Regulations Implementing the Food Safety Modernization Act

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Abstract

The FDA has been charged by the 2010 Food Safety Modernization Act (FSMA) with improving food safety in the United States. The four large regulations analyzed in this paper do not appear able to accomplish that mission. Part of the reason for this failure is that Congress has narrowly prescribed some of the reforms that must be in these regulations. In addition to those requirements, however, the FDA is proposing even more expansionist regulations. There are two problems with these regulations and the expansions proposed in the FSMA: either they do not address an actual food safety risk in the areas they cover, or, where there is a significant risk, analysis shows that they will not effectively reduce that risk. Either way, the costs of these rules exceed the benefits, in some cases by a great deal.

JEL codes: I1, D8, D6

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1. Introduction

The Food Safety Modernization Act (FSMA) was enacted on January 4, 2011, for the purpose of improving the safety of the food supply. Passage of the FSMA followed years of work by both the House and the Senate to broadly modernize food safety legislation. Congressional intent, as summarized by the Congressional Research Service, was to require that the Secretary of Health and Human Services improve (1) the capacity to prevent food safety problems, (2) the capacity to detect and respond to food safety problems; and (3) the safety of imported food.[1] The task of implementing the statute was delegated to the Food and Drug Administration (FDA).

Pursuant to this duty and authority under the FSMA, the agency recently proposed 10 regulations. Unfortunately, the FDA is unable to demonstrate that the benefits of these rules outweigh their costs. The current period of slow income growth is a particularly bad time to implement ineffective rules that will raise food prices for American households. The 10 regulations will actually have the same effect as a tax on food consumption because farmers and food producers will have to pass on the costs of the regulations in the form of higher prices. That regulatory "tax" would disproportionately burden lower-income Americans, who spend a larger portion of their income on food than those who are better off, making the "tax" extremely regressive.

Congress should revisit the FSMA because of its prescriptive nature. Congress has given itself the power to review major rules under the Congressional Review Act of 1996, and all the

[1] Congressional Research Service, Summary of H.R. 2751, 111th Congress, https://www.congress.gov/bill/111th-congress/house-bill/2751.

FSMA major rules represent an ideal place for Congress to intervene. Before passage of the FSMA, Congress did not have information on the likely costs or the benefits of all the regulations. Under the FSMA, Congress required that the FDA perform a number of studies intended to inform the design of proposed regulations.[2] However, the law requires only that the FDA complete these studies by the time that it finalizes the regulations. Congress should have requested that the studies be completed before passing the legislation that forced the FDA to issue new regulations.

Under FSMA, Congress mandated that the FDA promulgate a sizable number of costly regulations. In the response to date, the FDA has promulgated regulations relating to the following:

- Information required in prior notice of imported food shipments
- Record availability requirements

[2] The first study is of the food processing sector:

> (A) In general.—The Secretary, in consultation with the Secretary of Agriculture, shall conduct a study of the food processing sector regulated by the Secretary to determine—
> (i) the distribution of food production by type and size of operation, including monetary value of food sold;
> (ii) the proportion of food produced by each type and size of operation;
> (iii) the number and types of food facilities co-located on farms, including the number and proportion by commodity and by manufacturing or processing activity;
> (iv) the incidence of foodborne illness originating from each size and type of operation and the type of food facilities for which no reported or known hazard exists; and
> (v) the effect on foodborne illness risk associated with commingling, processing, transporting, and storing food and raw agricultural commodities, including differences in risk based on the scale and duration of such activities.
> (B) Size.—The results of the study conducted under subparagraph (A) shall include the information necessary to enable the Secretary to define the terms "small business" and "very small business", for purposes of promulgating the regulation under subsection (n). In defining such terms, the Secretary shall include consideration of harvestable acres, income, the number of employees, and the volume of food harvested.

