Businesses, which will not be impacted by compliance until Year 3, the costs are small and virtually non-existent in Years 4-10. As previously stated, these projections are subject to change with the implementation and almost-certain revisions to the PCHF rule.

Conclusion

Public health concerns and demands from consumers have driven the development of FSMA's rules. The economic impact of this legislation is difficult to quantify because of the many factors involved. The accuracy of FDA's cost and net benefit estimates may or may not prove to be correct over time. Furthermore, the share of compliance costs passed on to consumers is uncertain.

While industry-wide estimates of net impacts are questionable, the fact remains all non-exempt food manufacturers will face some compliance costs. The Robert M. Kerr Food & Agricultural Products Center (FAPC) at Oklahoma State University offers several services that can help businesses comply with the PCHF rule and identify the impacts to their individual businesses. These include:

- FSMA training workshops and conferences offered for Oklahoma's food processors to meet the PCHF guidelines.
- Assistance in developing food safety plans that meet the requirements of the PCHF rule.
- Mock audits to test the monitoring, record-keeping and responses to CGMPs in the firm's food safety plan.
- Engineering and business analysis assistance to determine the least-cost means of meeting PCHF rule requirements.
- Continued support and assistance to address future changes in the FSMA PCHF rule.

To learn more about how FAPC can help your business comply with the PCHF rule, visit www.fapc.biz or call the center at 405-744-6071.

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Table 2: Food manufacturers' aggregate costs for FSMA Preventive Controls for Human Food rule compliance. ($ million)*

Food Processors Size Category**	500 > FTEs	Small Businesses (<500 FTEs)	Very Small Businesses (<$1M/yr. gross revenue)	Total Undiscounted
Present Value of Total	*$343*	*$3,346*	*$109*	*$3,799*
Compliance Year: 1	*$63*			*$63*
2	*$31*	*$782*		*$728*
3	*$31*	*$325*	*$110*	*$465*
4	*$31*	*$325*		*$356*
5	*$31*	*$325*		*$356*
6	*$31*	*$325*		*$356*
7	*$31*	*$325*		*$356*
8	*$31*	*$325*		*$356*
9	*$31*	*$325*		*$356*
10	*$31*	*$325*		*$356*

*Source: FDA 2017.

***Numbers are aggregates for all firms within the same category, based on full-time employees (FTEs) or annual gross sales. This does not mean individual small/very small businesses have estimated compliance costs that are higher than individual large businesses.*

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FOOD TECHNOLOGY FACT SHEET

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405-744-6071 • www.fapc.biz • fapc@okstate.edu

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FSMA Preventive Controls for Human Food: What Are the Costs to My Food Business?

Parker Terrell
OSU Undergraduate Student

Ravi Jadeja
FAPC Food Safety Specialist

Andrea Graves
FAPC Business Planning & Marketing Specialist

Rodney Holcomb
FAPC Agribusiness Economist

Roughly 48 million people in the United States get sick, 128,000 are hospitalized and 3,000 die each year from foodborne diseases, according to the Centers for Disease Control and Prevention (CDC). In response to these alarming statistics, the Food Safety Modernization Act of 2011 (FSMA) was passed and hailed as the greatest sweeping change to food safety laws in more than 70 years. FSMA was deemed necessary because "producers and consumers, acting in the unregulated market place, are unable to observe the health risks of potentially injurious foodborne hazards that would be necessary to make well informed choices about the processing, distribution, sale and final consumption of potentially hazardous food products." (FDA, 2017)

FSMA focuses on proactively addressing the prevention of foodborne illnesses rather than responses to outbreaks. Under the Act, the Food and Drug Administration (FDA) was required to develop new rules to meet these purposes. According to an economic report issued by the FDA (FDA, 2017), FDA was mandated to "establish, through rulemaking, science-based minimum standards for conducting a hazard analysis, documenting hazards, implementing preventive controls and documenting the implementation of the preventive controls." The reasoning behind these newly-created rules is in a market where consumer demand is the only driving force, there is no way for consumers to distinguish firms that invest in food safety and those who do not. Thus, the overall aim of FSMA is to improve societal health and well-being through regulation, namely the creation of these seven rules:

- Preventive Controls for Human Food: updated Current Good Manufacturing Practices (CGMPs) for the food industry and placed a requirement on the food industry to use risk-based preventive controls to improve food safety.
- Produce Safety Rule: mandates practices related to food safety, sanitation, worker hygiene, water safety, soil amendments use and wild/domestic animal issues for produce farms.
- Preventive Controls for Animal Food: similar to the rule for human food but for entities manufacturing animal food.
- Foreign Supplier Verification Programs: impacts anyone who imports food into the United States and ensures the same food safety standards are required of domestic processors.
- Accredited Third-Party Certification: created a program to accredit third-party food safety auditors and issue certifications for foreign facilities and their food products.
- Sanitary Transportation: establishes sanitary practices to reduce food safety risks during transportation.
- Intentional Adulteration (Food Defense): generally for large companies whose food products reach many people, to protect against intentional contamination.

