

Review of the FDA Food Safety Modernization Act (FSMA): What it means, where it is headed, and why it matters

Paper prepared to further inform the US data collection for the European Commission project Analyzing the Effects from Non-Tariff Measures (NTM) in Global Agri-Food Trade

**Cory Belden and David Orden
Virginia Tech**

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Table of Contents

Introduction	1
What Prompted Change in the US Food Safety System?	1
Challenges in US food safety regulatory agencies, specifically in the FDA	1
Increased food borne illness outbreaks and new forms of contamination	2
The domestic costs associated with food borne illness	3
Creating Food Safety Regulations	3
Factors that influence the effectiveness of food safety legislation and regulations	4
The role of private incentives and action	6
Government Regulation in the US: Past, Present, and Future	7
Introducing the FSMA.....	7
Information requirements.....	9
Good manufacturing practice standards.....	10
Penalty, fee, and liability standards	11
Performance standards	12
Process standards.....	13
Prior approval requirements	15
Enforcement and implementation	16
Ongoing Debate and Concerns	18
The political environment	18
FDA capacity and resources	19
Costs to the government, private sector, and consumer.....	19
Equity in the farm and food sector.....	19
Impact on international trade	20
Other concerns	20
How Changes in Legislation could affect NTM data collection.....	21
Unresolved rule-making	21
Impacts on the data collected	21
What the NTM project may have missed.....	22
Works Cited	23

Introduction

Between November 30 2010 and January 4 2011, the Food Drug and Administration (FDA) Food Safety Modernization Act (FSMA), or HR 2751, was passed through the US governing bodies, representing the first large-scale change in US food safety law since the 1930s. For three years, federal food safety law was discussed in over two dozen congressional hearings (Johnson, 2010a). The text has undergone multiple revisions and collaborative efforts: legislation concerning fresh fruit and vegetable produce alone received over 700 comments from hundreds of stakeholders (Gorny, 2011). Though the US food safety regime is one of the best in the world, there were telling signs of needed change. US consumers now spend 1 trillion USD on food per year (Johnson, 2010b). Increases in food safety concerns like food borne illness have gained global visibility and have lead to negative trade consequences (the recent fatal E. Coli outbreak in Germany exemplifying this quite clearly). Industry and public support for the Act was strong from the onset, yet some policymakers, private sector stakeholders, and small producers remain concerned about implementation, costs, equal opportunity, and market and price effects.

This paper firstly gives reasons for the changes in food safety law and regulations in the US. A second section frames how food safety regulations are created—reviewing the challenges associated with science-based evidence, multi-actor expectations, and consumer knowledge. The paper discusses the current US regulations and how they will change in the coming years. Finally, the concerns raised about the implementation and regulatory design are reviewed, concluding with a short note on how these legislative changes may influence the data collected for the EU-NTM project.

What Prompted Change in the US Food Safety System?

Although many US food safety regulations have made significant leaps in assuring a safe and healthy food supply despite evolving hazards, three main rationales lead to legislative action in the US: 1) challenges in the US regulatory bodies, specifically the FDA, 2) increased outbreaks of widespread food borne illness along with new forms of contamination and 3) increasingly expensive domestic costs associated with food borne illness. This section will discuss these issues more in depth, explaining why revisions in food safety law were perceived as necessary.

Challenges in US food safety regulatory agencies, specifically in the FDA

Firstly, the US has 13 agencies that handle food safety law, regulation, and enforcement. The FDA, which was once a part of the United States Department of Agriculture (USDA), moved under what is now the Department of Health and Human Services in 1940. Since then, there has been a proliferation of agencies involved in US food safety. The FDA is the agency with the most responsibility for the US food supply, regulating approximately 80 percent of both domestic and foreign products that are sold in US retail. The USDA oversees the other 20 percent, including meat and poultry products. At times, these agency divisions make it difficult to coordinate food safety practices and respond to failures in the system. The new legislation in the US only addresses FDA oversight and regulations; this is because products strictly subject to USDA rule-making already follow Hazard and Critical Control Points (HACCP) and other more rigorous standards.

Inadequate inspections are additional drivers for the revisions in US food safety law. Recent episodes of slow action, misguided conclusions, and inadequate inspections are valid concerns. Most evident, FDA actions have been largely reactive rather than preventative with the exception of the HACCP rules for select products. For example, the FDA, charged with monitoring 30 percent of *all* products crossing the US border, inspects less than two percent of those products (Levine and Lui, 2008). In addition, the large majority of domestic and foreign food industries and firms do not have regular inspections by trained food safety professionals, and high-risk firms often only have safety inspections once every decade (Layton, 2010). These infrequent inspections have likely resulted in missed important opportunities to avert food borne illness outbreaks.

The FDA also has difficulty identifying sources of food borne illness due to the few traceability requirements in the US as well as the inherent difficulties in following food. In 2008, the FDA wrongly concluded that fresh tomatoes were the culprits behind a Salmonella outbreak¹. In 2008 and 2009, the FDA held over 200 peanut companies responsible for another Salmonella outbreak when the outbreak was eventually linked to just a single firm (Johnson, 2010a). Deer, wild pigs, dirty human hands, overflowing drainage ditches, and contaminated water were some of the sources blamed for the outbreak of E. coli in California spinach farms (DeLind and Howard, 2008; Nestle, 2006) although beef ranches were, in the end, the source responsible. In some cases, the starting place is never identified. Partially at fault for these difficulties is imperfect record keeping along the supply chain.

Some of the FDA's insufficient and ineffective inspection and traceability procedures are linked to insufficient and misused financial and human resources. In recent years, the agency received only 24 percent of the public expenditures put forth toward food safety inspection (Government Accountability Office, 2007). In 2010, the USDA Food Safety Inspection Service (FSIS) received 1.1 billion USD in government appropriate funds along with 131 million USD in industry fees. In comparison, the FDA received only 784 million USD, none of which came from user fees². Shortages in staff are also a problem: 450 FDA inspectors monitor more than 300 US ports of entry (ibid).

Increased food borne illness outbreaks and new forms of contamination

The US has seen an increase in the prevalence of food borne illness as well as new pathogens in the past two decades, which have led to both human illness and death. In 2006, contaminated organic spinach caused over 200 illness and 3 deaths. In 2008, more than 1,400 people in 43 states as well as in Canada were diagnosed with Salmonella poisoning, demonstrating the concerning expansion of contaminated products. In June 2011, 100 people became sick and one died due to Salmonella contamination in ground turkey (Neuman, 2011). Every year, one in four Americans, or 76 million people, is diagnosed with food related illness. Of these Americans exposed to pathogens, 325,000 are hospitalized and 5,000 die annually (Mead, et al.).

Like difficulties in tracing contaminated products, tracing food borne illness is also challenging. Only 40-45 percent of food borne illnesses is reported each year (ibid)³. Salmonella, E. coli, and Listeria are responsible for 75 percent of those reported and the other 25 percent cannot be accurately diagnosed. In fact, many food illnesses are rarely diagnosed correctly. Making diagnoses even more difficult is the prevalence of new contaminants, which are on the rise. Most of the pathogens considered dangerous to human health today (like Campylobacter, E. coli, and Listeria) were not acknowledged as such 20 years ago (ibid).

The US is experiencing increases in contamination and widespread food borne illness for a number of reasons. Firstly, highly centralized food processing systems lead to greater incidences of pathogens (Finz and Allday, 2006; DeLind and Howard, 2008)⁴, especially when food facilities are involved in multiple-

¹ Months later, the agency concluded that Serrano peppers from Mexico were at fault.

² The FDA is only allowed to charge fees for human and animal prescription drugs, human medical devices, human biologics, and tobacco products, as well as for export certification (non-food products). The levels of fees from these products are hard to predict due to variability.

³ It should be noted however that improved reporting even over the last few decades have likely contributed to the 'increases' of food borne illness. There has probably been an overall decrease in the incidences of food borne illness cases, but the spread of each illness is much larger due to centralized and large scale production and distribution.

⁴ One study in Germany showed that the risk for E. coli 0157 STEC infections rose by 68 percent per 100 additional cattle/km squared. Other studies found similar results for other E. coli strains like 0157:H7 (Kaspar, et al., 2009/2010). This could be a result of many issues, one being the stress induced by strict confinement. Other expert sources comment on the human implications of centralized processing facilities: whereas years ago a farmer would only be exposed to a small number of livestock, today's environment exposes them to thousands of animals each day (Pew Commission on Industrial Animal Farm Production, 2008). Human handling, if performed inadequately, can spread disease quickly in large facilities.

product processing⁵. This also helps to explain the increases in produce and organic contamination, which was rare in previous decades: as products become more industrialized, pathogen breeding grounds expand. Larger import volumes from diverse trade relationships increase the risks for contamination as well. Today, 60 percent of fresh fruits and vegetables as well as 80 percent of seafood consumed in the US are from foreign countries (Government Accountability Office, 2007). 12 million food shipments cross the US border each year. In addition, imports from traditional produce suppliers (Mexico, Chile, and Canada) dropped 10 percent from 1990 to 2000 (Calvin, 2003), a trend continuing in the ever-globalizing food trade. As the US trades with more countries and the need for increased oversight expands, it becomes more challenging to assess and be assured of the cleanliness and safety of all foreign and domestic facilities.