The second study is a science-based risk analysis relating to farm risks:

> (C) Science-based risk analysis.—In promulgating regulations under subparagraph (A), the Secretary shall conduct a science-based risk analysis of—
> (i) specific types of on-farm packing or holding of food that is not grown, raised, or consumed on such farm or another farm under the same ownership, as such packing and holding relates to specific foods; and
> (ii) specific on-farm manufacturing and processing activities as such activities relate to specific foods that are not consumed on that farm or on another farm under common ownership.

The regulation, including full descriptions of both studies, can be found at http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm247548.htm.

- Preventive controls for human food
- Fresh fruits and vegetables
- Criteria for ordering administrative detention of human and animal food
- Foreign supplier verification programs for importers of food for humans and animals
- Accreditation of third-party auditors for imported food
- Food for animals
- Intentional adulteration of food
- Transportation of human and animal food

The FDA's own preliminary estimates predict that the regulations required by the FSMA as written by the FDA would cost well over $2 billion on an annualized basis (see table 1). According to the FDA estimates, costs in the first year of implementation will be well over $3 billion. Those estimates may be low for a number of reasons. For example, the FDA foreshadowed that it might add a number of additional regulatory provisions to the final rules (the costs of which were not included in the estimates of the proposed rules). Further, the FDA's estimates might not include many of the costs of following the regulations that the food industry has identified in its comments on the regulations.

This paper addresses four of the most burdensome regulations drafted by the FDA:

- Proposed Rule for Preventive Controls for Human Food: Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food (the human food rule)
- Proposed Rule for Preventive Controls for Animal Food: Establish Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Food for Animals (the animal feed rule)

- Proposed Rule for Produce Safety: Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption (the produce rule)
- Proposed Rule for Focused Mitigation Strategies to Protect Food against Intentional Adulteration (the intentional adulteration rule).

Table 1. FDA Estimates of the Annualized Cost of Food Safety Modernization Act Regulations

Regulation	First FDA preliminary estimate	FDA preliminary estimate of additional supplemental regulations	Final FDA estimate
Prior notice	"negligible"		"negligible"
Administrative detention	less than $50 million		less than $50 million
Record availability	"small"		"small"
Preventive controls for human food	$619 million to $975 million	+$52 million to $77 million	
Fruits and vegetables	$630 million	−$100 million	
Foreign supplier verification programs and accreditation of third-party auditors (combined)	$462 million	−$76 million	
Food for animals	$87 million to $129 million	+$6 million	
Intentional adulteration	$367 million		
Food transportation	$46 million		

Source: Preliminary regulatory impact analyses for Food Safety Modernization Act rules.

Despite the high cost of complying with all those regulations, the FDA has been unable to show that significant systematic public health risks warrant some of these regulations or, in other cases, indicate that where such risks exist, the rules will make much of a difference. In fact, experience with mandating preventive controls in previous similar FDA regulations indicates that the FDA has overestimated the benefits of these new regulations. As might have been predicted, the FDA has no evidence that the new regulations will reduce foodborne risk to any degree that would make them worthwhile. What is clear is that the FDA has consistently used the

FSMA as an excuse to strengthen and to expand its regulatory grip on the entire food industry beyond what any evidence can support.

For any regulation to produce more good than harm, two factors must be present. First, there must be an actual problem to solve. Second, the regulation has to solve at least part of the problem (and at a cost that is justified by the benefit).

2. Missing Evidence of Systemic Problems

To justify the establishment of a federal regulation, an agency cannot simply identify a problem. Instead, there should be evidence of a large, recurring problem that is not likely to go away without a federal solution.[3] In fact, Executive Order 12866 (President Bill Clinton's order still in effect) demands that "each agency shall identify the problem that it intends to address (including, where applicable, the failures of private markets or public institutions that warrant new regulatory action) as well as assess the significance of that problem."[4] The executive order is the president's instruction to regulatory decision makers about how he expects them to make policy decisions. But in rulemaking for the FSMA, the FDA has been unable to identify a significant problem to justify some of the regulations as required by the ruling executive order.

