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Provisions and Economic Implications of FDA's Food Safety Modernization Act

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Agricultural and Food Policy Center

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Ron Knutson and Luis Ribera

Introduction

After many years of deliberation a new food safety law, the FDA Food Safety Modernization Act, was enacted during the lame duck session of the 111th Congress and subsequently signed by the President. This new law, hereinafter referred to as the Food Safety Modernization Law (FSML) was more than just a response to many recent foodborne illness incidents. The basic provisions of the previous law, dating back to as many as 70 years, has been ill-equipped to deal effectively and efficiently with contemporary food safety issues (Center for Science and the Public Interest 2009). The Congress and the FDA needed to update and reflect in U.S. food safety policy: (1) the global nature of the food system; (2) the increased importance of both fresh/raw and highly processed products in diets; (3) the increased importance of away-from-home consumption; and (4) the tremendous technological changes that have taken place in food production, handling, transporting, processing, and retailing.

In addition to reviewing the provisions of the new law, this paper discusses its potential economic impacts on the agrifood industry, the issues not addressed, and the research and extension implications and challenges. Also addressed will be several intended and unintended consequences of the new law. For example, while steps are taken to better coordinate a maze of food safety programs, there remains 15 federal agencies administering at least 30 food safety laws (GAO 2009). The regulatory activities of these agencies will need to be better coordinated if the objectives of the new law are to be realized. Despite all of these laws and agencies, several gaps remain in the food safety coverage that will likely be the topic of continuing debate and future legislation. In addition, while the new food safety law provides several largely undefined exemptions for small businesses, past changes in food safety regulation suggest that the costs and complexities imposed on the private sector creates the potential for major changes in the structure of the food industry. Finally, the 119 pages of legislative verbiage leave extensive room for administrative interpretation in the rule-making implementation process.

Historical Perspective on Food Safety Policy

While the charter for the formation of the U.S. Department of Agriculture (USDA) said nothing about either food safety or assuring the purity of the food supply, its agricultural and food industry knowledge base made USDA a logical initial home for these functions. The federal government food safety mission began in 1906 following the investigative reporting of Upton Sinclair, whose book *The Jungle* exposed the unsanitary conditions that existed in the Chicago meat packing business. *The Pure Food and Drug Act* (PFDA), prohibiting adulteration, and *the Meat Inspection Act* (MIA), placing federal inspectors in meat processing plants, became law on the same day. Curiously, the regulation of seafood was placed in the Department of Commerce (DOC), where this responsibility is currently shared with the Food and Drug Administration (FDA).[1] From its beginnings, there was conflict within USDA over how tightly the PFDA should be enforced (Merrill and Francer 2000). In 1938, federal food safety law was substantially expanded with an emphasis on curbing the marketing of untested drugs, the inclusion of unsafe food additives, false labeling, and the lack of ingredient labels. However, it was not until 1940 that FDA was moved from USDA to the Federal Security Agency (FSA) with the Public Health Service. In 1953, FSA became the Department of Health, Education and Welfare (HEW) and in 1979 it became the Department of Health and Human Services (HHS), where FDA is housed today. Responsibility for pesticide regulation was moved from USDA to the Environmental Protection Agency (EPA) in 1970. Rounding out the list of primary agencies regulating food safety, the Center for Disease Control (CDC) was established in 1947 with a primary objective of fighting malaria (CDC 2011).

From a current perspective, notwithstanding the enactment of the FSML, the responsibility for food safety in 2011 rests with five primary agencies (Rawson and Vogt 1998).

- USDA's Food Safety and Inspection Service (FSIS), is responsible for administering the Federal Meat Inspection Act, the Poultry Products Inspection Act, the Egg Products Inspection Act, and the Humane Methods of Slaughter Act. In 2010, FSIS employed over 9,500 personnel, including around 7,800 full-time in-plant and other front-line personnel protecting the public health in approximately 6,200 federally-inspected establishments (Mande, 2010). In addition, FSIS is responsible for seeing that about 30 state meat and poultry inspection operations are operating with standards that are at least equivalent to the federal standards. As a major policy change, FSIS initiated the adoption of HACCP, which was adopted in 1996. Previously, FSIS inspectors utilized organoleptic (sight, touch, and smell) procedures for individual carcass inspection.