Consumer preferences and population growth have also led to more vulnerability in food safety. The US consumed 339 pounds of produce in 2000 up from 249 pounds in 1981 (ibid), including foreign goods like tropical fruit. Consumers also eat at restaurants and other service establishments more often, which centralizes their consumption area and reduces their control over proper handling (ibid).

The domestic costs associated with food borne illness

The increasing costs associated with contamination and food borne illnesses also called for legislative review. Estimates suggest that food related illnesses cost the US over 152 billion USD each year (Peterson, 2010). Some experts felt that the costs of the pre-FSMA food safety regulation exceeded the benefits received (the benefits being consumer protection and reduced health expenses). This is not to suggest that costs of the previous food safety regulation were a result of too many expensive regulations; rather, that the regulations were not well-suited for the current food safety challenges in the US.

In addition, costs and problems for domestic producers who share a market with foreign producers can be more severe than those sharing markets with only domestic producers. For one, tracing an outbreak back to foreign farms or processing facilities is more challenging than tracing one domestically. Sources often go unidentified for longer periods of time, risking the international or regional industry's economic footing along with consumer health. Domestic seasonal products have the most risk during an outbreak. If the US produce season begins during an incidence of contaminated imports, they experience major losses because consumers do not often differentiate between domestic and foreign products. It is estimated that California strawberry producers lost 16 million USD when they were wrongly accused of *Cyclospora* contamination in 1996⁶ (Mishen, 1996). In the early 2000s, contaminated cantaloupe led to food borne illness in the US. By the time Mexican farms were identified as the source, US farmers who had just started their season bore most of the economic losses in retail (Calvin, 2003).

Creating Food Safety Regulations

Food safety regulations are essential to consumer protection, fair and competitive markets and trade, as well as the promotion of quality health. Their creation involves many stakeholders, including consumers and taxpayers, domestic and foreign food manufacturers, packers, retailers, and growers, as well as the government at national and local levels (Henson and Caswell, 1999). Governments must create food safety policies where the marginal benefits and marginal costs of food safety meet (Henson and Traill 1993). This 'social optimum' for the level of safety achieved minimizes summed costs for the government (e.g. reduced medical costs and a small public budget), the costs for the private sector (e.g. minimal compliance costs, increases in profits), and the consumer (e.g. lower and fair price of food, reduced hospital visits).

⁵ Not suggesting that this food system should or could be changed; only stating that these are reasons for revised legislation.

⁶ The contamination came from Guatemalan raspberries. It was never resolved, but some experts say the outbreak was caused by as few as 6 farms (Herwaldt, et al., 1999).

Identifying the policies most likely to result in social optimization means identifying risks for a variety of products and then employing regulations that intend to address them in a cost-effective manner. In general, governments rely on two types of prevention and protection: 1) *private sector incentives and action*, and 2) *government regulation*. Private sector incentives reduce threats to the food supply because firms are economically inclined to use processes that produce healthy, safe products. “Management-determined actions” (where private firms select and pay for food safety controls without regulations) are prompted by a variety of incentives and disincentives including the threat of legal liabilities, the potential loss of reputation, and the potential increases in profits (Ollinger and Moore, 2008).

However, market failures also result in the private sector’s failure to adequately provide safe food. Food consumption (both the purchase and intake of) is not fully transparent process because consumers’ have imperfect or incomplete information on the attributes of the product they choose to purchase. Three attributes of a product influence a consumer’s purchases: *search* (e.g. the color of the packaged chicken meat), *experience* (e.g. the product life of milk), and *credence* (e.g. the amount of additives in a child’s cereal) (Darby and Karni, 1973). The first attribute shapes the consumer’s decision pre-purchase. The second influences it over time as he or she experiences the product’s quality after purchasing and perhaps after multiple purchases. The third attribute is much more difficult to scrutinize: food products with ‘hidden’ attributes like additives or pesticide residuals—which are often related to safety—are not visibly apparent pre-purchase or post (except in the case where the product becomes harmful to human life many years later). As a result and unlike search and experience attributes, the customer may not be willing to pay more for a product that maintains credence attributes nor will the private firm producing them (Josling, et al., 2004). Unlike adding technologies to improve a product’s quality where the consumer can easily associate the product to the company (search and experience attributes), lack of transparency and imperfect consumer information minimizes the profitability of implementing food safety controls (Ollinger and Moore, 2008).

The nature of imperfect information on food calls for government intervention in order to prevent the dilapidation of important credence attributes that are sometimes overlooked by private firms due to low levels of economic return (Traill and Koenig, 2010). Government regulation attempts to fill the voids in safety where private incentives may not reach while also reinforcing incentives that function naturally in the market (Josling, et al., 2004). Like the private sector, the federal government is also motivated by public demand, public confidence, and political reputation. Though the contributions of both private action and government regulation are not well understood and vary country to country, the uses of both are critical to a well-functioning food safety system (Ollinger and Moore, 2009).

Factors that influence the effectiveness of food safety legislation and regulations

Many factors influence the effectiveness of food safety regulatory strategies. Science-based evidence, perceptions, and varying levels of consumer knowledge impact how food safety regulations are formed and implemented and their effectiveness. These are important to highlight before discussing government regulation, as they frame the environment in which food safety controls can or cannot be implemented.

➤ Science-based evidence

Science based evidence plays a crucial role in food safety. Despite the importance of cost-benefit analysis in determining whether regulations would help governments get closer or further from the social optimum, an equally if not more important analysis in food safety is derived from science. Food toxicology, microbiology and other food sciences are critical aspects of improving global food safety. These disciplines help governments and private enterprise identify pathogens, sources of contamination, and risks; more importantly, science contributes to designing and developing preventative measures including performance and process standards and microbial and residual limits. The science in food safety also helps to determine the levels of technical skill need for laboratory testing or effective

implementation of control measures. For these reasons, scientific evidence antecedes and is often more important than economic assessments of regulatory proposals (Josling, et al., 2004).

The benefits of scientific evidence are not limited to knowledge creation and capacity to prevent and react to contamination. Making scientific evidence fundamental to food safety regulations also helps to maintain objectivity in food safety law and regulation, which is vital to fluid global trade. For example, scientific evidence concerning a particular food or process should not vary greatly between countries producing the same products in similar environments. Therefore, neither should the food safety controls. Science-based regulations are less subjective than those based in perception, opinion, and culture, allowing for greater consistency in regulatory frameworks between countries.

Because food safety regulations are forms of non-tariff measures and affect the quality of the international market, the WTO requires that food safety regulations be based in scientific evidence. Requiring producers to provide labels, use specific technical equipment, and sample products makes it more difficult for firms in other countries (specifically developing) to access markets, making a ‘science-based’ approach essential to more equitable competition. Though the science-based requirement is critical for this reason, the science itself is actually often controversial (Josling, et al., 2004). Zero risk in food safety is unattainable. As such, governments can argue that varying levels of risk are ‘safe’ or ‘unsafe’. A fitting example of this challenge are the differences between the US and EU perception of risk. Where the US asserts that certain foods are safe unless health hazards can be proven provided that the product is examined for any recognized hazards, the European Union upholds the “precautionary principle”, which maintains that food is risky until proven safe (Entine, 2006). These discrepancies and manipulative definitions of ‘risk’ and ‘science’ make the ‘science-based rule’ ineffective at times.

➤ **Perceptions and Culture**

Additional factors influence legislative decisions on food safety and its effectiveness. Cultural and social attitudes play a major role in food safety. Perceptions on what is safe to eat vary country to country often times without conclusive evidence on its safety. For example, European countries that use long-standing traditional processing methods on cheeses have not concluded that raw milk poses significant risks to human health (Echols, 1998). The US, on the other hand, where producers and consumers are not accustomed to such traditional methods, maintains that raw milk is dangerous to human health. Raw cheese must be aged for 60 days at 32 degrees before being sold in retail.