The best illustration of this argument is the intentional adulteration rule. The FDA already has four anti-bioterror regulations in place:

1. Establishment and Maintenance of Records under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, 69 Fed. Reg. 71561–655 (December 9, 2004).

[3] Jerry Ellig, *Ten Principles for Better Regulation* (Arlington, VA: Mercatus Center at George Mason University, 2013).
[4] Exec. Order No. 12866, 58 Fed. Reg. 51735 (October 4, 1993). Reaffirmed in Exec. Order No. 13563, 76 Fed. Reg. 3831 (January 21, 2011), http://www.whitehouse.gov/sites/default/files/omb/inforeg/eo12866/eo13563_01182011.pdf.

2. Registration of Food Facilities under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, 70 Fed. Reg. 57505–9 (October 3, 2005).
3. Criteria Used to Order Administrative Detention of Food for Human or Animal Consumption under the FSMA, 78 Fed. Reg. 7994–97 (February 5, 2013).
4. Information Required in Prior Notice of Imported Food under Public Health Security and Bioterrorism Preparedness and Response Act of 2002, with minor amendments under the FSMA, 78 Fed. Reg. 32359–62 (May 30, 2013).

In addition to these rules, the FDA has issued food defense guidance and initiated numerous education and outreach efforts to ensure that the food industry has taken sufficient precautions. All those FDA activities (with the exception of the two rules mentioned above) had been occurring well before the passage of the FSMA. And just as the FDA has been active, food companies have undertaken extensive activities to protect their businesses from being attacked by terrorists and from being used as tools to attack others.[5] Furthermore, no instances of intentional contamination of the US food supply have occurred at the growing, manufacturing, or distribution level since the passage of the FSMA. At least from the standpoint of addressing a real, systemic problem, no apparent need exists for Congress to require the FDA to issue a fifth regulation aimed at preventing intentional contamination.

The FDA also is unable to point to any systematic problem with animal feed to justify that regulation. In fact, the regulation's preliminary regulatory impact analysis (PRIA) appears to present evidence that the rule is *not* needed. It shows that costly recalls have created the right incentives in the animal feed industry to prevent further recalls. For the events mentioned in the PRIA, the majority of animal feed recalls came from one instance, the intentional adulteration of

[5] See, for example, Rhona S. Applebaum, "Protecting the Nation's Food Supply from Bioterrorism," *Food Safety Magazine* February/March 2004.

pet food with melamine in China. Other than that, three Salmonella outbreaks between 2007 and 2012 arose from contact with pet food, but no problems occurred with farm animal feed. Thus, at a minimum, the only rule necessary might be one for pet foods.

3. Limited Effectiveness of Earlier Preventive Controls Rules

In responding to the FSMA's requirements to establish preventive controls regulations, the FDA has chosen to implement a system that is essentially equivalent to a preventive controls system that was invented by the food industry (in conjunction with the US Army and NASA). This concept, invented for the space program, was developed in the 1970s and is called Hazard Analysis and Critical Control Points, or HACCP.[6] Table 2 shows that the FDA regulations implementing the FSMA essentially impose HACCP on the entire food industry.

Table 2. Elements of HACCP and HACCP-Like Requirements of FSMA Regulations

Elements of HACCP	Requirements of FSMA Human Food Rule
Perform hazard analysis	Proposed § 117.130—Hazard Analysis
Establish controls at critical control points and set critical limits	Proposed § 117.135—Preventive Controls for Hazards That Are Reasonably Likely to Occur
Develop HACCP plan	Proposed § 117.126—Requirement for a Food Safety Plan
Monitor critical control points	Proposed § 117.140—Monitoring
Identify corrective actions	Proposed § 117.145—Corrective Actions
Keep records of monitoring	Proposed § 117.175—Records Required for Subpart C
Perform verification	Proposed § 117.150—Verification

Source: FSMA Supplemental Notice of Proposed Rulemaking for Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food, Docket No. FD-2011-N-0920, Preliminary Regulatory Impact Analysis.

Note: FSMA = Food Safety Modernization Act; HACCP = Hazard Analysis and Critical Control Points.