- FDA is responsible for ensuring that domestic and imported foods, except for meats and poultry, are safe, sanitary, nutritious, wholesome, and honestly labeled (CRS 1998). Since 1938, these responsibilities have been carried out under the statutory rubric of prohibitions of adulteration and misbranding, which itself spoke for the need for updating food safety regulation (Johnson *et al.* 2010). Despite a general lack of mandated authority, FDA had refined and adopted HACCP procedures for low-acid processed foods, specified drinks and seafood. Legal questions regarding its authority have led FDA to limit its regulation of potentially hazardous on-farm activities to issuing good agricultural practice (GAP) guidelines (Burrows 2008). In cooperation with its state public health counterparts, FDA has statutory authority for ensuring sanitary operations of over 250,000 licensed

[1] This initial division of responsibilities appears to have been a case of dividing up the regulatory spoils of the 1906 Act. The Departments of Treasury, Agriculture, and Commerce were designated to write the rules for implementing the food safety statute. Historically both USDA and FDA have contended that they are better equipped to regulate seafood than the DOC (Merrill and Francer).

domestic food operations and 165,000 international establishments. It has responsibility for conducting federal inspection-related activities of over 65,000 food establishments. It was expected to carry out these responsibilities with an FY 2009 budget of about $650 million, a Center for Food Safety and Applied Nutrition (CFSAN) staff of about 800 and a field staff of about 2,500 (Shames 2008 and Johnson *et al.* 2010). In addition, FDA holds statutory authority for ensuring sanitary operation of 700,000 establishments for which state public health authorities are responsible for inspection. The daunting task that has faced FDA is indicated by comparing the field staff of the FDA (2,500) with that of FSIS (7,800).

- DOC's National Marine Fisheries Service maintains a cooperative inspection agreement with FDA, the primary agency responsible for ensuring the safety, wholesomeness, and labeling of domestic and imported seafood products. For the approximately 20 percent of the fish that is consumed domestically, U.S. based fishing vessels and plants are inspected on a user fee basis. A primary inspection activity involves conformance with FDA's HACCP guidelines for seafood. FDA maintains responsibility for inspecting seafood import facilities.

- Environmental Protection Agency (EPA) has responsibility for ensuring that chemicals used on crops do not endanger public health. It accomplishes this task by the statutory requirement that all new pesticides be registered. Periodically, with cause, groups of pesticides may be required to be reregistered. Pesticides have been defined to include plant-incorporated protectants that are the product of genetic modification of plant materials (Phillips, 2011). Registrations are based upon review of the applicant's required detailed analyses of pesticide safety for the health of consumers, animals, farmers, workers, and handlers of pesticides and for their longer-term environmental effects.

- The Centers for Disease Control and Prevention (CDC), like FDA, is an agency within HHS. Its Food Safety Office (FSO) has primary responsibilities for prevention of foodborne illness diseases. Its main activities include: supporting epidemiology, laboratory, and environmental health capacity at the state and local levels; providing information and recommendations based on public health surveillance and epidemiology through programs such as FoodNet; and maintaining links with FDA and USDA (Food Safety Office Website 2011).

Many other agencies could be listed as affecting food safety. For example, USDA's Animal and Plant Health Inspection Service (APHIS) has responsibilities for protecting the health of animals and plants from domestic and international sources. In addition to protecting the food supply, APHIS protects against the transmission of animal diseases, some of which are transmittable to humans (Knutson and Ochoa 2007). *The Organic Foods Production Act* (1990), administered by AMS/USDA, authorize the establishment of standards for the production of organic standards for organic foods. Ironically it gives little or no attention to the safety of organic products. AMS/USDA also offers on a user fee basis third-party inspection audits for compliance either public or private sector food safety standards. At the state level, the California Department of Food And Agriculture established the California Leafy Green Products Handler Marketing Agreement (LGMA) in 2007 as a cooperative public-private sector good agricultural practices (GAP) audit program to assist in cubing foodborne illness outbreaks in fresh leafy green produce (LGMA, 2011). Under the LGMA over 100 handlers, representing approximately 99% of the volume of California leafy greens, have committed themselves to sell products grown in compliance with the food safety practices through a system of mandated audits.

Side-by-Side Comparison of Food Safety Policy/Program Changes

This section provides a side-by-side comparison of the FSML with the previous law. This compassion was developed utilizing a combination of the FSML as signed by the President and an excellent side-by side CRS (2010) compilation of previous law provisions compared with the House (H.R. 2749) and Senate (S. 510) passed bills prior to final amendments. While the final bill passed by both houses of the Congress (H.R. 2751) tracked S. 510 closely, the adopted amendments were significant, largely because of the exemptions they contained.

In reviewing this side-by-side comparison it is important to recognize that the authors have done a great deal of condensation of the provisions of both the current law and of the previous law. In the following discussion only the major changes in policy and those that present important economic questions. These questions will be discussed in a subsequent section. Readers interested in further details are encouraged to read the FSML, which is actually quite readable. However, the previsions and impacts of all legislation depend on how it is implemented. Finally, at various points in the law, emphasis is placed on the expectation that its provisions shall be carried out in coordination among FDA, as the primary implementing agency, and the other agencies having food safety responsibilities (primarily USDA, DOC, CDC, and EPA). Contrariwise, the point is made at various points that the FSML shall not affect the provisions and implementation of the current laws as administered by other agencies. This potential incongruity will likely present implementation issues and could become the basis for future changes in food safety policies and programs. Examples will be presented subsequently. To the extent possible, this side-by-side comparison section is written without evaluation, which will be the topic of subsequent sections.

