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How does the Food Safety Modernization Act Affect Farms and Food Marketing Firms?

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On January 4, 2013, exactly two years after passage of the Food Safety Modernization Act (FSMA), the U.S. Food and Drug Administration (FDA) proposed the first two of five formal “rules” mandated by FSMA (FDA, 2013c). These rules cover on-farm practices for produce safety and post-farm “hazard analysis and preventive controls” for food including produce¹. The produce safety rule does not apply to produce that is rarely consumed raw², or produce that undergoes processing that reduces the risk of foodborne illness. The legislation itself did not specify actions required of farms and processors, and instead required FDA to write rules or regulations, including these two rules, to specify required actions.

In this brief, we review the FDA’s estimates of compliance costs for smaller and larger farms, and draw attention to the way the produce safety rule may change the structure of the fresh produce industry³. We base our analysis on the FDA’s recently released Regulatory Impact Analyses for each of the two proposed rules. We do not assess the credibility of FDA’s compliance cost estimates in this brief, but use the FDA estimates to illustrate the general scope

1 Defined as fruits, vegetables, mushrooms, sprouts, peanuts, tree nuts, and herbs. Grains are specifically excluded from the definition of produce.

2 The produce on the following exhaustive list are considered to be rarely consumed raw: arrowhead, arrowroot, artichokes, asparagus, beets, black-eyed peas, bok choy, Brussels sprouts, chickpeas, collard greens, crabapples, cranberries, eggplant, figs, ginger root, kale, kidney beans, lentils, lima beans, okra, parsnips, peanuts, pinto beans, plantains, potatoes, pumpkin, rhubarb, rutabaga, sugarbeet, sweet corn, sweet potatoes, taro, turnips, water chestnuts, winter squash (acorn and butternut squash), and yams. In addition, FDA-regulated crops that are not considered “raw agricultural commodities” are not regulated under this rule.

3 The cost of compliance with the preventive controls rule is much lower, compared with revenue, for the food processing industry, which is dominated by larger firms.



and scale of compliance burdens. We also do not evaluate the expected effectiveness of the regulations in reducing foodborne illness.

All farms and food processing firms have inherent motivation to produce safe food, because their reputations depend on it. The new FDA regulations mandate that farms and firms follow specific processes that have no guarantee of improving the safety of their product. This brief focuses on the compliance burden for small farms relative to large farms, a burden that may affect the continued economic viability of those small farms covered by the regulations.

Overall, the FDA estimates that the two rules will cost U.S. farms and food marketing firms \$935 million per year, and will cost foreign farms and firms \$671 million per year⁴. However, FDA expects the benefits, in terms of reduced illness and reduced cost of illness, to outweigh the costs of compliance (FDA, 2013a,b). These regulatory costs are projected to be large relative to revenue. For firms and farms with lower revenue, the regulations are expected to be even more costly, relative to revenue, than for larger competitors. For example, FDA estimates that for produce farms with less than \$250,000 in annual production value, the cost of compliance will be 6.3% of production value (FDA, 2013b). The FDA explicitly exempts many farms from compliance with the regulations, but the exempt farms produce only a tiny share of domestic fresh produce. We discuss the exemption criteria in more detail later in this brief.

⁴ In this brief, as in the FDA analysis, all costs of compliance that spread over more than one year are annualized using a 7% discount rate.

Table 1. Major Foodborne Illness Outbreaks in the United States, 2006–2012

Year	Commodity or product	Pathogen	Number of confirmed illnesses	Number of deaths
2006	Tomatoes	<i>Salmonella</i>	183	0
2006	Fresh spinach	<i>E. coli</i>	199	3
2008	Beef	<i>E. coli</i>	49	0
2008	Jalapeño and Serrano peppers	<i>Salmonella</i>	1442	2
2008–09	Peanut butter	<i>Salmonella</i>	714	9
2009	Raw alfalfa sprouts	<i>Salmonella</i>	235	0
2010	Shell eggs	<i>Salmonella</i>	1939	0
2011	Cantaloupes	<i>Listeria</i>	146	30
2011	Ground turkey	<i>Salmonella</i>	136	0
2012	Raw scraped ground tuna product	<i>Salmonella</i>	425	0
2012	Cantaloupes	<i>Salmonella</i>	261	3

Data from Centers for Disease Control and Prevention, 2012: Multistate Foodborne Outbreak Investigations. <http://www.cdc.gov/outbreaknet/outbreaks.html>. Accessed October 16, 2012.