[6] Dan Flynn, "HACCP: The Space Program's Contribution to Food Safety," *Food Safety News*, July 1, 2013.

To the extent that the two systems diverge, the FSMA regulations are almost always more burdensome than are the existing HACCP regulations. For example, Congress required that the businesses covered under the FSMA rule establish preventive controls for radiological hazards in addition to the biological, chemical, and physical hazards covered by the HACCP rules. HACCP controls are established only at identified critical control points: points in the production process at which contamination of the food can occur or be controlled and the final point in the process at which contamination can be prevented or reduced.

In the FSMA preventive controls paradigm, preventive controls are established throughout the production process, not just at critical control points. The FSMA paradigm significantly multiplies the number of points in the process at which businesses will be expected to expend more resources. Businesses that have already successfully implemented a HACCP system would still need to establish preventive controls at more points in the production process to satisfy FSMA, despite the lack of evidence that extra monitoring would provide additional benefits. If attention became divided between critical and noncritical points in the production process, the outcome could be less safe than in the existing system.[7]

Numerous food companies have voluntarily adopted HACCP since the 1970s, primarily driven by market forces, not by regulations.[8] William Sperber, who has been credited with being the first to use HACCP while at the Pillsbury Company in the early 1970s, has written that HACCP has been oversold. He argues that "despite the widespread use of HACCP in the food industry, many outbreaks of food borne illness still occur. However, these food safety failures

[7] "As the size of the size of the rule set increases, it is harder for the firm to identify which rules are relevant." Andrew Hale, David Borys, and Mark Adams, "Regulatory Overload: A Behavioral Analysis of Regulatory Compliance" (Mercatus Working Paper, Mercatus Center at George Mason University, Arlington, VA, November 2011), 16.
[8] John G. Surak, "The Evolution of HACCP," *Food Quality and Safety*, February/March 2009.

are rarely HACCP failures. Rather, they are frequently failures of cleaning and sanitation practices or the lack of management awareness and commitment to provide the necessary training and resources."[9] In fact, the combination of a focus on sanitation with traceability may ultimately prove to be the best way to actually begin making serious improvements in food safety.[10] Unfortunately, research has shown that compliance with HACCP does not necessarily improve compliance with sanitation standards.[11] It may be the case that Congress and the FDA have been careful to avoid calling the FSMA regulations HACCP regulations because the three existing HACCP regulations have not shown evidence of being successful.[12]

Before Congress passed the FSMA, the FDA had promulgated preventive controls rules in two different sectors of the food industry. The first was the seafood HACCP rule.[13] The FDA produced an analysis of the benefits and costs of the rule that proved to be wrong after implementation. For the costs, one author noted, "The results show that FDA generally underestimated the costs of HACCP adoption in both models used in its regulatory impact analysis."[14] For the benefits, the primary problem with applying HACCP to seafood is that without a kill-step (a process that kills the germs that cause illness), there are no effective controls for shellfish consumed raw.[15]

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[9] William H. Sperber, "HACCP Does Not Work from Farm to Table," *Food Control* 16 (2005): 513–14.
[10] Ibid.
[11] Anna Alberini, Erik Lichtenberg, Dominic Mancini, and Gregmar I. Galinato, "Was It Something I Ate? Implementation of the FDA Seafood HACCP Program," *American Journal of Agricultural Economics* 90, no. 1 (February 2008): 28–41.
[12] Richard A. Williams, "A New Role for FDA in Food Safety" (Mercatus Working Paper, Mercatus Center at George Mason University, Arlington, VA, November 2010).
[13] "Procedures for the Safe and Sanitary Processing and Importing of Fish and Fishery Products," 60 Fed. Reg. 65096 (December 18, 1995), http://www.gpo.gov/fdsys/granule/FR-1995-12-18/95-30332/content-detail.html.
[14] Corinna Colatore and Julie A. Caswell, "The Cost of HACCP Implementation in the Seafood Industry: A Case Study of Breaded Fish," in *The Economics of HACCP: Costs and Benefits*, ed. Laurian Unnevehr (Saint Paul, MN: Eagan Press, 2000), 45–68.
[15] A critical control point is a point in the process at which hazards may either be prevented from contaminating food or be controlled.