Proactive prevention of foodborne illness and death

The provisions and implementation of the previous law placed emphasis on dealing with issues of food adulteration, contamination, misbranding, and labeling in an ex post manner. That is FDA followed up on reports of illness outbreaks and complaints received by FDA field staff and their state public health counterparts. The new law defines an illness outbreak as two or more cases and places substantially greater emphasis on prevention and early detection. For example, the FSML states that there exists sufficient cause for FDA to investigate food handling a facility if "The Secretary believes that there is a reasonable probability that use or exposure to an article of food … will cause serious adverse health consequences or death to humans or animals …. (Section 101)

Registration

While the previous law required registration of food handling facilities, it had no provisions designed to keep a current register of all facilities. The effect was to make it difficult for FDA to efficiently and effectively follow up on the potential scope of a foodborne illness associated with a particular food. The FSML remedies this problem by requiring biennial registration of domestic and foreign food-handling facilities. Exempt from FSML registration are farms, roadside stands, farmers' markets, community-supported programs, and other direct farmer sales. The previous law exempted farms, restaurants, retailers, fishing vessels, and certain nonprofit establishments, but was unclear regarding direct farm sales.

The FSML provides authority to inspect food handling facility records and related premises if it is believed that there is reasonable probability of adverse health consequences. However, such inspections should be at reasonable times, within reasonable limits, and in a reasonable manner. In the event a violation is found of the FSML, FDA is given the authority to revoke the registration, meaning that operations at the facility can be shut down. Under the previous law, inspections depended on evidence of adulteration and foodborne illness incidents. The ability of FDA to shut down a business was severely limited and required clear evidence of harm, illness, or death.

HACCP

The FSML requires the development and implementation of HACCP plans for food-handling facilities including on-farm packing and holding facilities. The HACCP plan must include: (1) identify of reasonable foreseeable hazards, including those that may be introduced as a result of terrorism; (2) identify preventive controls and control points to minimize, prevent, or control hazards; (3) identify means of monitoring the effectiveness of preventive controls; (5) identify corrective actions to be taken if controls are found to be ineffective; (6) identify means of monitoring and verifying the adequacy of controls, including maintaining two-years of monitoring and verification records; and (7) provisions for reanalyzing the HACCP plan every three years. FDA is required to issue benchmark performance standards that would serve as a guide for controlling processing risk and determining food safety. In the rulemaking process, the FSML requires FDA to set forth the on-farm packing, holding, manufacturing, and processing activities that are proposed to be covered by the HACCP requirements.

The previous law contained no explicit statutory authority for the promulgation of HACCP regulatory procedures. However, FDA had developed and implemented HACCP rules for high-risk products including thermally-processed low-acid foods, seafood, and juice. For other high-risk products and businesses, including on-farm packing and holding facilities, voluntary guidelines and safeguards had been issued. The previous law provided no benchmark performance standards for controlling processing risk or determining food safety.

The FSML contains extensive verbiage regarding the application of HACCP requirements to small businesses and to very small businesses also referred to as "qualified facilities." These provisions will likely only be fully understandable following authorized studies of the appropriate definition for small and very small businesses. In the meantime, it appears that a very small business has sales of less than $500,000 adjusted for inflation. Moreover, small and very small businesses will have 6-month and 18-month flexibility, respectively, for compliance with FSML provisions.

The "exemption" for a very small qualified business requires submission to FDA documentation that potential hazards have been identified, that preventive controls are being implemented, and that a monitoring system for preventive controls exists to assure that the controls are effective. Alternatively, the very small facility may submit documentation that the facility is in compliance with applicable non-federal food safety laws. This alternative has similarity to the FSIS regulation providing a state compliance alternative for plants that do not sell products in interstate commerce. However, for FSIS there is a federal-state food safety standard and inspection equivalency requirement, which is not readily apparent in the FSML. Under the FSML the food must be properly labeled for all facility sizes.

Produce provisions and FDA regulation of on-farm activities

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 GAPs. In the face of persistent foodborne illness outbreaks related to produce, the LGMA was developed. LGMA has been considerably more aggressive in regulating on-farm activities than the FDA guidelines (Paggi 2010 and Palma *et al.* 2010). Likewise, EPA pesticide regulation has been more aggressive in regulation on-farm activities than FDA (Knutson *et al.* 1990 and Knutson *et al.* 1994).

The full scope of produce regulation contained in the FSML can only be fully understood by combining the regulations of two sections: (1) increased regulations for on-farm handling, holding, and pack operations, are treated as a food facility, as discussed in the previous section; and (2) the "Section 105 Standards for Produce Safety" regulating farming and harvesting activities. Therefore, a typical produce grower-shipper would be regulated both by the food facility regulations as a processor and as a farmer.