Note that very few foodborne illness cases are confirmed by culture testing, so the actual number of illnesses associated with each outbreak in the table is likely to be between 25 and 100 times larger than the number reported in the table. See Scallan, E., R.M. Hoekstra, F.J. Angulo, R.V. Tauxe, M.A. Widdowson, S.L. Roy, J.L. Jones, and P.M. Griffin. 2011b. "Foodborne illness acquired in the United States—major pathogens." *Emerging Infectious Diseases* 17:7–15.

Background

The FSMA was in the works for many years, but was enacted in 2011 after a series of major food-safety scares. Table 1 reports the number of confirmed illnesses associated with particular outbreaks, which are either relevant to the produce industry in the western United States or are the largest outbreaks associated with a prominent food product. Note that 6 of the 11 major outbreaks reported in this table are commodities subject to the new produce safety rule, and another is regulated by the preventive

controls rule. Some of the produce commodities may also be processed off-farm, and so subject to both rules.

Despite all of the negative headlines surrounding food safety events in the United States in recent years, the overall rate of laboratory-confirmed infection with most major foodborne illnesses trended downward over 1996–2010 (CDC, 2011). Of the illnesses frequently caused by contaminated fresh produce, only infections with *Salmonella*—a type of bacteria found in the intestinal tracts of animals and birds—increased over the period. And, *Salmonella* infections increased by only 3%. Infections with *Listeria*—which is often found in food and water—decreased by 38%. Infections with *E. coli*—a type of bacteria normally in the feces of humans and animals—decreased by 44%. All of these bacteria have been periodically associated with contaminated fresh produce.

Regulatory Costs by Size and Exemptions from FSMA Regulations

FDA estimates that the average compliance cost for farms with under \$250,000 in annual revenue that do not qualify for exemption is 6.3% of revenue. For the average farm with more than \$1,000,000 in annual revenue, average compliance cost is 1.2% of revenue. See Table 2, Figure 1, and Figure 2 for more details.

The FDA proposes to completely exempt those farms or firms with sales below the revenue thresholds of \$25,000 per year for farms and \$250,000 for processors. Partial exemptions are also available for “qualified facilities,” including farms or firms with less than \$500,000 in annual revenue that make more than half of their sales directly to consumers, restaurants, or retail food establishments within the same state or within a 275-mile radius. “Retail food establishments” include vertically integrated retailers such

Table 2. Characteristics of Farms Affected by the Produce Safety Rule and Their Cost of Compliance^a

	Farms not covered by the rule ^b	Partially exempt, “qualified” farms	Farms fully covered by the rule			
	Less than \$25,000 annual production value	\$25,000 to \$500,000 annual production value	\$25,000 to \$250,000 annual production value	\$250,000 to \$500,000 annual production value	More than \$500,000 annual production value	All fully covered farms
Number of farms	113,870	13,522	26,947	4,693	8,571	40,211
Percent of national production value of covered commodities	2.8%	6.0%	7.1%	5.3%	78.9%	91.2%
Average annual production value	\$7,000	\$127,000	\$75,000	\$321,000	\$2,638,000	\$650,000
Average cost of compliance	\$88	\$520	\$4,700	\$13,000	\$31,000	\$11,000
Average compliance cost as percentage of average production value	1.3%	0.4%	6.3%	4.0%	1.2%	1.8%

^a Farms not covered by the rule are all those with less than \$25,000 in annual production value, and in addition all farms that grow only commercially processed produce or produce that is rarely consumed raw (as determined by FDA). “Qualified” farms are those with less than \$500,000 in annual sales that make more than half of their sales directly to consumers, restaurants, or retail food establishments within the same state or within a 275-mile radius. Data from FDA (2013b).