➤ **Varying Levels of Consumer Knowledge**

Consumer knowledge as aforementioned, is fundamental to the economics of food safety, and therefore shapes a country’s level of food safety and law as well as the effectiveness therein⁷. Not only does the problem of imperfect information reduce incentives for firms to use private action voluntarily, it also damages private sector income during an outbreak of food borne illness. During and occurrence of food borne illness, consumers rightly respond by avoiding the product, yet this can have detrimental effects on firms that did not cause the outbreak. In addition, consumers do not have the ability to easily distinguish between companies that adhere to good manufacturing practices (GMPs) and other standards and those that do not (Calvin, 2003) thus assuming that all food sold from a particular retailer is of equal safeness. This also leads to a degradation of food safety controls, as companies that use GMPs for example (which are heavy in costs) do not often receive economic benefits such as consumer preference or the ability to sell at a higher price.

⁷ For example, despite scientific evidence that irradiation drastically reduces the potential for contamination in the early 1990s, the American Meat Institute found that over 60 percent of consumers were concerned that the technology caused birth defects or cancer (Frenzen, et al., 2000). Several studies show that as US citizens became more knowledgeable about irradiation’s positive outcomes, they became more willing to buy irradiated meat products (ibid). This illustrates how consumer awareness determines the effectiveness of regulations that require certain treatments.

The only way to improve these incentives is to improve consumer access to better information. An analysis at the US Department of Agriculture's Economic Research Service (ERS) on the effects of the bagged spinach E. coli outbreak showed that consumers use all of the information [readily] available to make specific distinctions between products (e.g. bagged versus loose spinach) and make their purchases accordingly (Arnade, et al., 2010)⁸. Communication flow during outbreaks and how food safety information is disseminated are crucial considerations in the development of food safety regulations.

Finally, it should also be noted that consumers' knowledge of safe handling (like cooking to appropriate temperatures) reduces the chances of food borne illness and exposure. If consumers are unaware of or do not use these practices, a government cannot rely on them as effective food safety controls.

The role of private incentives and action

As stated, food safety relies on two primary interacting factors: private action and government regulation. This section discusses the first in more detail, focusing on the safety techniques that firms can employ to improve the protection.

The private food sector has many incentives to ensure the safety of their product(s). As a result, their actions serve as a key component of food safety processes. Food facilities—especially those with high-risks—'self-regulate' by implementing internal controls that guarantee product quality, consistency, and safety (Henson and Caswell, 1999). These controls involve a variety of techniques, divided between preventative actions that are used to avoid failure and remedial actions that are employed once failure has occurred (ibid). Countries must pay careful attention to these management determined actions—regulations that incur high transaction costs are not necessary where food facilities and growers are likely to implement good and preventative practices without government intervention. This is particularly true given the many studies that show private actions contribute more effectively to the safety of the food supply compared to government regulation and inspection (ibid).

➤ Incentives for self-regulation

The threat of contamination and the repercussions thereafter provide strong incentives to the private sector. Financial incentives are the most apparent: sales of the associated product drop dramatically during an outbreak of food borne illness or voluntary recall (Shiptova, et al., 2002). Despite its large market share, Jack in the Box almost went bankrupt during an outbreak of food borne illness in the 1990s (Ollinger and Moore, 2008). In 2006, after the FDA told consumers that bagged spinach products were contaminated with E. Coli 0157:H7, the entire industry experienced losses over 201 million USD in just a little over a year's time (Arnade, et al., 2010).

Related to financial incentives, growers and processors also have incentives to protect their markets and reputation. Retailers are less likely to stock brand names associated with food borne illness or those whose food safety practices are risky. Fearing that retailers will switch to a competitor's product, food facilities are motivated to implement food safety controls (Buzby, 2003). Foreign exporters must also protect their markets, particularly when they specialize in products with limited domestic demand. A firm that exports to the US only for example may lose their whole market if an outbreak occurs.⁹

➤ Possible action for private firms

Private firms can employ a variety of technologies and practices to ensure food safety. They can invest in human capital, which can include hiring additional labor, requiring formal training, and encouraging

⁸ It should be noted however that there is evidence proving otherwise. When Guatemalan raspberries were held responsible for the Cyclospora outbreak in the late 1990s, consumption of blackberries also declined (Arnade, et al., March 2010).

⁹ For example, the eggplant industry in Mexico, which has a large market share in the US, has a very limited domestic market (Calvin, 2003).

employees to take a more active role in internal food safety steps. Companies can also improve food safety through physical investments like new technologies, better equipment, ventilation and sanitation systems, and improved drainage (Ollinger and Moore, 2008). Good manufacturing practices (which are typically provided through government agencies) can also be adopted as preventative measures.

Food facilities can also perform third-party audits and gain applicable certifications. Third-party audits, in which a firm hires an outside laboratory or safety expert to evaluate the level of food safety, can serve as independent evidence of a firm's commitment to consumer protection. Improving transparency in the supply-chain, the buyer can be assured of the proper food safety controls. Certification, where quality standards are designed by an industry or retailer, serves a similar purpose (Henson and Caswell, 1999).

Another form of private action is creating a contractual relationship between buyers and sellers or producers. Buyers can require food facilities to enter contracts that guarantee that their products are safe when they reach the shelf. Contracts typically require the seller to make investments in food safety equipment and good practices (Hobbs, et al., 2002). These vertical agreements can be highly detailed, with the buyer in primary control of quality assurance. Although the demands placed on the supplier may be high, the contracts are usually lucrative because the agreement minimizes competition (Golan, et al., 2004). Contractual relationships are becoming increasingly common today, as chain restaurants and retailers that purchase massive amounts of product from one firm cannot afford to take chances with their customers' level of safety. The agreements are also effective. Studies on US firms have found that the prevalence of Salmonella occurrences in sampling drops in facilities involved in vertical contracts with their buyers (Ollinger and Moore, 2009).

Growers' organizations are a form of horizontal contracts. As noted, industries, particularly those that are high-risk, have strong incentives to certify that all companies growing and selling their product are paying careful attention to safety. To prevent widespread losses to industry, suppliers may create voluntary or mandatory safety schemes for the industry (Calvin, et al., 2004). A participating producer is responsible for meeting these standards.

Despite the overwhelming incentives for private action to assert safe practices, there are still cases where food facilities do not employ the proper precautions. Depending on the firm's characteristics, incentives for preventative action can also be weak (Ollinger and Moore, 2009). The lack of immediate pressure (compared to the very immediate pressure after an outbreak), loopholes, and uncertainty encourages some firms to 'test their luck' and employ minimal controls. This is even more prevalent in poor economic periods, where financial resource constraints are high in many food facilities (Johnson, 2010a).

Government Regulation in the US: Past, Present, and Future

Government regulation is an equally critical component to food safety, serving as an extension where private incentives end. Governments must analyze risk, levels of private action, public demand or concern, costs of compliance, government capacity, and science-based evidence to determine appropriate regulatory frameworks. The US has developed a variety of regulations for domestic and foreign firms over the course of the past five decades. However, the government has also relied heavily on private action. Yet the reliance on private action is clearly and increasingly ineffective due to complex food networks, increased food-borne illness, and expanding import sectors (Johnson, 2010b; Echolds, 1998).

Introducing the FSMA

Given the budget constraints and uncertainties afflicting the US government, along with the concerns regarding the partisan politics so evidently at play in recent legislative matters, how FSMA was passed through Congress is important to review briefly. After interactions with the public and industry representatives as well as after the US mid-term elections, the Senate passed HR 2751 on November 30

2010. Amendments to the original Bill included exemptions for small businesses, the omission of maintaining electronic records, and making registrations free (previous language would have required registration fees of 500 USD each) (Layton, 2009). On December 21, less than 20 days after the Senate revised and passed the Act, the House also passed it without revisions. The pie charts below represent the Democrat and Republican ye and nay votes for both the House and Senate¹⁰. Particularly in the House, the Act was passed primarily with votes from Democrats.