The obstacle particularly applies to oysters from the Gulf of Mexico because on rare occasions they are already contaminated with a harmful pathogen, *Vibrio vulnificus*, before they are taken from the water.[16] Oysters are removed from the Gulf and taken straight to restaurants to be served raw. In this pattern of distribution, there are no critical control points at which to reduce or eliminate the pathogens if they are present. Nevertheless, 50 percent of the benefits of the seafood HACCP rule were attributed to reducing *Vibrio vulnificus*–related illnesses from consumption of raw oysters taken from the Gulf of Mexico.[17] Contrary to the FDA's predictions, illnesses have increased. In 1995, the FDA estimated that the number of cases of *Vibrio vulnificus*–related illnesses would be reduced from 60 cases to between 30 and 48 per year.[18] In 2011, the Centers for Disease Control and Prevention reported 113 cases of illness caused by *Vibrio vulnificus*.[19] Just as the FDA's seafood HACCP rule failed to reduce the risk associated with seafood that was not subject to a kill-step, one can expect that establishing preventive controls for fresh produce that include no heat treatment between the farm and the family table will likewise be ineffective at reducing fresh produce risks.

The other FDA experience with preventive controls was implementation of HACCP for raw, unprocessed juice. Raw juice, particularly apple juice, should be processed, not sold raw. Using the century-old, but still enormously effective, technology of pasteurization (essentially cooking) eliminates any possibility of contamination as long as post-pasteurization packing is handled carefully. The FDA mandated HACCP at an annualized cost

[16] *Vibrio vulnificus* is a pathogen that kills about one-third of the people who get sick from it.
[17] 60 Fed. Reg. 65096.
[18] Id.
[19] National Center for Emerging and Zoonotic Infectious Diseases, "National Enteric Disease Surveillance: COVIS Annual Summary, 2011," Division of Foodborne, Waterborne, and Environmental Diseases, Centers for Disease Control and Prevention, August 2013, http://www.cdc.gov/ncezid/dfwed/PDFs/covis-annual-report-2011-508c.pdf.

of $400 million with all of the monitoring and recordkeeping when pasteurization would have and did solve the problem.[20]

A third preventive controls rule precedes the FSMA. In 1996, the US Department of Agriculture's Food Safety and Inspection Service (FSIS) implemented preventive controls for meat and poultry processing plants.[21] It is not clear whether any improvements in food safety can be attributed to the implementation of the FSIS version of HACCP or to the effect of additional sanitation and end-product testing also required with the regulation. A 2000 study by John Antle estimated that if the regulations were 20 percent effective, the estimated annual benefits would be $198 million to $738 million and the costs could range from $500 million to $5 billion, not including quality control costs of about $100 million per year.[22] Antle concluded that "the costs of food safety regulation could plausibly exceed the benefits."[23]

Understandably, members of Congress, like consumers, are concerned about food safety issues, but the evidence did not support passage of the FSMA requiring federally mandated preventive controls. The FSMA appears merely to offer an opportunity for the FDA to expand its size and influence. Predictably, the FDA has used the FSMA to make a strong case for more funding.[24] As noted in a report coproduced by the Regulatory Studies Center at George Washington University, "The Food and Drug Administration, which added an estimated 1,731 new personnel in 2014, is set to add another 1,033 people in 2015" and "Its