^b This column includes only farms with less than \$25,000 in annual production value, and does not include the larger farms that are not covered by the rule because of the crops they produce.

as Safeway, which buys food directly from growers and then may further distribute food to its individual stores.

Given the magnitude of the costs of the regulations, some farms and firms may adjust marketing practices to qualify for an exemption. For example, they may split a farm, integrate a distribution arm of the firm, or change their distribution channels to favor local retailers. However, the FDA may revoke the exemption if it determines that an outbreak or other food safety problem is associated with an exempt farm or firm, or that farm practices or conditions are a risk to public health. Nonetheless, by exempting certain small farms and firms from its new food safety regulations (as prescribed in the legislation) FDA allows the firms and farms meeting exemption criteria to use different production practices than other firms in their industries. Perhaps this is justified from an administrative efficiency perspective. The cost of regulating many small operations is high per unit marketed and individual food contamination events caused by exempt firms are likely to be more local and affect fewer people each. Of course, if many small firms cause outbreaks, this would have large total consequences for public health and for the reputation of the produce industry in general.

Given that the regulation is anticipated to raise costs per unit much more for smaller farms, we expect it will encourage large farms to become larger and encourage non-exempt smaller farms to sell their operations, consolidate or find some way to become exempt.

In the following sections, we discuss the expected economic effects of the two proposed rules separately.

Produce Safety Rule

This rule covers the on-farm growing, packing, harvesting, and holding of produce for human consumption. Exemptions apply to commodities that are rarely consumed raw or those that will be processed in a risk-reducing way (such as by canning). “Qualified” farms, as defined in the preceding section, are eligible for a partial exemption from the rule. Farms that qualify for partial exemption must indicate to buyers the name and address of the farm through labels or a sign at the point of sale and keep re-

Figure 1. Fresh Produce Production Value by Farm Size or Exemption Category

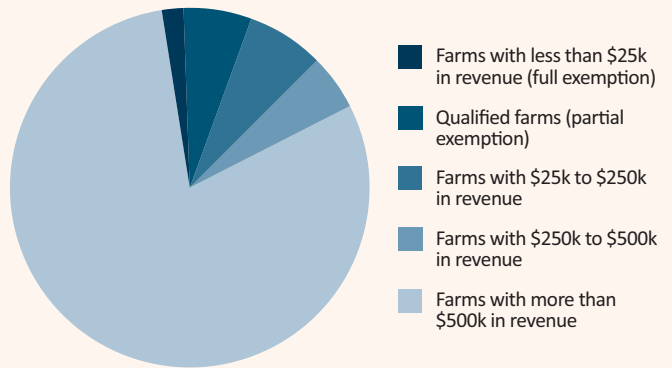
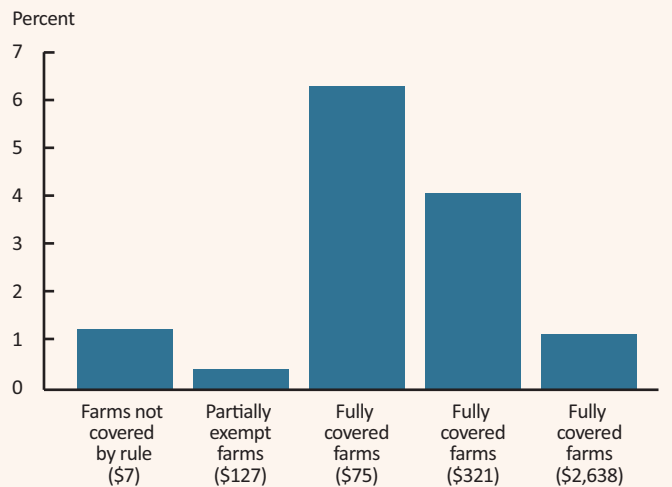


Figure 2. Produce Safety Rule Compliance Cost by Farm Size Category or Exemption Status, Relative to Production Value



Note: Average annual production value for each category, in thousands, listed in parentheses.

records to demonstrate that they maintain qualified status. Only farms with more than \$25,000 in annual revenue are covered by the rule, but farms falling below that threshold must incur recordkeeping cost to document that they are not covered by (that is, exempt from) the rule.