Figure 1: Senate votes in favor and against FSMA

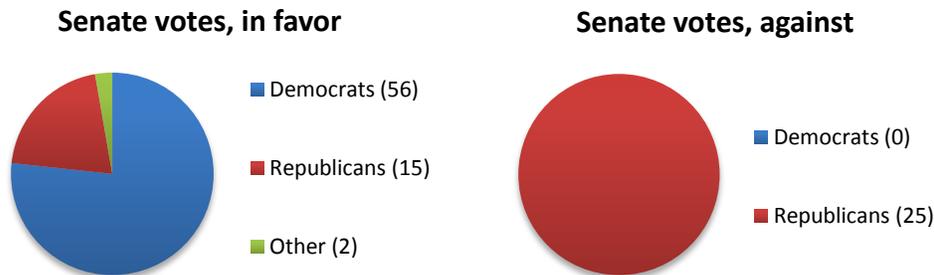
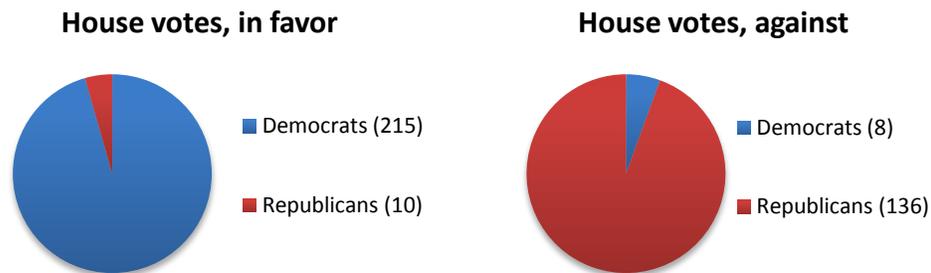


Figure 2: House of Representatives votes in favor and against FSMA



The four titles of the new legislation include: *Title I: Improving the Capacity to Prevent Food Safety Problems*, *Title II: Improving Capacity to Detect and Respond to Food Safety Problems*, *Title III: Improving the Safety of Imported Food*, and *Title IV: Miscellaneous*. In sum, the FDA Food Modernization Act has two overarching themes: firstly, it increases the authority and enforcement capacities of the FDA, and secondly, it increases preventative and reactive regulations concerning contamination of both domestic and foreign products, especially in high-risk produce. These two changes attempt to respond to the evolving risks associated with the food supply, and for the first time in US history, reflect food safety controls from the farm to the household¹¹. Although the Act has passed through legislation, the FDA must revisit regulations and create new performance and process standards based in science.

The FDA has made progress in rule making proposals since the law's inception. The deadlines for implementation as well as updates on the regulatory process can be found at the new FSMA website¹².

¹⁰ In the House, 41 Democrats and 33 Republicans did not vote. 2 Republicans abstained from the Senate vote.

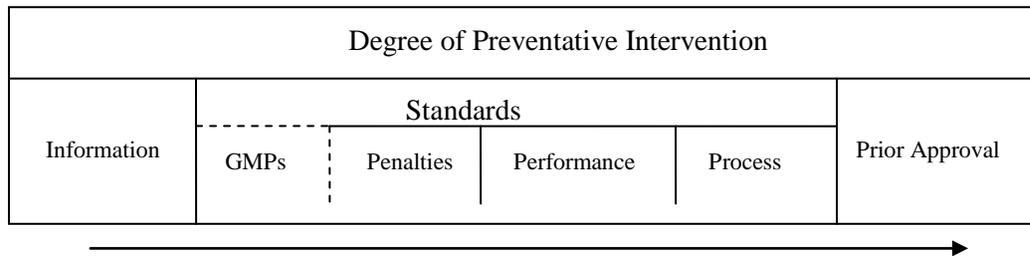
¹¹ Unless locally grown products are purchased. Small local businesses are exempt from the regulations.

¹² <http://www.fda.gov/Food/FoodSafety/FSMA/ucm250568.htm>

Rules for administrative detention and the authority to suspend registration went into effect on July 3 2011. Dockets for public comment are currently (August 2011) open on topics related to small business and preventative controls.

Figure 3 illustrates the range of measures and controls the government can and has introduced to ensure safety in the food supply. The controls are ordered in the “degree of preventative intervention” from the restricted intervention (requesting information) to the most invasive intervention (requiring prior approval before a product goes markets). The following section describes these degrees of intervention which governments can employ to regulate food safety, including information, standards such as guidelines for good manufacturing practices (GMPs), penalties, performance standards, process standards, and prior approval. After each option is described, the US regulations *before* and *after* the codification of FSMA are explained, along with justifications for these regulatory choices and changes¹³. The US maintains regulations in each category, with the newest regulations mostly falling into the process category. Regulations in other categories, like information and performance standards, will also increase due to the changes in legislation. Following these descriptions, a section on the enforcement of the new regulations is presented.

Figure 3: Degrees of preventative intervention, from least to restricted to greatest



Source: Adapted from Henson and Caswell, 1999; Ogus, 1994.

Information requirements

Governments can firstly and usually most easily generate information regulations, which are rules that require disclosure. The information is typically required in ‘good faith’, where a firm is expected to provide the information when requested at the time it is requested, yet their products are not automatically restricted from the market before the request is made. When information is not provided, penalties may ensue (dependent upon the information asked for). Information regulations can take many forms.

Registrations, record-keeping, labeling, and certifications are all forms of information requirements. The US has used information as a form of intervention in a variety of regulations. Previously, select food facilities were required to register with the FDA. Traceability information has also been mandatory: since 2002, facilities, transport organizations, storage facilities, and other food handlers have been responsible for recording information including addresses, description of the products, and phone numbers on the recipient and provider of their goods if they cross state borders (one-step forward, one step back). Country-of-origin regulations (which require all retailers to provide labels with the country source on all meat and certain agricultural products) are also a form of information and are mandated for meat products and some raw agricultural goods. These records must be stored for two to five years depending on the product. The US maintains other basic information requirements concerning food suppliers and retailers, each similar in nature to the two described above.

¹³ It should be noted that the information used to describe the new regulations comes primarily from recent briefs (e.g. Johnson, 2010a; Knutson and Libera, 2011) and presentations (e.g. Faber et al., 2011; Taylor, 2011) related to the new legislation, along with the text of the Act itself.

There are a number of increased information requirements put forth in the new legislation. All food facilities will have to register biannually with the FDA beginning in 2012. The registrations are free of cost and will include additional information compared to the registration previously required for some firms. In addition, all food facilities including those that ‘manufacture, process, pack, distribute, receive, hold, or import’ must maintain records of inspections, audits, food safety plans, verification of the food safety plans, and recalls. Importantly, this includes large fruit and vegetable farms and processors. These records can be kept on paper, and do not have to be kept electronically or provided remotely, which will limit government intrusiveness or potential breaches in trade secrets. This resolved one major concern of private industry (Johnson, 2010a).

Traceability is expected to improve due to some of the new record-keeping requirements. FSMA mandates that the FDA also conduct studies on the effective tracing of agriculture products (including the costs, technologies, experiences in other countries, and feasibility). These results may eventually lead to a federal tracing system for agricultural products. To improve customer information, chain grocerers, will be required to provide more specific information on the product and company at fault for recalls for a longer period of time. This may help to improve customers distinguish between products within the same industry.

Table 1: Synopsis of changes in information regulations due to FSMA

Title	New law and/or regulation	Previous regulation
Title 1	All facilities must register biannually, free of charge (Sec 102).	Registration was required only when facility first opened.
Title 2	Improving the Reportable Food Registry: large grocery store chains (15 stores or more) will be required to place information on a recall in a prominent place within 24 hours of a recall for at least 14 days. Information will include SKU numbers, description of product, company name and contact information (Sec 211).	The Reportable Food Registry has been a place for industry to report when there is reasonable probability that a product will harm in health or death to human or animals. Law required ‘responsible parties’ (any facility that holds, packages, or manufactures food) to report the product to the FDA. Posting information as described in the new law was not required.
Title 2	All facilities, including those that transport, hold or receive food must keep records on internal audits, food safety plans, and recalls. FDA can have access to these upon demand. High-risk facilities (designated by the FDA) will have additional record-keeping requirements (Sec 204).	Record keeping required, but primarily for traceability purposes (when food was transferred from party to party) rather than internal food safety maintenance and enforcement. The FDA did not have authority to demand records unless food borne illness occurred.
Title 2	FDA will pilot tracing programs, specifically related to produce, and create a domestic and import product-tracing system (Sec 204). The program will not be implemented until pilots are completed and analyzed.	Tracing products in the US has been limited to one-step forward, one-step backward. Facilities moving products (including produce) were required to document the party they sold to and bought from, keeping these records from 2-5 years.

Good manufacturing practice standards

Governments can also provide guidelines for industry. Commonly called good manufacturing practices (GMPs), these regulations are essentially recommended performance or process procedures (in few cases, they are required and enforced). They can include guidelines on equipment, operations, maintenance, employee practices, and sampling. Though most are not mandated, many private firms use them. In the US, most of the GMPs are for firms that pack, manufacture, or hold food products; there have been few

for those that harvest, store, or distribute them (Johnson, 2010a). GMPs are especially important because it is so difficult to accurately test for and detect pathogens, even through performance standards.

Yet GMPs can be costly to enforce and a cause of conflict in some cases. After an outbreak of Hepatitis A on green onions in Mexico, GMPs for green onions were created to reduce the prevalence of contamination. Implementing these practices cost firms 700,000 USD and in some cases, upwards of 2.5 million (Calvin, et al., 2004). Due to such high costs, not all firms were willing or could afford to use them, illustrating the problems created when consumers cannot distinguish between firms that employ safer practices and those who do not.