[20] "Procedures for the Safe and Sanitary Processing and Importing of Juice," 66 Fed. Reg. 6138 (January 19, 2001, FDA, HACCP).
[21] "Pathogen Reduction; Hazard Analysis and Critical Control Point (HACCP) Systems," 61 Fed. Reg. 38805 (July 25, 1996, US Department of Agriculture, FSIS).
[22] John Antle, "No Such Thing as a Free Lunch: The Cost of Food Safety Regulation in the Meat Industry," *American Journal of Agricultural Economics* 82, no. 2 (2000): 310–22.
[23] Ibid., 321.
[24] Lydia Zuraw, "FDA Needs More Resources for FSMA Implementation," *Food Safety News*, February 6, 2014, http://www.foodsafetynews.com/2014/02/fda-needs-more-resources-for-fsma-implementation/#.U7paeU1OVok.

budget has risen by $1.8 billion—or 45 percent—since passage of the Food Safety Modernization Act in 2011."[25]

4. Unjustified Benefits Claims

The FDA repeatedly claims that its regulations will reduce food recalls. If the claims were true, the benefit would be wide-ranging, because recalls impose costs on entities all along the supply chain and on to consumers. However, the FDA offers no evidence to support its claims, which are oft-repeated assertions by government officials and quality-control-system salespeople. But the evidence proves the opposite. Instead, more regulation seems to lead to more recalls, not fewer. It is not clear why this is the case, but it may be that when more regulations are in place, food that is probably safe is recalled because *potential* problems are identified at critical control points that have "conservative" controls designed to ensure that no possible problem will occur.

The Food Safety Inspection Service's Pathogen Reduction; Hazard Analysis and Critical Control Point (HACCP) Systems final rule[26] became effective for producers with 500 or more employees in January 1998, for producers with 10–499 employees in January 1999, and for producers with fewer than 10 employees or sales of less than $2.5 million in January 2000. That regulation is a preventive-control type of regulation, similar in many ways to the FDA's proposed FSMA regulations. Figure 1 shows the number of meat and poultry recalls reported by the Food Safety Inspection Service on its website.[27]

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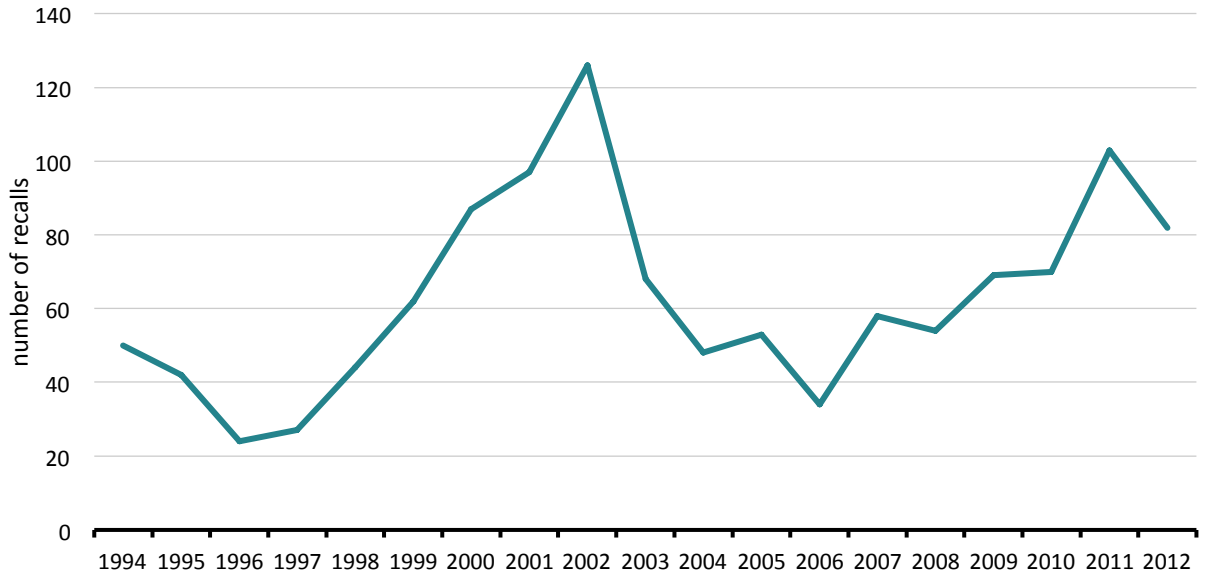
[25] Susan Dudley and Melinda Warren, "Economic Forms of Regulation on the Rise: An Analysis of the US Budget for Fiscal Years 2014 and 2015" (Working Paper, Regulatory Studies Center at George Washington University, Washington, DC, and Weidenbaum Center on the Economy, Government, and Public Policy at Washington University in Saint Louis, MO, July 2014).
[26] 61 Fed. Reg. 38806.
[27] "Recall Case Archive," Food Safety and Inspection Service website, last modified February 27, 2015, http://www.fsis.usda.gov/wps/portal/fsis/topics/recalls-and-public-health-alerts/recall-case-archive.