This fact sheet summarizes the basic premises of the Preventive Controls for Human Food (PCHF) rule for food processors, including exemptions to the rule, and discusses the food industry's estimated financial impacts associated with compliance to this rule.

Preventative Controls for Human Food

According to the text of the PCHF rule, any person/entity who manufactures, processes, packs and/or holds any food for human consumption is expected to comply with some or all parts of these new regulations. Businesses or individuals manufacturing food and beverage items already covered by other specific regulations (e.g., low acid canned foods, juices and alcoholic beverages) must register with the FDA and comply with CGMPs but may be exempt from most of this rule's requirements by complying with their industry-specific regulations. Other food businesses will have to follow the

newly updated CGMPs and develop a food safety plan that identifies potential hazards, includes preventive controls for identified potential hazards and has steps (monitoring, corrective actions, validations, verifications) for management/oversight of those preventive controls.

Food processors that must fully comply with the PCHF rule, must have at least one employee complete the Preventive Controls Rule training to become a Preventive Controls Qualified Individual (PCQI) to help create the food safety plan. This is very similar to the USDA-mandated Hazard Analysis of Critical Control Points (HACCP) implemented for the meat industry in the late 1990s. As with meat industry HACCP, this FSMA rule requires processors to put in place certain procedures to minimize the risks of foodborne pathogens. This may require food industry members to make capital improvements, change production practices, and invest time and resources in training and amenities for employees. The costs and economic impacts of these new regulatory requirements are important issues for food industry members. While the greatest issue for most food production entities will be the implementation of the preventive measures, the economic impact may not be immediately recognized. However, in the long run these impacts may be substantial in one or more key areas of operation.

Exemptions to the Preventive Controls Rule

Food businesses that only perform certain low-risk and/or certain on-farm processing manufacturing activities (e.g. baking bread or on-farm canned jams/jellies) may be eligible for an exemption to some parts of the rule, depending on their size. FDA has a list of these exempt low-risk activities (see 21 CFR 117.5). Also, storage facilities that hold packaged food not exposed to the environment are exempt, although if the packaged food requires refrigeration, the business must document properly controlled temperature for those foods.

Company size also may give a food business a qualified exemption from some parts of the rule and only require CGMP compliance. Those meeting the criteria of a "qualified facility" are either/or:

- Very small businesses with three-year average annual food sales of less than $1,000,000, adjusted for inflation based on 2011 dollars.
- Facilities that, during the last three years, had less than $500,000 in annual sales (adjusted for inflation) AND more than half of their annual sales went to "qualified end-users," i.e. the actual consumer of the food or a restaurant or retail food establishment within 275 miles (and within the same state/Native American reservation) of the processor.

Industry Impacts

The Unfunded Mandates Reform Act of 1995 (UMRA) requires all government agencies to submit a written statement if a proposed rule or mandate will result in expenditures to U.S. industries of more than $100 million, adjusted annually for inflation. In 2018, that number is approximately $150 million, and the FDA has estimated the first full-year financial impact on the food industry to be higher than $150 million when the FSMA rules are phased in. In fact, the FDA Economics Staff have estimated the total costs to domestic food processors over a 10-year span, discounted back to present dollar values, will be between $2.7 billion and $3.3 billion (FDA 2017). Tables 1 and 2 provide the average cost estimates per facility from these analyses.

Comments and Responses to Estimated Industry Impacts and Net Society Benefit

Although costs were estimated, the FDA received comments concerning the failure to quantify benefits or show the PCHF rule will have a net benefit to society. The FDA responded by pointing out the lack of independent economic studies that quantify the health benefits of HACCP or similar food safety systems. Understandably, quantifying benefits and a net societal impact for the rule is difficult. However, food industry members have a reasonable request that a net societal benefit should be justified if the industry is expected to incur additional regulatory burdens.