US guidance documents are available for a wide variety of industries including beef, poultry, and produce. Most recently, in 2009, the FDA created guidelines for melons, leafy greens, and tomatoes. These recommendations came after a number of food borne illness outbreaks in these specific products.

GMPs were not directly included in the new legislation, but they may be created during the regulation formation process. Due to the continuous outbreaks on farms and in fruit and vegetable products, many of what are now and what would be considered GMPs will become performance or process regulations.

Penalty, fee, and liability standards

Federal governments often use penalties, fees, and liabilities in regulations concerning food safety and in other cases. ‘Product liability’ is regulation that assigns penalties to firms that produce and market items that harm consumers (Henson and Caswell, 1999). Punishing firms financially for defects in quality encourages food facilities to employ safe practices. However, these ex post penalties can be more hurtful than helpful. Firms already experience massive losses after an outbreak, barely surviving if at all. Adding economic penalties can result in even more damaging effects for domestic business, employment, and the economy at large.

The US generally maintains distance from hefty fines if an outbreak occurs. Chronic failure to comply with HACCP standards can result in penalties (Ollinger and Moore, 2008) (HACCP will be discussed further in the section on process standards below). Firms that market adulterated or misbranded products are also exposed to criminal and civil penalties (Johnson, 2010b). In addition, though forcing a recall that results in economic penalties and consequences could be considered a government regulation, recalls in the US have been voluntary.

Financial penalties related to food safety have not changed substantially with FSMA. If records are not made available to the FDA upon request, penalties will ensue. If a facility is subject to re-inspection, costs associated with the inspectors’ travel and time, follow-up, corrective action, and public notifications are allocated to the company—not the FDA or state agencies.

In the form of ‘punishment after offense’, the new legislation also boosts FDA authority on recalls. In previous rules, the FDA could only *request* a recall; the firm’s decision to recall was voluntary. With FSMA, the FDA can force a mandatory recall if necessary. Semantics posed problems in the previous food safety law. “Credible evidence or information indicating” has been replaced with “reasonable probability” and “presents a threat of serious adverse health consequences or death to humans or animals” is now “adulterated or misbranded”. These changes provide the FDA with more authority and flexibility to detain products that may not yet be proven contaminated. Although many food facilities already voluntarily recall products if sufficient evidence presents itself, the decision to recall has been too slow in some cases to prevent expansive food-borne illness. Thus the new law creates more incentives for food producers and processors to pause their production in the early onset of pathogen contamination (Taylor, 2011). If a product causes illness or death, the firm’s registration is temporarily revoked and the company is prohibited from shipping from the adulterated facility. Registration is restored after the facility takes

proper corrective action. These rules apply to both domestic and US-owned foreign facilities.

Table 2: Synopsis of changes in penalty regulations due to FSMA

Title	New law and/or regulations	Previous regulation
Title 1	The firm with a recalled product or evidence of adulteration is responsible for covering the costs associated with re-inspection (Sec 107).	Inspection and re-inspection were paid by the government agency; the company was not financially responsible for the violation or recall.
Title 2	FDA can make mandatory recalls and choose to suspend facility production, distribution, and registration if there is “reasonable probability” that is “adulterated or misbranded” (Sec 206 and 207).	Recalls were strictly voluntary. FDA could not suspend facility production without a court hearing.

Performance standards

Performance standards are generally the most common type of food safety standard. They are “specific, quantitative measurements of a property or a substance in food that are selected to serve as benchmarks for whether the food is safe in a broader sense” (Johnson, 2010a, p.14). These benchmarks are framed as maximum limits or action levels that reduce risks. By sampling foods for the presence of contaminants, governments can identify the firms that produce foods that are too risky for sale. The general consensus among economists is that performance standards trump other regulatory measures (like process standards or liabilities) because of their flexibility. End-product testing allows firms to use processes appropriate for their product to meet requirements.

However, performance standards are not always effective. For one, costs of compliance can be higher for firms with high-risks or overwhelm firms that are subject to multiple regulations or who work on a small-scale. In addition, studies have shown that performance standards sometimes fail to prevent contamination (Unnevrer and Jensen, 1996). Loopholes (like firms that use unaccredited labs for testing), poor enforcement (such as low testing frequency), and lack of science (some contaminants are difficult to detect) can result in poor prevention. These problems became visible in the US regulatory system. They not only resulted in FSMA, but were also the basis of the 1996 HACCP regulations for certain meats, seafood, juice, and low-acid canned products. In these cases—where risks are high and performance standards failed to prevent outbreaks—process standards were and are necessary and cost-effective additions (Unnevrer and Jensen, 1996; Crutchfield, 1997).

The US uses a number of performance standards. Over 300 pesticides have maximum limits for residues. Additives and aflatoxins also maintain action levels (maximum limits) and advisory levels (suggested limits) in the US regulatory framework. Most importantly concerning pathogens, the US requires sampling and testing for Salmonella and E. coli in large slaughter facilities.

A number of new performance standards are expected as a result of FSMA. Firstly, the FDA will likely create select performance standards for fruit and vegetable production. After reviewing the relevant health data and analyses—focusing on the contaminants and products that pose the greatest risks—action levels related to proper water hygiene and soil quality will be created for fresh produce production. The FDA will try to maintain flexibility for various products and product categories. The agency will also conduct science-based testing every two years to determine the highest risks to food safety, shaping performance standards to the most relevant threats. Any performance standard created for domestic facilities will also apply to foreign facilities. The FDA will also begin accrediting laboratories that test facilities for their adherence to performance standards.

Notably, regulations do not require facilities to meet performance standards through sampling or inspection when new, small food quantities are used. Understanding that firms may test competitor ingredients or make changes in their product, the new law does not require compliance unless used in the long-term and distributed to the public.

Table 3: Synopsis of changes in performance regulations due to FSMA

Title	New law and/or regulation	Previous regulation
Title 1	Fruits and vegetable producers and other facilities involved in their production will have to abide by FDA-created performance standards for the safe production of produce for the first time. These regulations will not apply to small ingredient amounts used in research (Sec 105).	Performance standards were not specific to produce supply chain. Good manufacturing practices were main component of produce protection.
Title 1	FDA will conduct science-based testing every two years on the most significant food safety threats and create or change performance standards as necessary (Sec 104).	No legislative requirement for regular testing and rule-making.

Process standards

Process standards can be effective additions to performance standards. A process standard “requires a firm to use a minimal or pre-specified amount of risk control input” (Cho and Hooker, 2009). Risk control input means using technological tools or additional human capital during production. Process standards can include sanitary or sterilizing equipment requirements, preventative production processes like pasteurization, and good manufacturing practices like employee hygiene. Although performance standards can reduce compliance costs, in some cases, process standards are cheaper and more effective (Besanko, 1987) in others. One study concluded that if inefficient firms are common, process standards are more effective because they set a minimum use for control inputs and equipment (Cho and Hooker, 2009)¹⁴. Another study showed that process standards are preferred when information is asymmetric and unavailable to the regulator (Marino, 1998). Finally, Ollinger and Moore (2009) found that though the importance of process regulations fluctuates, they account for 50 percent or more of the food safety controls in US firms. It should be noted however, that process standards do not apply to all firms: some products lack an innovative processing technology that eliminates pathogens like pasteurization does for milk (Calvin, 2003).

The most prominent and widely used process standards in the US are the Hazard Analysis and Critical Control Point (HACCP) standards. When HACCP was first introduced to US food safety regulation in 1996, it was favored largely by industry (Committee on the Review of the Use of Scientific Criteria and Performance Standards for Safe Food, 2003). HACCP includes performance standards and penalties, but it is primarily concerned with process regulations. Based on HACCP rules, plant managers must design their own safety processes to meet a set performance standard (e.g. maximum number of samples for E. coli). There is some flexibility in these requirements; however, firms must generally stick to Standard Sanitation Operating Procedures (SSOPs)¹⁵ (Ollinger and Moore, 2008). Persistent failure to comply with the performance or processing standards results in financial penalties. Studies have demonstrated that

¹⁴ Cho and Hooker (2009) show that the variability in the levels of industry compliance influence the effectiveness of performance standards. They used 5 factors in their simulation to show this, including: the variances of input use, the proportion of inefficient firms in the industry, the means of the error term for inefficient firms, and the degree of risk preferences of the regulator.

¹⁵ SSOPs include the regular cleaning and sanitization of buildings, facilities, surfaces in which food makes contact, and transport vehicles. Cleaning compounds should be tightly stored away from production and processing areas. Proper pest control, water control, waste management, and worker hygiene are also included in SSOPs.

HACCP has been quite effective at reducing cases of contamination. An ERS study found that SSOPs have the largest positive effect in pig facilities, and FSIS contends that declines in Salmonella samples in pig, cow, and ground beef meats are due to HACCP regulations and the action that follows (ibid).