Section 105 authorizes FDA to establish science-based minimum standards for safe production and harvesting of fruits and vegetables that are raw commodities to minimize risk of serious adverse health consequences or death. It specifies that such standards shall be: (1) sufficiently flexible to be applicable to a wide range of entities producing and harvesting fruits and vegetables, including small businesses; (2) include with respect to growing, harvesting, sorting, packing, and storage operations science-based minimum standards related to soil amendments, hygiene, packing, temperature controls, animals in the growing area, and water; (3) consider hazards intentionally or unintentionally introduced; (4) take into consideration conservation, wildlife, and environmental standards; and (5) for organic farms

not conflict with or preempt *Organic Production Act of 1990* standards but shall provide the same level of health protection as for other farms.

The FSML produce section provides for FDA "flexibility" in applicable production and harvesting standards. This is particularly the case for small and very-small farm businesses producing products having low-risk of serious adverse health consequences for which the standards may be modified or eliminated. Likewise, exempt are direct farm marketings by farms having sales of less than $500,000. Direct marketings include sales to consumers, restaurants, or retail food establishments located within the state or with 275 miles from the farm. Small and still covered by the regulations, following these exemptions, would have one extra year while very-small farms would have two years to comply.

Inspection, reinspection, and related fees

The FSML authorizes risk-based and compliance-based inspection. However, it requires that inspections of domestic facilities take place a minimum once within five years and thereafter once every three years. Inspections of foreign facilities exporting to the United States, which in the past have been very low, are accelerated sharply on an annual basis, from an increase of 600 in year-one and doubled each year thereafter. However, foreign FDA inspections likely will still represent a small share of import facilities for a number of years once all facilities become registered. High-risk and noncompliant facilities will be subjected to more frequent inspection. The FSML provides authority for the imposition of fees to cover the reinspection costs including administrative expenses.

Sample food testing

In the past, FDA product testing has been limited to the ex post identification of the specific microbiological causes of foodborne illness, the presence of contaminants, or the product contents. Neither the authority nor the resources were provided for random sampling of food to test for compliance. The FSML specifically authorizes sample food testing as deemed appropriate by FDA or on behalf of facility owners.

Food recalls

Except for infant formula, the previous food safety provisions were dependent on voluntary recall compliance by the facility owner/manager. Voluntary recall created the potential for time delays in initiating and accomplishing the recall of food that had been demonstrated to cause foodborne illness or was misbranded. The FSML authorizes mandatory food recall if food is found to be adulterated, misbranded, or will cause adverse health consequences or death in humans or animals. As a related requirement it directed FDA to develop science/risk-based record keeping requirements and grocery store/consumer food safety notification systems.

Traceability

The ability to trace the origins of foodborne illness or other contaminants is basic to remedying food safety problems. The previous law required that the facility keep records of the immediate previous product source and the immediate subsequent recipient of the food. This so called one-step before/after approach to the traceability has been helpful but it generally does not ensure the ability to identify the ultimate source for farm-level origins or for many imported products. The FSML recognized that there is no easy solution to the traceability problem. As a result, it mandated the development and testing of pilot tracking/traceability systems for three diverse types of food having a foodborne illness history. At least one of these pilot traceability systems shall be for fresh produce and one other for a processed product.

Importer compliance verification

The FSML requires 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. As for domestic facilities, records must be maintained for a two-year period and produced as requested by FDA. Consistent with this requirement, foreign facilities may voluntarily receive a certification that they operate in a manner that ensures compliance with U.S. food safety standards. In cases where safety risks are known to exist, FDA may require certification that the product complies with the requirements of the FSML and indicate the certified facilities at which the product is being produced. To facilitate this process of importer certification, FDA is authorized to enter into arrangements with foreign governments to inspect foreign facilities, suppliers, and food types, which may be supported by foreign capacity food safety building programs.

Smuggled food imports

While all food entering the United States is required to be declared and inspected, smuggled food is sometimes adulterated, mislabeled, and the potential cause of serious adverse health consequences or death. For example, cheese produced in Mexico from raw milk and improperly aged is regularly reported by public health officials in California to be smuggled across the Mexican board, is often sold, and is frequently a source of serious foodborne illness outbreaks (Knutson *et al.* 2010). The FSML directs FDA in coordination with DHS to develop and implement a strategy for better identifying smuggled food and for preventing its entry into the United States.

Increased field staff and increased appropriation authorizations

Johnson *et al.* (2010) reports that in FY 2010 FDA had 2,505 field staff, which primarily carry out inspections. The FSML mandates an increase to 4,000 in FY 2011 and annually thereafter reaching 5,000 in FY 2014. The FSML authorizes appropriations in such sums for FY 2011-15 as is necessary to carry its specified provisions and activities. CBO scoring indicates that the FSML will cost an additional $1.4 billion to implement over these five years (CBO 2010). FDA's FY 2010 appropriations were $784.1 million (Johnson *et al.* 2010)

Accreditation for third-party inspectors and laboratories

The FSML recognizes that, despite the increased field staff and appropriation authorizations, many of the mandated inspections cannot be carried out without the use of certified third-party inspectors and certified food analysis laboratories. Therefore, the FSML provides for FDA to establish accreditation procedures to be applied to both domestic and foreign facilities. Previously, there were no third-party accreditation/certification procedures.