The list below shows the six major areas of the rule, with FDA estimates of the annual cost of compliance to domestic industry indicated in parentheses.

1. Agricultural water must be safe and sanitary, and must be inspected at the beginning of each growing period (\$49 million);
2. Fertilizer and compost of animal origin is subject to certain handling and storage requirements, and a certain period of time must elapse between application and produce harvest (\$9 million);
3. Basic worker health and hygiene measures, such as having toilets and hand-washing stations in the fields, are required (\$138 million);
4. Farms must take reasonable measures to prevent animal feces from contaminating produce (\$38 million);
5. New sanitary standards for equipment, tools, and buildings (\$59 million);
6. New requirements specific to growers of sprouts from beans or seeds (\$8 million).

Full compliance costs include \$157 million per year to train workers, learn the rule, and keep records, and \$2 million per year in costs of corrective actions. The total cost to domestic industry is estimated to be \$460 million per year. The personnel cost of learning the rule, training workers, and keeping records of a farm's compliance—rather than costs directed to actions that actually improve the safety of the food produced—are estimated to be 34% of the total compliance cost of the rule. Note that some of the requirements, such as those for worker health and hygiene, are already required as part of state laws, including California state law. The FDA's estimated compliance burden accounts for the farms that already follow the new regulations, and reflects only the new costs from the regulations.

In its analysis of this proposed rule, the FDA estimates that there are 3.1 million illnesses associated with the fresh produce commodities covered by the rule each year. In addition, 2.6 million illnesses are associated with other FDA-regulated food products, and over 33 million foodborne illnesses are associated with products not regulated

by FDA. The FDA estimates that the implementation of the produce safety rule will reduce the number of illnesses associated with the regulated commodities by 56%, or 1.75 million illnesses. The average cost of such an illness is about \$600, with average costs per infection ranging from \$200 for unidentified infections to \$39,000 for hepatitis A. FDA estimates that contamination of these commodities is responsible for about 95 deaths per year, and because they estimate the value of a life to be \$7.9 million, these deaths significantly increase the overall estimate of the cost of illness. In all, FDA estimates that the reduction in illness from implementation of the produce safety rule would reduce annual cost of foodborne illness by over \$1 billion.

Within the proposed produce safety rule, FDA offers several alternatives to the proposed \$25,000 revenue threshold for regulatory coverage. With the proposed \$25,000 threshold, the rule covers about 40 thousand of the total 150 thousand farms that grow fresh produce often consumed raw. However, these 40 thousand farms account for about 91% of the production value of fresh produce in the United States. If this threshold were raised, it would reduce some of the expected differential in compliance cost between different types of firms. However, this expanded partial exemption from the produce safety rule would reduce the number of averted illnesses. For example, the FDA estimates that increasing the threshold for regulatory coverage to \$500,000 would increase the number of foodborne illnesses by about 0.3 million per year and more than double the production value of produce that qualifies for at least a partial exemption from the produce safety rule.

Preventive Controls Rule

This rule requires non-farm facilities that manufacture, process, pack, or hold human food (including fresh produce) to implement "hazard analysis and risk-based preventive controls." These requirements are largely similar to the existing hazard analysis and critical control plan (HACCP) system, which processors of dairy products, juice, meats, and seafood are currently required to implement. HACCP is a system under which facility managers identify hazards that threaten food safety and implement a system for reducing or eliminating those hazards. Regulatory

compliance includes a written food safety plan for the facility with:

1. A hazard analysis document (\$63 million);
2. Preventive controls including process controls (\$131 million), food allergen (\$16 million), and sanitation controls (\$39 million);
3. Monitoring that processes are consistently performed and verification of process implementation and effectiveness (\$85 million); and
4. A recall plan (\$11 million).