Food safety plans, which mimic HACCP plans, are required under the FSMA for all food products and facilities. These food safety plans include a number of steps, beginning with a hazard analysis. Food facilities must first explore internal risks specific to their production and subsequently create controls. Risks or foreseeable hazards include pesticides, parasites, drug residues, allergens, and chemical or radiological hazards. Controls to prevent environmental and health risks can vary according to needs. Employee training, sanitation processes, sampling, and machine testing are examples of these controls. Additional examples (that the FDA may eventually require through regulations) can be reviewed in the HACCP plans. Every food facility must reanalyze their hazards and controls every three years or if major changes are made within the facility.

Table 4: Synopsis of changes in process standard regulations due to FMSA

Title	New legislation and/or regulation	Previous regulation
Title 1	Written food safety plans are required for every food facility. Facilities must analyze their hazards and create controls to prevent failure. These controls must be verified by the owner as effective; corrective action must be taken by facility if failure occurs. FDA also requires reanalysis every 3 years or if significant changes are made to the facility or production (Sec 103).	HACCP plans were only required for a certain few products deemed high-risk regulated by the FDA (e.g. juice and seafood). Produce facilities and others did not have to create HACCP plans.
Title 1	Businesses that make \$500,000 or less in sales (accounting for inflation), distribute products less than 275 miles, and sell half of their product to end-users (very small businesses) will be exempt from the above (Sec 103).	Exemptions did not exist because HACCP regulations for these process standards did not exist for these types of products.
Title 3	Agency will create regulations for the new Foreign Supplier Verification Program (FSVP), which requires importers to verify that imported food is produced in compliance with applicable US laws and is not adulterated or misbranded. (Sec. 301)	This type of FDA verification program did not exist for foreign facilities not under HACCP. Foreign firms not under HACCP were required to provide appropriate import certificates (e.g. phytosanitary certificates) when product entered U.S. Inspection and risk-based analysis were completed at border.

Process standards for fruits and vegetables specifically are critical topics in the FSMA. Food safety plans as described will be required for firms that grow, harvest, and pack fresh produce. Creating regulations like these are essential to consumer protection because there are not as many safe ‘at home’ practices for produce as there are for meat products (e.g. cooking at high temperatures). Like the performance standards for produce, the FDA is expected to create science-based (flexible) minimum standards for the safe production of these products including those related to temperature controls and animals in the growing area.

The process standards for domestic products also apply to foreign products from both US-owned facilities and foreign facilities. The Foreign Supplier Verification Program may be the most serious compliance challenge for both food companies and the FDA. If a US food company operates facilities on foreign soil, it must create a food safety plan, including risk assessment and verification for that foreign facility to meet new process and performance standards.

There are important exemptions from the process standards that should be noted. Firstly, firms that already comply with HACCP do not have to create new food safety plans. In addition, very small businesses that make sales of less than 500,000 USD per year¹⁶, have a confined distribution less than 275 miles, and sell half of their product directly to end-users (local restaurants or consumers) will not be subject to such stringent routine inspection, are exempt from some regulatory standards, and will have the option of using less costly HACCP controls (Knuston and Ribera, 2011). If a small business is found responsible for public health risks, the FDA can manipulate these rules. Importantly, the FDA has at least 18 months to determine the exact definition of a ‘small business’ (ibid). Regulations for these firms may vary in comparison to ‘very small businesses’. Also undetermined is whether similar exemptions will also hold for small foreign businesses.

Prior approval requirements

Prior approval is the most intrusive type of government regulation. Prior approval means that the food facility must receive the ‘ok’ to proceed before putting their product on the market. Prior approval is not common in most food safety regimes, as it restricts and usually cripples the free market. However in some cases, prior approval is a reasonable response to food safety threats.

The US has had few prior approval requirements in its food safety regulations. Typically, these regulations have to do with cross-border movement. Veterinary and plant health certificates are required for some imported products. In addition, the FDA requires prior notice for any food product coming into the US. Without prior notice, the shipment is rejected at the port of entry.

Prior approval for domestic products is unlikely to change in final FDA regulations. However, prior approval will increase for imported products. Along with the foreign supplier verification program, some facilities that manufacture, process, pack, or hold food will require additional certification. These additional certifications will depend on the risks associated with the product, country, or region, and will be used to ensure compliance with US standards. To expedite these prior approval processes, a US firm can apply for the fee-based Voluntary Qualified Importer Program, which ensures faster and more long-term clearance. The new prior approval regulations will take time to implement and enforce given their expansive nature.

Table 5: Synopsis of changes in prior approval requirements due to FSMA

Title	New law and/or regulation	Previous regulation
Title 3	FDA is required to establish a voluntary qualified importer program for firms that wish to expedite imports (Sec. 302). Eligibility will be determined based on risks, country food safety standards, compliance, and other factors deemed appropriate.	The expedited program did not exist.
Title 3	If FDA determines that certain import facilities have higher risks, the agency will be permitted to require additional certifications (Sec 303).	Certifications were required for imports based on risk, but were more generalized to industry (e.g. beef or apples). New certificates may have different requirements than those currently in U.S. regulations.

¹⁶ Defined not as AGI, but as the three-year average “annual monetary sales”, adjusted for inflation (Johnson, 2010a).

Enforcement and implementation

Regulations require enforcement, which is also addressed in the new legislation. Enforcement can take many forms and are appropriate based on the type of regulation. The US has used a variety of techniques to enforce previous legislation, relying mainly on inspection. Enforcement requires more funding than regulation creation and design; this is a key consideration in any food safety strategy. The following section discusses the forms of enforcement that will be used in the coming regulations.

Inspections continue to be a leading form of enforcement. Inspections will be more frequent, particularly for high-risk firms (in this way, targeting the priorities first). Domestic high-risk facilities will be inspected once from now until 2016, and then once every three years thereafter. Less risky facilities will be inspected once from now until 2018, and then once every seven years thereafter. On-site inspections of foreign facilities are also required, as well as thorough examinations of the foreign regulatory environment. In previous years, approximately 600 foreign food facilities were inspected each year. Considering FSMA requirements, the FDA estimates that 19,000 foreign facilities will require inspection in 2016 (Faber, et al., 2011). Due to such large changes in inspection scope, inspections and certifications for foreign facilities will likely remain limited over the next few years (Knutson and Ribers, 2011)¹⁷.

Audits and laboratory testing are also required under the new law. These are split into two groups: regulatory and consultative. Regulatory audits are routine, FDA-mandated, and performed by accredited or certified auditors; consultative audits are voluntary and conducted by the firm's external hires. Even though the latter is voluntary, both audit records must be available for FDA perusal. More importantly, both auditors are required by law to immediately report any serious public health hazard to the FDA if identified during the inspection. If a consultative or regulatory auditor does not alert the FDA, he or she can lose his or her accreditation. Oversight in auditing is now being enforced (Calvin, 2003) due to corruption in the past. Evidence shows that some food facilities would send samples to various labs until a positive response was heard, thus it was rare that the FDA received accurate information concerning risky facilities.

Building capacity is another prominent initiative of FSMA. Reinforcing communication and information systems, guiding inspectors through new regulations, and providing trainings at the state and local levels—who are often the first responders to food contamination—are critical to ensuring effectiveness. FSMA aims to increase the number of qualified laboratories. Five new 'Integrated Food Safety Centers of Excellence' will serve as resources on food safety for health professionals, inspectors, auditors, and other relevant parties. The FDA will also assist in building capacity in foreign food safety agencies to ease this transition. Meeting performance standards, certification, and food safety requirements are also expected from non-US firms who want to export to the country. Importantly, certifications on foreign soil can be made by qualified third party foreign agencies.

Finally, employees are given whistle-blower protection through FSMA. Any employee in a food facility that reports hazards, participates in a hearing, or raises concerns to the FDA cannot be discriminated against or fired from his or her company.

¹⁷ It is also difficult to determine how the final regulations and certification schemes will look.