Economic Issues and Impacts

Up to this point the content of this paper has been based on the factual content of the food safety laws. The remainder of the paper is analytical in nature and is designed to explore the economic consequences of the FSML as it is being implemented.

Several economic issues are raised by this legislation. Some of these issues are matters of definition, which are required by the FSML to be studied and addressed in the process of FDA implementation. For example, FDA is required to determine the size parameters for a small or very small business. 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 having expertise in food, agribusiness, and agriculture can make significant contributions to analyzing such issues and, thereby, assist designing realistic implementation provisions where the potential consequences can be taken into consideration.

Consequences of budget constraints

The $1.4 CBO estimated price tag associated with this legislation will likely receive much attention in these times of substantial budget constraints and the federal, state, and local levels. Considering the federal budget constraints and the resolve of the new 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 FSML. With state and local governments also being strapped for cash, this strategy is likely to meet with substantial resistance, but yet is a likely reality. Also, with increased authority for accreditation of third-party inspectors and laboratories, FDA will likely pursue a strategy of passing as much costs as they can/are allowed to the domestic private sector. Importers will have incentives 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 FSML will place substantial costs on the private sector. These costs will have substantial structural impacts. They will also raise food prices. These declaratory conclusions are based on economic logic/theory backed by analyses of the impacts of the implementation of virtually identical food policies and programs by FSIS/USDA, for similar programs implemented by the LGMA, and by research indicating the impacts of food safety import regulations. The impact analyses conducted in each of these areas will be discussed separately.

The most revealing and documented studies of private sector costs impacts were associated with the 1997-2000 implementation of the Pathogen Reduction and Hazard Analysis and Critical Control Points (PR/HACCP) for meat and poultry plants. In requiring the development and implementation of HACCP plans, all plants were required to implement Sanitation Standard Operating Procedures (SSOPs) and pathogen testing. During the rule-making process and prior to implementation of these regulations (at the time commonly referred to as mega-regs), Knutson *et al.* (1995) completed a detailed interdisciplinary economic/food science study[2] of the prospective economic impacts of the proposed food safety regulations. They found that complying with the regulations would impose substantial fixed costs associated with the development and implementation of the required HACCP plan and substantial variable costs. 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. The study concluded that many plants could reasonably be expected to discontinue operations if the proposed regulations were implemented and that the magnitude of these adverse impacts would be inversely related to the size of plant. That is, smaller plants would be much more adversely impacted than larger plants.

When the Knutson *et al.* study was submitted to FSIS/USDA during the rule making comment period, it was dismissed as overestimating both the costs and the economic impacts of the proposed regulations (USDA, 1996). USDA found a cost difference of less than $0.0011 to $0.0013 per pound of products. It was then asserted that extra time for small plant compliance would negate any cost disadvantages

[2] One of the food scientist was previously an administrator of FSIS and another wash responsible for administering the Texas A&M University meats laboratory, which included a slaughtering and processing facility.

on small firm. This argument appears to be based on the dubious assumption that over time the costs for small and larger firms would become equal.

Thereafter, a series of studies of the costs and benefits of HACCP were published, several of which were published in the excellent compendium of articles edited by Unnevehr (2000), by Crutchfied *et al.* (1999) and by Unnevehr and Jensen (1999). Subsequently, Hooker *et al.* (2002) provide an overview of the compliance cost results for these studies and for their primary data analysis. Their review found a compliance cost ranges of from $0.03 to $0.17 per pound by Antle (2000) to $0.0004 to $0.4351 by Nganje and Mazzocco (2000). The Hooker *et al.* analysis indicated a cost range of from $0.02 to $0.20 per pound and an average of $0.05 per pound.

Subsequently, Muth *et al.* (2002) completed a study designed to determine which characteristics of meat slathering plants contributed most to the probability that a plant exited the industry during PR/HACCP regulatory implementation. While controlling for other plant characteristics that affect plant exit, the analysis found that very small and small plants were the most likely to exit during the PC/ HACCP implementation period. The ex post analysis results confirmed the conclusion reached by the series of independent studies cited in this section that the PR/HACCP regulations would more adversely impact small plants than their larger counterparts and that the regulations likely contributed to the exit of many small firms from the meat packing industry.