For determining net societal benefit, assumptions were made regarding the prevention of food-borne illnesses resulting from the PCHF rule – including the prevention of undetected illnesses. The FDA received several comments about the highly speculative calculations for undetected illnesses, including comments that the economic burden for these illnesses (according to Scallen et al., 2011) was over-valued. The FDA responded by defending its incorporated methodology, even referring to Scallen et al. (2011) for the estimation model used. The FDA also argued its estimates were derived from peer-reviewed, published research and considered more long-term health outcomes.

Two of the biggest challenges for estimating the savings associated with preventing one human illness due to foodborne pathogens are:

- Identifying the source of the contamination (e.g. the farm, the processor, mode of transportation, warehouse, etc.).
- Estimated healthcare costs associated with different types of illnesses (e.g. resulting from various pathogenic bacteria, viruses or parasites).

In its efforts to identify some impact, the FDA applied a weighted average cost of each type of illness; for example, the average burden of a case of listeriosis was estimated at more than $1 million. The FDA Economics Staff estimated a variety of different scenarios, determining the social welfare gain of preventing roughly 157,000 illnesses per year would offset the expenses to the food processing industry. However, the dollar impacts of these preventions were not included in the final report (FDA 2017).

Table 1: Summary of FSMA Preventive Controls for Human Food projected costs and health benefits – Years 1-3 of implementation and recurring annual costs. ($ millions)*

PCHF Provision	First Yr. Compliance Period (One Time Cost)	Second Yr. Compliance Period (One Time Cost)	Third Yr. Compliance Period (One-Time Cost)	Annual Cost (Annually Recurring Costs)	Total Annualized Cost at 7%	Total Annualized Cost at 3%
Learn about Rule	*$6*	*$96*	*$21*	*$0*	*$16*	*$14*
Education and Training	$17	$148	$21	$15	$35	$34
Attest Qualified Status to FDA	$0	$0	$1	$0	$0	$0
One-time Label Change	$0	$0	$67	$0	$8	$7
Total Costs Subpart A & D	$17	$148	$88	$15	$43	$41
Subpart C Hazard Analysis and Risk-Based Preventive Controls						
Hazard Analysis	***$0***	***$51***	***$0***	***$26***	***$29***	***$29***
Hazard Analysis for Economically Motivated Adulteration	***$1***	***$11***	***$0***	***$22***	***$21***	***$21***
Process Controls	***$2***	***$57***	***$0***	***$66***	***$65***	***$65***
Allergen Controls	***$1***	***$15***	***$0***	***$14***	***$14***	***$14***
Sanitation Controls	***$1***	***$27***	***$0***	***$10***	***$12***	***$12***
Environmental Monitoring	***$0***	***$2***	***$0***	***$17***	***$15***	***$15***
Product Testing	***$0***	***$0***	***$0***	***$45***	***$41***	***$42***
Supplier Approval and Verification Program	***$4***	***$11***	***$0***	***$70***	***$64***	***$65***
Corrective Actions	***$0***	***$4***	***$0***	***$33***	***$29***	***$30***
Recall Plans	***$0***	***$4***	***$0***	***$6***	***$6***	***$6***
Monitoring/Verification	***$0***	***$1***	***$0***	***$31***	***$27***	***$27***
Total Costs Subparts C & G	***$9***	***$183***	***$0***	***$340***	***$323***	***$326***
Total Domestic	***$32***	***$427***	***$109***	***$355***	***$382***	***$381***
Costs						
Total Foreign Costs	***$68***	***$915***	***$234***	***$760***	***$820***	***$817***
Total Costs	***$100***	***$1,342***	***$344***	***$1,115***	***$1,202***	***$1,198***
Total Health Benefits	***Not quantified (across all sectors). Estimated break-even occurs when 157,000 illnesses are prevented per year.***					

**Source: FDA 2017. Numbers for total costs might not add up due to rounding.*

Table 1 shows the estimated FSMA PCHF rule's compliance costs. These cost estimates were based on data obtained by FDA and feedback from industry members regarding expected changes in operations due to FSMA compliance. Although some aspects of the rule will most likely be altered during/after full implementation, these projections are the best guesses available to the public at this time. As for compliance in foreign facilities, the FDA declared they lacked the information about foreign consumers' current exposure to the hazards associated with contaminated foods across the many countries that currently sell covered foods throughout multiple markets.

Table 2 provides a breakdown of Table 1's costs to show the estimated compliance costs for Small Businesses (less than 100 full time employees) and Very Small Businesses (less than $1 million in annual gross sales). The table outlines compliance to the PCHF rule over a 10-year span and discounts those years by an inflation factor back to a present value. After Year 2, for Small Businesses, the compliance costs decrease significantly and level out. For Very Small