Table 6: Synopsis of how the regulations will be enforced according to FSMA

Title	New legislation and/or regulation	Previous regulation
Title 2	Enhanced Food borne Illness Surveillance System (FISS) includes improved tools for epidemiological detection, centralized database, and improved capacity at state and local levels to identify and contain contaminated products and conduct inspections. The FDA will also administer extension services and training to local and state governments (Sec 205 & 209).	Local to federal response systems, along with FISS, were not as detailed in legislation.
Title 2	Inspections increase based on facility risk. High risk facilities will be inspected every three years and low-risk facilities, every seven years. Each year, FDA must report inspection frequency and outcomes to Congress. Inspections will also be increased for high-risk foreign firms (Sec 201).	Inspections were infrequent and based on the firms with the most risk or if adulteration occurred (specific yearly inspections were not required by legislation).
Title 2	FDA will provide technical assistance and training to foreign governments whose industries export to the US (Sec 305).	The US provided technical assistance to some countries (often based on trade agreements), but food safety law did not require this assistance.
Title 2	Five Integrated Food Safety Centers for Excellence will be designated by the FDA in partnership with the Center for Disease Control (CDC) to serve as resource centers for public health professionals to respond to foodborne illness outbreaks. Resources will include timely information on symptoms, testing, effective communication and prevention, outbreak surveillance and investigation, and trainings for State and local personnel (Sec 210).	Food Safety Centers for Excellence did not exist.
Title 2	Laboratories that respond to food borne illness or conduct testing (foreign and domestic) will increase and must be accredited by the FDA; the program requirements will be determined by the agency (Sec 202 & 203).	Laboratories used for food emergencies were not FDA-accredited. No formalized legal role in responding to food crises.
Title 3	Certain foreign food facilities will require inspection (600 additional in the first year after enactment and doubled every year after that); authorized third-party accreditors will carry out these inspections (Sec 306 & 307).	Inspections of foreign food facilities were infrequent or nonexistent. No authority to oversee third-party accreditation.
Title 4	New law requires FDA staff increases of at least 14,000 (Sec 401).	FDA maintained fewer staff.
Title 4	Whistle blower protection: employees who report adulteration or risks to the FDA are protected from lawsuits or discrimination thereafter (Sec 402).	Not mandated in previous law.

Ongoing Debate and Concerns

Although wide benefits may come from the FSMA, there are some valid concerns that require discussion between policymakers and analysts. The following section briefly describes and analyzes these debates, which will influence the formation and execution of the new regulations.

The political environment

Despite the widespread claim that the passage of FSMA was bipartisan¹⁸, certain evidence proves otherwise and alludes to future implementation and funding challenges. Figures 1 and 2 display the votes taken to pass HR 2751 through the Senate and the House. While the Senate maintained some Republican votes in favor of the Bill, the House votes in favor were entirely Democratic. It is also fairly clear that the Bill's quick passage through the House related, in part, to the impending Congressional party change: Democratic Representatives used the lame-duck session to pass a law that would not have such proclivity of passing in January 2011 when Republicans became the majority. These issues suggest that political agreement may not have been as strong as advocated during and immediately after the passage of the bill.

Though division between Republican and Democratic Party lines is expected in law-making activities that further regulate the private sector, these voting patterns imply that the FDA budget might face severe cutbacks and rule-making severe criticism from the Republican majority House (and potentially Republican Senate or White House after 2012). Representative Jack Kingston (a Georgia Republican), now the Chairman of the Agriculture, Food and Drug Administration and Related Agencies Appropriations House Subcommittee stated before the Act's passage that "there's a high possibility of trimming this whole package back...the system we [already] have is doing a darn good job", signaling that the funding expected for the law's implementation may be reduced at some point (Peterson, 2011). Other forms of resistance point to reduced enthusiasm: political financial contributions from industry and organizations in opposition of the Act exceeded those in favor before its passage (Maplight, 2010).

Yet political opposition does not necessarily set the law's implementation paths toward failure. First, there is certainly some conservative support of increased food safety. Second, the coverage of food safety in the media is bound to increase consumer demand and awareness of food safety. Big industry, so long as regulations are deemed appropriate, has and will likely continue support for FSMA. Recent bottlenecks regarding new regulations for E. coli strains illustrate this point well. The US historically regulated and tested for E. coli 0157:H7, yet six additional strains have caused food borne illness in both the US and other developed countries. Despite this threat, President Obama delayed in authorizing new testing (due to the associated costs and political pushback against continued 'over-regulation') (Horsley, 2011). During this delay Costco and Beef Products Inc. recently announced that they would begin testing for these strains without government requirement to do so. Large firms' incentives to protect their food supply are more pronounced than those with fewer products and less reach, but their decision may imply that management-determined actions are more suitable than government regulations in this case. Yet their actions might also mean that consumers are more informed about the dangers of food contamination and therefore more inclined to purchase products from retailers and producers that implement wide reaching food safety controls (enhancing the visibility of credence attributes). In either case or both, industry's self-induced testing is a strong indicator that up-to-date and cost-effective food safety regulations are important and a priority to both consumers and producers, which neither political party can ignore.

¹⁸ For example: "Senate Passes Sweeping Law on Food Safety, December 1st, 2010. New York Times: <http://www.nytimes.com/2010/12/01/health/policy/01food.html>

"Senate Passes Sweeping Food Safety Bill". November 30th, 2010. Washington Post: <http://www.washingtonpost.com/wp-dyn/content/article/2010/11/29/AR2010112903881.html>

FDA capacity and resources

The FDA's capacity to conduct regular inspections (even through state and local inspectors), maintain records, and verify import safety will be limited if the budget is cut. Yet even if an acceptable budget were at the FDA's disposal to implement the law, it is also acknowledged that in addition to the agency's strained human and financial resources, bureaucracy is widespread. In fact, some argue that the country needs an FDA with better oversight, management, and procedures, not increased regulation and food safety laws (Layton, 2010). Yet with the new law comes increased FDA responsibility: over the course of the next year, the agency must generate multiple science-based regulations that match the FSMA. Creating these regulations and enforcing them could be very slow, especially if the hiring process (which will require at least 14,000 new inspectors) is restricted due to funding (ibid). The FDA staff also require training to conduct proper inspections, understand the science behind the standards, and identify risky or ineffective controls. This technical assistance alone is expensive, even more so considering the large domestic and international capacity building initiatives the agency is expected to undertake. The FDA has made substantial progress in food safety even despite minimal law change—this should not be disregarded. However, improved food safety cannot be achieved without the quality implementation from the agency.

Costs to the government, private sector, and consumer

Costs are a major concern not only to the federal government. The new fees for re-inspection, the Voluntary Qualified Import Program, and other regulation processes will cover a minor fraction of the costs induced from these legal changes. Over the next four to five years alone, FSMA is estimated to incur federal costs from \$1.4 to 2 billion dollars (Layton, 2010; Johnson, 2010a). Due to the US budget crisis and changes in Congressional party leadership, the FDA may not receive sufficient resources. Budget constraints are not limited to the federal level: state and local programs, as well as foreign governments, will also pay more to ensure food safety compliance as the FDA transfers more responsibility to these entities (Knuston and Ribera, 2011).

To account for compliance costs (for recalls food safety plans and import assurance), the prices of some food products may increase (Johnson, 2010b; Knuston and Ribera, 2011). On the other hand, costs to the consumer may not increase dramatically if the new legislation reduces the financial burden associated with food-borne illness. In 1997, Crutchfield, et al. estimated that reductions in food borne illness due to the use of safer food technologies could lower health costs by 1.9 billion dollars. ERS survey data examining the economic impacts of the HACCP rules for beef and poultry slaughter plants also found that costs of meat increased approximately 1 cent per three pounds (Ollinger et al., 2004). Considering that the new legislation mimics HACCP rules in many ways, changes in costs and prices may be comparable for high-risk products.

Equity in the farm and food sector

Depending on final regulations, small firms could be more adversely affected economically compared to large firms. Due to the costs and documentation burden associated with compliance, smaller producers are concerned about how the new legislation may affect their overall competitiveness. Large firms like Kellogg's or Kraft will have less difficulty paying fees or meeting regulatory demands compared to smaller ones, especially because the main food safety technologies have fixed costs (not sliding), so the marginal costs drop as plant size increases (Ollinger and Moore, 2008). These disadvantages could have negative impacts, especially because local production systems and markets have been regaining popularity (the number of farmers' markets rose over 50 percent from 1998 to 2009 (Martinez, 2010)). Effectiveness is also in question because smaller firms have much different and localized food safety problems (Waltner-Toews, 1996; DeLind and Howard, 2008).

Although small producers are exempt from some of the major regulations of FSMA, challenges remain. Questions are now being raised about the producers that do not meet all of the exemption requirements, especially in areas where they are a critical source of employment. Complying with the new regulations may make it difficult to continue operation in these low to middle income situations. Previous regulations have resulted in poor outcomes for the smaller food firms. Dairy producers are often used as an example of these outcomes in the US: with such stringent food safety regulations, most smaller farms have disappeared or participate in direct marketing without any regulations (DeLind and Howard, 2008; Knutson and Ribera, 2011). Scaled solutions, where technologies and control methods depend somewhat on the size of production and the context could be more appropriate than pure exemption (DeLind and Howard, 2008). However, the inspection costs and complications for the government may be even higher with an even further diversified food safety system.