Concentration in the meat packing industry and has been the subject of substantial economic analysis (Purcell, 1997) and political criticism (GIPSA, 1996). Concerns about concentration extend more generally through the food processing and retailing industry as demonstrated by the Farm Foundation/ American Agricultural Economics Association sponsored conference featuring a series of presentations by leading agricultural economic analysts on the economics of structural change and competition in the food system (Farm Foundation, 2010). From a market structure perspective, smaller plants represent the competitive fringe of firms that provide important elements of competition in otherwise highly concentrated markets (Fellner 1960 and Knutson 1968). 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 competitive and consumer choice factors such as product diversity and product prices. The clear implication from this analysis is that, in implementing the FSML, FDA should be aware of, concerned about, and 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. For economists, this is an important area for further analyses.

Food facility size considerations and exemptions

As noted in the side-by-side comparison, both the size specifications for a small and a very small business and the specific nature of the exemption will be unclear for at least 18 months. The rule making issue involves both the size of business and the specifics of the regulatory requirements. To the extent that precedence plays a role, federal government definitions of small businesses varies. 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. Keep in mind, however, that being a small or very small plant only appears to give food facilities regulated by the FSML more time to comply with federal or equivalent state standards. From an economic perspective, FDA should be interested in: (1) the type and size distribution in terms of both numbers and percent of facilities and products, which the FSML recognizes; (2) the related foodborne illness experience, which the FSML recognizes; (3) the cost of compliance by type and size of facility, which the FSML apparently does not recognize; and (4) the potential impacts on the market structure. FDA needs to strike a balance between food safety, the laws 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 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, the 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, more difficult to control, and more costly to control. Continuing periodic foodborne illness outbreaks experienced by meat and poultry suggests both 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 the FSIS experience.

While both the tone and the verbiage of FSML the farm produce provisions provide for “flexibility” and is less specific than for 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 for 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 sales are less than $500,000.

While the FSML simply instructs the FDA to define a small farm and a very-small farm, that simplicity defies its complexity. USDA defines a small commercial farm as those having less than $250,000 sales (Hoppe *et al.* 2007). A very-small (noncommercial) farm is defined as one that has less than $10,000 sales (Johnson *et al.* 2010). While these definitions are a benchmark, they are not very helpful because little is known about produce farm size. While larger produce farms may specialize in produce production, smaller farms are frequently diversified.

Also, very little data is available on the costs of complying with food safety standards, such as the LGMA standards. Research on this issue by Paggi *et al.* (2010) is the only known scientifically-sound attempt to collect and analyze the cost of LGMA compliance. Due to limited financial support, this data is not broken down or analyzed by size of farm, which is an important and a basic need for developing a sound policy approach to on-farm HACCP-type regulation (Palma *et al.* 2010b). Cervantes-Goday *et al.* (2007) 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 for which there is no food safety regulation under the FSML. 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

The FSML mandates three pilot projects to development and test tracking/traceability systems for three types of food having a history of foodborne illness. Once the results of these pilot projects are reported to FDA, the next steps for traceability are unclear. Economists devote substantial resources to analyzing supermarket scanning data. Surely these systems can be further developed and utilized as critical tools for traceability systems. 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 FSML 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 zoonosis diseases, such as bovine tuberculosis or brucellosis to the U.S. cattle herd and to the general public (Ortega and Peel 2010). In addition, zoonosis incidents are regularly detected in the states where the vector is believed to be wildlife. Policy makers have bowed to the political pressures of cattle-raisers' interest groups not to effectively deal with these issues (Anderson 2010 and Knutson 2010). In the meantime, the Canadian Food Agency in cooperation with its cattle industry has made substantial progress in developing and implementing and effective traceability system (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. Instead of developing reliable traceability systems, regulators were forced by zealous protectionist interests to implement divisive Country of Origin Labeling (COOL) regulations (Rude *et al.* 2006).

Direct marketing exemption

In a lame duck session amendment, direct marketings were excluded from the food safety regulatory provisions of the FSML. The magnitude of this exemption relative to food sales is unknown. Available data suggest that direct local food sales by farmers account for less than 2 percent of farm sales (Martinez 2010). However, they may account for as much as 10 percent of farmers' fruit and vegetable receipts (Lucier 2006; McFadden 2011 and Martinez 2010). This estimate does not include farmers' direct sales to restaurants (mostly organic) and community supported programs, the value of which is unknown. Based on the above analysis of the potential FSML foreclosure of major commercial markets to small and very-small farms, the exemption of this rapidly growing direct marketing segment as defined in the FSML could become an even more significant regulatory loophole. Closing that loophole could become a significant item for the future food safety agenda.

Overlapping regulation

It was noted previously that the GAO identified 15 federal government agencies having food safety regulatory responsibilities. This finding combined with many continuing food safety incidents and issues has led GAO to devote substantial resources to this issue (GAO 2005 and GAO 2007). One of their major findings in these reports has been the existence of major gaps and overlaps in domestic and imported food safety regulations. For example, they identified 1,451 dual jurisdiction facilities that produce foods regulated/inspected for similar issues/functions by both agencies (GAO 2005).

