foodborne illness experience; (3) the cost of compliance by type and size of facility, which the FSMA apparently does not recognize; and (4) the potential impacts on the market structure. FDA needs to strike a balance between food safety, the law's primary objective, and market performance. Economists should be able to help FDA in striking that balance.

Produce Facility and Farm Size Considerations and Exemptions

Arguably the produce issues are more complex than those for the processing sector because: (1) produce has experienced a substantial number of foodborne illness incidents; (2) seasonal import sources are very important; (3) like meat and poultry, products are fresh and comingled; (4) on-farm harvesting, handling, holding, and packing functions are often done as an extension of production; and (5) the sources of adverse health consequences are more diverse and are more difficult and costly to control. Continuing periodic foodborne illness outbreaks experienced by meat and poultry suggests that HACCP is not a magic bullet and that on-farm HACCP-type controls are important components of a food safety policy.

Much can be learned by FDA from studying both the LGMA experience, and from the experience of retailers that are in the process of implementing HACCP-type systems at the farm level. The LGMA was established in 2007 and under its terms signatory members are required to verify compliance with a specific set of food safety practices by submitting to mandatory government audits. To date close to 99% of the volume of California leafy greens are grown with practices that fall within the standards of the voluntary grower, packer, and shipper initiative. USDA has recently endorsed the creation of the National Leafy Greens Marketing Agreement, based on the success of the LGMA.

While both the tone and the verbiage of FSMA farm produce provisions provide for "flexibility" and are less specific than for processing plants, the prescription appears to be for the application of science-based and risk-based HACCP-type procedures and standards. These standards for production and harvesting are to be applied to all produce operations except in cases where particular types of fruits or vegetables are determined to be a low risk and do not present a risk of serious adverse health consequences. Also, small and very-small farms are given two important considerations: (1) small farms are given one extra year for compliance and very small farms are given two years for compliance, and (2) farms that market direct are exempt if their three-year average annual sales are less than $500,000 and their scope of distribution is either intrastate or within a 275 mile radius.

Defining a small farm is more complex than it appears. The Economic Research Service/USDA defines a small farm as one having less than $250,000 sales (Ahearn, 2011). A very small farm is defined as one that has less than $10,000 sales. While these definitions are a general benchmark, they are not very helpful because little is known

about the specifics of produce farms. While larger produce farms may specialize in commodities, smaller farms are frequently diversified.

Very little data is available on the costs of complying with food safety standards, such as the LGMA standards. What data are available is either anecdotal or has not been broken down or analyzed by size of farm, which is an important and basic need for developing a sound policy approach to on-farm HACCP-type regulation. A small number of international studies have found that many small farms were denied access to U.S. export markets resulting from imposed regulatory requirements following foodborne illness incidents. If not carefully designed, HACCP-type regulation could result in small and very-small produce farms being limited to direct marketing where food safety regulation under the FSMA is lacking. In the process, an important segment of the competitive fringe of produce farms would be eliminated from commercial produce markets.

Remaining Issues and Prospects for the Future of Food Safety Policy

Traceability

Identifying the source of a foodborne illness outbreak requires the ability to trace its origin, which may be to a single field plot, as was the case in a 2006 spinach incident (California Emergency Response Team, 2007). Currently, the only requirement is for a retailer/processor to trace one-step forward and back in the supply chain. The FSMA mandates three pilot projects to develop and test tracking/traceability systems for three types of food having a history of food borne illness. Once the results of these pilot projects are reported to FDA, the next steps for developing and implementing traceability systems are unclear. One of the frequently cited problems involves the issue of comingling of raw materials and multiple ingredients. This issue should not be allowed to stand as a barrier to developing traceability systems. The use of traceability information identification for multiple sources is far better than no information.

An important traceability issue not addressed in the FSMA is the implementation of a reliable animal identification system (animal ID). The United States imports large numbers of feeder cattle each year having the potential for spreading zoonotic diseases, such as bovine tuberculosis or brucellosis to the U.S. cattle herd and to the general public. In addition, zoonotic incidents are regularly detected in the states where the vector is believed to be wildlife. Policymakers have bowed to the political pressures of cattle raising interest groups to avoid effectively dealing with these issues. In the meantime, the Canadian Food Agency in cooperation with its cattle industry has made substantial progress in developing and implementing an effective traceability system (for further reading see Carlberg, 2010). The animal ID lessons learned by the Canadian industry can serve as a model for both the U.S. livestock industry and for FDA in developing and implementing traceability systems.

Direct Marketing Exemption

Direct marketings were excluded from the food safety regulatory provisions of the FSMA. The magnitude of this exemption relative to the value of food sales is unknown. Available data suggest that direct local food sales by farmers account for less than 2% of farm sales, but they may account for as much as 10% of farmers' fruit and vegetable receipts. This estimate does not include farmers' direct sales to restaurants (mostly organic) and community supported agriculture, the value of which is unknown.

In addition, the FSMA allows direct marketing exemptions for distribution either intrastate or within a 275 mile radius. If the distance exemption is applied, then producers and consumers of border states could be affected as produce from Mexico and Canada that falls within a 275 miles radius of the U.S. market would be exempt. Since the FSMA may close major commercial markets to small and very-small farms, the exemption of the rapidly growing direct marketing segment as defined in the FSMA could become an even more significant regulatory loophole. Closing that loophole could become an important item for the future of the food safety agenda.

Overlapping Regulation

The National Academy of Science lists 15 federal government agencies as having food safety regulatory responsibilities. The result is major gaps and overlaps in domestic and imported food safety regulations. For example, the GAO has identified 1,451 facilities that produce foods as being regulated/inspected for similar issues/functions by two agencies. The FSMA sends a mixed message regarding this overlap issue. On the one hand, it calls for increased cooperation among the primary food safety regulatory agencies. On the other hand, it clearly states that nothing in the law alters the USDA's jurisdiction under each of its major food safety and marketing programs

Single Food Safety Agency

Under the FSMA both FDA and FSIS have responsibilities for risk-based HACCP regulation of food facilities. One would think that a single food safety agency could perform these functions more effectively than two separate agencies, to say nothing about 15 agencies with regulatory functions. Two comprehensive studies of the single food safety agency issue are by the National Academy of Sciences (2010) and by Merrill and Francer (2000). Their results indicated the best option would be for the agencies to be combined into one organization directed by a single head. The notion of a single food agency may not be a pipe dream if the Congress and the President make significant cuts in federal spending. It happened in Canada with the formation of the Canadian Food Inspection Agency (CFIA) in 1997 despite pushback from a number of the traditional departments and agencies. It was primarily a matter of a need to increase the consistency of regulations, improve efficiency, and reduce costs. And, firms regulated were fed up with multiple audits and verifications.

Summary and Conclusions

The FSMA is a very important step toward a modern science and risk-based approach to food safety but it most certainly is not comprehensive. Substantial care will need to be taken in designing implementation strategies that minimize adverse structural impacts while reducing the risks of foodborne illness. Even effectively implemented, food safety is likely to be on the policy agenda for several years to come.

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