Impact on international trade

Regulations rooted in FSMA are likely to impact trade relationships between the US and its partners. Foreign compliance with some regulations will be difficult to achieve due to costs and limited resources. This will be more pronounced in developing country trade partners. In addition, tight regulations and inspection for foreign producers could also lead to shipment delays (Buzby, 2003), costing the companies, governments, and consumers. As Knutson and Ribera (2011) pointed out in their early analysis of the new legislation, the US should not downplay the importance of seasonal imports (and other primarily imported products). Rigid FDA regulations could be deleterious to US markets and consumers who regularly purchase these products (as well as the foreign industry exporting them). It could be that certain regulations will indeed be socially optimal for all products, but economic analyses will be critical to ensuring that requirements are effective and cost-reducing over the long run.

It is also quite reasonable to conclude that some regulations, if established, will be brought to the WTO in a trade dispute. The most recent and similar regulation coming from the US is the Country-of-Origin Labeling (COOL) executed in 2008. In 2008, Canada (Dispute 384) and Mexico (Dispute 386), along with the European Union, Brazil, India, New Zealand, and others issued a dispute with the US over the regulation, deeming it incongruent with the Agreement on Technical Barriers to Trade (TBT), restricting market access, and favoring domestic goods (World Trade Organization, 2010). Both Canada and Mexico claim that the agreement puts their countries' livestock producers at a disadvantage. One such example is the COOL requirement that allows US designation only when an animal is born and raised in the US alone. This prevents cattle that are raised and slaughtered in the US, but born in Mexico, to receive the US label, which could potentially lower the price of the foreign-born animals. In early July, the WTO panel made a preliminary ruling in favor of Canada and the others, stating that the regulations do indeed violate the TBT while not fulfilling the goals of protecting the US consumer (Beef Magazine, 2011). Though the reasons for this ruling have not been publically announced and explained in greater detail, it does hint at future difficulties involving cross-border food safety requirements.

On the opposite side, increases in US food safety regulations could have positive effects on trade. When the US created HACCP regulations for beef products, Canada followed suit to retain access to these markets (Hobbs, et al., 2002). As a result equivalency agreements were formed, allowing for some flexibility in Canadian inspection routines, regulations, and rules. Due to the potentially wide reach of US regulations, these equivalency agreements may gain popularity, which could reduce costs. At the least, many developing countries could see increases in their food safety regulations if the US intensifies its technical assistance.

Other concerns

The overall effectiveness of FSMA is being questioned for the reasons listed above as well as others. For example, the new discretionary power of the FDA, which allows the agency to make its own exemptions, is a concern for certain stakeholders. Will the FDA abuse its new power? (Farm-to-Consumer Legal

Defense Fund). Will the increase in power lead to adversarial relationships between the government and industry (Johnson, 2010a)? Are there too many potential loopholes with the included exemptions? Is the FDA sufficiently qualified and resourced to make such scientifically difficult regulatory decisions (Faber, et al., 2011)? The exemptions for small facilities illustrate these arguments. As small producers applauded the exemptions, other organizations such as the Producer Marketing Association and Consumers Union claimed that all food should be safe and regulated—including food in local markets and smaller firms (Layton, 2010). These organizations and others believe that certain corporations could somehow take advantage of these legal allowances.

Some risks related to incentives have also been raised. For example, auditors are now held accountable for public health. They are deeply incentivized to report risks, yet this may lead to ‘crying wolf’ syndrome—where time is wasted, fees are incurred, and real threats may go unrecognized.

Finally, while the government is making efforts to coordinate between agencies and streamline regulations, there are still 13 agencies administering numerous food safety laws and regulations.

How Changes in Legislation could affect NTM data collection

Given the depth of the information collected for the European Commission project “Analyzing the Effects from Non-Tariff Measures (NTM) in Global Agri-Food Trade” (the NTM project), we consider it interesting to reflect on how the FSMA may or may not influence the answers provided in the questionnaires and data sets for the US. Briefly, this section comments on three main topics: 1) the difficulties associated with predicting the undetermined regulations, 2) which of the nine NTM project data collection queries will be most affected by the new legislation and how, and 3) what the NTM project may have missed in the data due to evolving food safety scares and systems. Each of these topics is based in educated assumptions, which are based on the legislation and several verbal presentations from FDA officials.

Unresolved rule-making

Importantly, the rules outlined in FSMA do not delineate the actual regulations. The new law mandates that the FDA propose and determine appropriate science-based regulations for the facilities and products outlined in the Act. While clear that performance and process standards will be created, it is not clear in what shape these standards will take form. Moreover, it could take a couple of years to make formal regulatory decisions. Pushback from industry and policy-makers is expected in some cases. Pushback may be even stronger from foreign facilities and governments. If the regulations pose significant challenges to accessing US markets, disputes may be raised even as far as to the WTO.

Unresolved rule-making is also critical because of the serious complexity in forming the rules requested. Creating regulations for fruits and vegetables is incredibly difficult due to the inconclusive scientific evidence on how they attract, receive, and spread contaminants and pathogens. Identification of pathogens in produce, even in infected produce, is even more arduous. As noted, the diversity of the products: size, geography, classification, and type (e.g. with a shell or without) could play a major role in regulations. Deciding how great the role of the diversity should be is still in question. A “framework for diversity”, which attempts to adapt to multiple products, is under construction (Taylor, June 7, 2011). Once this framework is legally binding, regulations will likely look different from those currently recorded in NTM data.

Impacts on the data collected

The answers given for the US on the animal health and labeling questionnaires, along with the additives, pesticides, contaminants, and veterinary data sets will not likely be affected by the changes set forth in FSMA. Animal products are covered through USDA—not the FDA, and thus FSMA does not apply.

Pesticides are not typically held responsible for pathogen outbreaks, making the performance standards for these applications invariant to FSMA. Veterinary health is also unlikely to change due to FSMA. The contaminants data set, though related to adulteration, addresses toxins that are not often associated with food borne illness outbreaks. The answers provided on the labeling questionnaire are not likely to change greatly, unless the FDA determines that facilities should label the food safety controls applied to their products. Imported products may require additional labeling based on the import programs it came through, but this is also doubtful due to increased costs that would be placed on foreign facilities.

In contrast, the answers supplied in the microbial data set may alter after FSMA regulations are formed. Firstly and most obviously, the US may create new microbial performance standards for certain agriculture products. Like for beef and pig facilities, these standards will primarily address *E. coli*, *Salmonella* (and possibly *Cyclospora* and *Listeria* strains). They may require facilities to test and sample for pathogens at the farm, packing, holding, and/or transport levels.

The answers given on the plant health questionnaire will change most substantially. Though regulations are not finalized, the new import programs for all products under FDA jurisdiction will certainly influence how plants, produce, and even grains enter the country and how certifications are allotted to facilities. Inspection frequencies will increase both at the border and in the country of origin. The FDA may also revamp post-harvest treatment (e.g. cold storage, heating to lethal temperatures), aligning these rules with the science-based regulations formed in the coming years. The country-specific questions may also have divergent answers: import conditions will likely become tighter for certain countries and may actually be ‘facility-based’ in some cases. Pre-clearance will be required for all products and countries in one way or another, and pest risk assessment might be conducted on foreign soils, rather than at the border.

Finally, the answers on the NTM project traceability and conformity assessment questionnaire will also shift. Record-keeping requirements are increasing quite dramatically. All facilities will have to maintain records on more diverse information including food safety plans and corrective actions. The FDA may also decide that to increase the “one-step forward, one step back” requirements in the traceability framework, perhaps also extending the years required for records maintenance. Produce growers and handlers will also be required to document occurrences of diseases or pests, along with samples and diagnostics taken at regular FDA-mandated audits, which is not the answer currently given on the NTM questionnaire.

What the NTM project may have missed

With the severe increases in widespread pathogen outbreaks, many governments are overhauling their food safety regulations. Process standards are on the rise: regulations that mirror HACCP rules are expanding as experts recognize their importance in protecting fruit and vegetable supplies. Some of the most innovative food safety rules may come from FSMA. Process standards that address major opportunities for hazards on farms and produce facilities may reduce the occurrences of pathogen contamination. Requiring these facilities to maintain a specified distance from livestock farms, assure the safe application of manure, and create food safety plans may result in regulations that look entirely different from the current food safety controls used globally. Performance standards that test water hygiene and soil qualities and contents are also new to the food safety regulatory environment. Although these new regulations would have been captured somewhere in the US answers for the NTM questionnaires and data sets, questions aiming to capture them were not included explicitly. Hence it may be worthwhile to explore what these ‘farm to table’ practices mean on a larger scale. Will these standards—that may address the threats of a commercialized, centralized, and international food system—be more often used and in many countries? If so, these standards should be further examined in the NTM project moving forward (or thereafter in similar projects). This is further validated given that these standards imply increases in governments’ regulations, and as such, presumably increases in barriers to and disputes in international trade.

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