Figure 1. Number of Meat and Poultry Recalls, 1994–2012



Source: "Recall Case Archive," Food Safety and Inspection Service website, last modified February 27, 2015, http://www.fsis.usda.gov/wps/portal/fsis/topics/recalls-and-public-health-alerts/recall-case-archive.

5. Disregarding Better Alternatives

The FDA has consistently written regulations that stretch the intent of the FSMA to the extreme limits of its possible coverage. In almost every case, more narrowly targeted rules would have made for far more justifiable regulations.

The most obvious example is the animal food regulation. The only significant hazards relating to animal food that the FDA can point to are associated with microorganisms that cause human illness when people touch or consume contaminated pet food. A regulation that applied only to pet food processors would apply to only about 300 to 400 facilities. Regulation scholar Jerry Ellig and I have estimated that benefits might even exceed costs for a pet food–only rule (one that would exclude farm animal feed).[28] Yet the FDA plans to apply the regulation to

[28] Jerry Ellig and Richard Williams, "Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Food for Animals" (Public Interest Comment, Mercatus Center at George Mason University, Arlington, VA, March 4, 2014).

processors of food for any type of animals. The FDA's rule would apply to between 4,000 and 7,000 facilities (depending on the size of the small business exemption). With the FDA's expansive coverage, annual costs are likely to exceed annual benefits by about $100 million.

Similarly, the FDA applies its requirements in the intentional contamination rule to all facilities with more than $10 million in annual sales (excluding farms, retailers, and warehouses). The FDA calculates that 14,260 facilities would have to take actionable steps to comply with its rule at an annualized cost of $367 million. The FDA could reduce that cost dramatically by considering shelf life in the coverage of its regulation. I have estimated that by limiting the coverage of the rule to only facilities that do not produce shelf-stable products, the costs of the rule could be reduced by 75 percent to about $92 million annually.[29]

In implementing the produce safety rule, the FDA has insisted on covering all fruits and vegetables that are commonly consumed raw (see table 3). However, a few commodities account for most of the fruit and vegetable outbreaks in almost every year: herbs (e.g., basil, parsley), whole and especially fresh-cut leafy greens (e.g., lettuce, spinach), melons (e.g., cantaloupe, honeydew), alfalfa sprouts, and tomatoes (whole and fresh-cut). According to the FDA, over a six-year period those commodities accounted for 17 of 22 of outbreaks and 59 percent of illnesses associated with fresh fruits and vegetables.[30] The remaining five outbreaks and illnesses are associated with other products. From 2003 to 2008 (the years that the FDA uses for its data), the other products associated with outbreaks were raspberries/blackberries, raw almonds, green onions, jalapeño/serrano peppers, and snow peas. In what appears to be a blatant attempt to inflate its benefits estimate with no supporting evidence, the FDA uses those few other products

[29] Richard A. Williams, "Focused Mitigation Strategies to Protect Food against Intentional Adulteration" (Public Interest Comment, Mercatus Center at George Mason University, Arlington, VA, June 30, 2014).
[30] "Standards for the Growing, Harvesting, Packing and Holding of Produce for Human Consumption, Proposed Rule," 79 Fed. Reg. 58433 (September 29, 2014, FDA).

as proxies for all other fruits and vegetables. The FDA takes the point of view in the produce rule that because outbreaks are possible—even though they are not probable—they should be covered. That regulatory philosophy pervades the FSMA rules: the regulations overreach by attempting to control all possible problems, no matter how improbable they may be.