The FSML sends a mixed message regarding the 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 in Section 403 that nothing in the law alters the jurisdiction with the USDA under: (1) *The Agriculture Marketing Agreement Act of 1946*, which authorized organic and direct marketing programs; (2) The Federal Meat Inspection Act; (3) the Poultry Inspection Act: (4) the Egg Products Inspection Act; (5) the U.S. Grain Standards Act; or (6) the Packers and Stockyards Act. As a step in the direction of ensuring increased coordination, it directs the Food and Agriculture Government Coordinating Council (homeland security jurisdiction) and the Food and Agriculture Coordinating Council to report annually to the Congress progress in facilitating partnerships to enhance protection of food and agriculture systems; to exchange information on steps to enhance food security; to identify methods to improve federal, state, and local coordination; and to protect against outbreaks of animal and plant diseases.

Single food safety agency

Under the FSML 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.

Agricultural economist public policy and food safety analysts apparently feel uncomfortable venturing into the highly controversial issue of merging the food safety functions of the plethora of food safety regulators into a single food safety agency. There appear to be only a few exceptions to this statement (Sparling and Caswell 2006). The two comprehensive analyses of the single food safety agency issue appear to be by Merrill and Francer (2000) and by the National Research Council of the National Academy of Sciences (2010). After a thorough analysis of the history of food safety regulation, the agencies and their track record, and the incidence of food borne illnesses, Merrill and Francer concluded under the heading "*Consolidation as an ideal"* that, if not constrained by politics and the existing structure, there would be advantages in combining many of the federal food safety functions into one organization directed by a single head. "If Congress were able to begin with a slate clean, it could allow a unified agency greater discretion in its choice of methods to identify, prevent, and respond to foodborne hazards than either the FSIS or the FDA enjoys." (p. 163). They expressed pessimism that this would happen as revealed in the FSML. However, in a 2010 report the National Research Council continued to endorse the recommendation to form a single food agency in its seminal report, *Ensuring Safe Food: From Production to Consumption* (1998). Despite the limited scope of the FSML, the single agency option is likely to resurface as the most viable option for ensuring a safe U.S. food supply. The notion of a single food agency is not a pipe dream. It happened in Canada with the formation of the Canadian Food Inspection Agency (CFIA) in 1997 (CFIA 2011). The confluence of forces that led to the formation of CFIA was described by Knutson *et al.* (2008) in the executive summary for a North American Agrifood Market Integration Consortium workshop (NAAMIC) on the evolving nature of food quality and safety standards as follows:

> The development of CFIA occurred 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, efficiency, and reduce costs. Firms were fed up with multiple audits and verifications.

Research and Extension Implications

If implemented as written and enacted into law, the FSML would provide numerous opportunities for research and extension. Many of the economic research opportunities are embodied in the issues discussed previously. While other research opportunities involve the need for development of new investigative, detection procedures, and recordkeeping/management systems, for extension, there are extensive provisions for training grants. The most competitive projects/programs will be of an interdisciplinary nature. There will also be new competitive grants opportunities for universities having knowledge of food production, processing, and distribution to partner with State Departments of Health to become FSML authorized Food Safety Centers of Excellence. The prime responsibility of these centers will involve serving as resources for federal, state and local public health professionals. The most competitive land-grant universities for these centers will be those where the states have a track record of providing consistent support for and excellence in food safety research and education.

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Table 1. Side-by-Side Comparison of New Food Safety Law with Previous Law

FDA Food Safety Modernization Act	**Food safety provisions before enactment of Food Safety Modernization Act**
Title I: Improving Capacity to Prevent Food Safety Problems	*Capacity to Prevent Food Safety Problems*
A. Expands proactive authority to food FDA believes there exists a reasonable probability of serious health consequences or death	A. Incidents were primarily addressed reactively following adulteration or misbranding complaints and/or illness outbreaks
B. Requires biennial registration of domestic and foreign food handling facilities	B. Registration required but not on a periodic basis, therefore, registrations may not be current
C. Exempts registration by farms, roadside stands and farmers' markets, community supported ag programs and other direct sales	C. Exempted farms, restaurants, retailers, fishing vessels, and certain nonprofit food establishments
D. Can suspend registration and related business activity if violation could result in serious adverse health consequences	D. Authority suspend business activity requires court injunction
E. Provides authority to inspect records if reasonable probability of serious adverse health consequences to humans or animals	E. Records inspected for reported illness outbreak, contaminant/adulteration; records required for source and recipient
F. Requires HACCP risk-based food safety plans that identify hazards, control measures, monitoring, verify corrective actions	F. No FDA statutory authority for HACCP but implemented by FDA for seafood, some juices, and low acid canned foods
G. HACCP plan required for on-farm packing or holding of food	G. On-farm high-risk safeguards and guidelines encouraged for use by on-farm packing and holding facilities
H. HACCP requirement delayed 6 months for small businesses and 18 months for very small businesses	H. Food safety safeguards encouraged; required to be applied in the event of illness outbreak or contamination incident
I. Requires FDA to establish performance standards as benchmarks for controlling processing risk and determining food safety	I. Does not explicitly authorize performance standards to verify safe food processing
J. Authorizes promulgation of produce farm procedures, processes, and practices to minimize serious adverse health consequences	J. Issues voluntary microbial hazard guidelines
K. Small businesses produce compliance within 1-year and very small businesses within 2-year flexibility; limited exemption for direct sales	K. Not applicable to guidelines
L. Authorizes re-inspection for noncompliance cases and collection of fees for re-inspection activities based on cost and business size	L. No re-inspection fees