In addition to the costs listed above, the industry is expected to incur \$61 million in labor costs to learn about the rule. Corrective actions are expected to cost around \$52 million. Qualified facilities will incur \$16 million in total compliance costs, not listed above. The total cost of the rule for domestic industry is estimated at \$475 million. FDA estimates the total value of domestic processed food at \$905 billion, so the cost of compliance to the industry is less than 0.06% of revenue.

Using similar methodology as in its analysis of the produce safety rule, the FDA estimates that the industries covered by the preventive controls rule are associated with about 900,000 foodborne illnesses and allergy-related illnesses each year, at a total cost of almost \$2 billion. The FDA has not estimated the number of illnesses that will be prevented by implementing the rule. Based on the estimated cost of regulation and current cost of illnesses associated with the regulated industry, we estimate roughly that a reduction of illnesses of about 24% (\$475 million/\$2 billion) would balance cost of implementation of the preventive controls rule with costs of illness prevented.

Qualified facilities may obtain a partial exemption from the preventive controls rule. Instead of meeting the requirements outlined above, qualified facilities must either (a) notify FDA that they are addressing hazards through preventive controls and monitoring the effectiveness of those controls or (b) comply with local food-safety laws and label its products with the name and business address of the processing facility. In addition, FDA proposes to define facilities with less than \$250,000 in annual revenue as qualified facilities for the purpose of the preventive



controls rule. FDA also suggests alternative thresholds of \$500,000 and \$1,000,000 in annual revenue. Regardless of the threshold, the vast majority of processed food would be processed by firms covered by this regulation. FDA estimates that these three thresholds would give partial exemptions to the processors of less than 0.5%, less than 1%, and less than 2% of all processed food, respectively.

Traceability

Requirements for a tracking and tracing program are not mentioned in either of the proposed rules. FDA initiated a pilot tracking and tracing program in September 2011. If new tracking and tracing rules are forthcoming, they seem likely to follow the outcomes of the pilot project. Such a requirement is likely to be expensive to implement. The Produce Traceability Initiative is a set of collective standards currently being implemented by members of the produce industry, and any mandatory traceability program will closely resemble these standards. Ducharme and Kennedy (2010) estimated that the costs of implementation of the Produce Traceability Initiative were 7.1% of revenue in the first year and 2.4% of revenue in subsequent years, for a vegetable farm with \$31,000 in annual sales. For the

largest vegetable farms in their study, those with average annual sales of \$7.4 million, the implementation costs were 0.7% of revenue in the first year and 0.5% of revenue in subsequent years.

Conclusion

The FDA expects that its proposed rules implementing the Food Safety Modernization Act will significantly increase the compliance costs of farms that grow fresh produce, while reducing incidence of foodborne illness. According to the FDA, the requirements of FSMA are less costly per unit of sales for food processing firms than they are for farms that grow fresh produce. The cost of compliance, relative to revenues, is expected to be highest for non-exempt smaller farms and firms, which creates incentives for these farms and firms to pursue ways to meet the exemption requirements. Meeting exemption requirements may involve shifting away from certain products, seeking a different type of buyer, or even splitting a business into multiple firms. For farms that do not qualify for any exemptions, the increase in compliance costs will raise their costs compared with exempt farms. Much remains unknown about the causes of foodborne illness and the risk factors facing different types of producers. Given that the new standards under FSMA are likely to reduce incidence of foodborne illness, any expansion of the exemption criteria intended to mitigate compliance burdens would likely result in greater overall incidence of foodborne illness and reduce the effectiveness of FSMA. The more difficult question is where the balance lies between costs and benefits of exemption criteria and more research is required on both the costs and benefits sides. ■

FOR FURTHER READING

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