Table 1. Continued

FDA Food Safety Modernization Act	Food safety provisions before enactment of Food Safety Modernization Act
Title II: Improving Capacity to Detect and Respond to Food Safety Problems	*Capacity to Detect and Respond to Food Safety Problems*
A. Inspections are risk and compliance based; domestic high-risk facilities inspected once within 5-years, thereafter once in 3-years.	A. Authorizes, but does not require, inspection of food facilities
B. Inspections of foreign facilities accelerated from 600 in first year and doubled in each subsequent year	B. Authorizes, but does not require, inspection of food facilities
C. Establishes accreditation procedures for third-party private inspection laboratories and establish model lab standards	C. No authority to accredit third-party private inspection laboratories nor to accredit private laboratories
D. Sample food testing shall be initiated by FDA within 30 months on behalf of facility owner or as deemed appropriate by FDA	D. Testing limited to cases of suspected adulteration of adverse health incidents
E. Authorizes mandatory recalls if food is adulterated, misbranded, or will cause serious adverse health consequences	E. May request voluntary recall; no explicit mandatory authority to recall adulterated foods except for infant formula
F. Directs FDA to establish science/risk-based record keeping requirements and grocery store/consumer notification system	F. Reportable Food Registry requires FDA notification of any food having a probability of adverse health consequences
G. Directs the development and testing of pilot tracking/traceability systems for 3 types of food having foodborne illness history	G. Requires records that allow identification of immediate previous source and immediate subsequent recipient of food
H. Small businesses produce compliance within 1-year and very small businesses within 2-year flexibility	H. Not applicable
I. Defines foodborne illness outbreak as 2 or more cases; requires FDA coordination of improved federal, state, and local systems	I. Foodborne illness surveillance is carried out by state public health authorities in cooperation with CDC

Table 1. Continued

FDA Food Safety Modernization Act	Food safety provisions before enactment of Food Safety Modernization Act
Title III: Improved Safety of Imported Foods	*Safety of Imported Foods*
A. Requires importer to verify compliance with U.S. food safety processes, procedures, and hazard analysis/risk-based controls	A. FDA empowered to refuse entry of any food imports that appear to be adulterated or mis-branded; 1% examined
B. Establishes a process for voluntary facility certification to accompany imported food and expedited review of such imports	B. No current provision for facility certification
C. Provides authority to require certification that high-risk foods are as safe as similar foods manufactured processed or paced in U.S.	C. No current provision to demonstrate equivalent safety compliance
D. Authorizes arrangements/agreements with foreign governments for inspection of foreign facilities/suppliers of high-risk foods	D. No current FDA facility/supplier preventative inspection authorizations
E. Establishes accreditation procedures for third-party compliance auditors and for private laboratories	E. No third-party accreditation procedures; publishes lab guidance manual; AMS/USDA third-party user fee certification
F. Authorizes capacity building of foreign governments with respect to requirements for safe food and system harmonization	F. No foreign food safety capacity building authorization
G. Directs FDA to develop and implement a better strategy to identify and prevent entry of smuggled food into U.S.	G. Current policy prohibits entry of smuggled food
Title IV: Miscellaneous Provisions	*Miscellaneous Provisions*
A. Authorizes appropriations to implement the enacted activities; CBO scored law as costing an additional $1.4 B over 5 years	A. 2010 appropriations were $784 million
B. Increases the number of field staff progressively from 4,000 in FY 2011 to 5,000 in 2014	B. FY 2010 field staff was 2,505
C. Provides private employee protection for reporting violations of FDA food safety regulations	C. *Whistleblower Protection Act* does not apply to information provided by private employees re FDA violations

Sources: H.R. 2791. FDA Food Safety Modernization Act. U.S. Congress, Washington D.C. Available at: http://thomas.loc.gov/cgi-bin/query/C?c111:./temp/~c111jYrBrQ (accessed January 14, 2010) and Johnson *et al.* Food Safety in the 111th Congress: H.R. 2749 and S. 510. Congressional Research Service Report 7-5700, Washington, D.C.