Table 3. US Consumption of the 17 Most-Consumed Fresh Fruits and 12 Most-Consumed Fresh Vegetables Covered by the FDA's Proposed Produce Safety Rule

Commodity	Pounds per person per year	Associated with outbreaks?
Bananas	25.4	no
Apples	15.5	no
Watermelon	13.3	no
Tomatoes	**12.7**	**yes**
Oranges and Temples	10.4	no
Onions	7.9	no
Head Lettuce	**7.3**	**yes**
Strawberries	7.2	no
Grapes	7.2	no
Cantaloupe	**7.0**	**yes**
Pineapples	6.1	no
Romaine and Leaf Lettuce	**5.1**	**yes**
Avocados	5.0	no
Bell Peppers	4.3	no
Carrots	4.0	no
Tangerines	3.8	no
Peaches	3.7	no
Lemons	3.7	no
Cabbage	3.0	no
Cucumbers	2.7	no
Pears	2.7	no
Celery	2.6	no
Broccoli	2.5	no
Limes	2.4	no
Mangoes	2.4	no
Grapefruit	2.3	no
Mushrooms	1.7	no
Honeydew	**1.4**	**yes**
Spinach	**0.7**	**yes**

Source: 2012 Loss-Adjusted Food Availability Data from the US Department of Agriculture Economic Research Service, http://www.ers.usda.gov/data-products/food-availability-%28per-capita%29-data-system.aspx.

Note: FDA = Food and Drug Administration.

What stands out from the evidence are the fruits and vegetables that are covered by the proposed rule and have *not* been associated with an outbreak. These include bananas, apples, oranges, grapes, carrots, celery, and cucumbers, some of the fruits and vegetables most frequently consumed overall and particularly by children with underdeveloped immune systems. The FDA cannot legitimately claim that its regulation is risk based when it ignores the basic data that outbreaks have been associated with items that are a very small part of the diet, such as alfalfa sprouts and basil, but not with products that are far more commonly consumed in large volumes.

6. Solutions

There are two possible solutions related to the FSMA rules. The first issue is the law, FSMA. The law has far too many prescriptive requirements that the FDA needs to enforce, and even the weak RIAs produced by the FDA establish that many of the requirements are not likely to make food safer. Congress should use the information provided by comments, including this paper, and the information that the FDA will produce for the mandated risk assessments to revisit the provisions in FSMA. Congress should move quickly to eliminate the statutory deadlines, put a hold on any FDA rules going final, and carefully re-examine the provisions to see which rules may potentially be functional. A functional rule is one that addresses a real systemic problem and has benefits that exceed the costs.[31] Such action seems particularly necessary given that the FDA has already been sued over its failure to adhere to congressionally mandated timelines as well as

[31] If the rules are to be as efficient as possible, the regulatory option should be selected for which benefits exceed costs by the maximum amount. In order to choose the right overall regulation, each requirement within the regulation needs to be evaluated separately for benefits and costs.

the fact that there is a dearth of evidence that shows either problems or solutions in the areas I have addressed above.[32]

The second issue, which would be unnecessary if Congress were to act, is that the FDA should focus the rules as narrowly as possible on only the products that have proven to pose human health risks and on areas for which the FDA is able to produce evidence that regulations will reduce the risk to particular products at a justifiable cost. Following are some suggested solutions that more closely target solutions to possible problems.

Human Food Rule

Section 103 of the FSMA is fairly explicit about what the FDA must do to require HACCP-type preventive controls for human food, although a number of exemptions are possible. The FDA acknowledges that it does not know how much of all foodborne illness is caused by packaged human food, but it cobbles together disparate data for an estimate of 1 million potential cases."[33] The FDA acknowledges in a footnote to the PRIA that the 16 outbreaks recorded by the Centers for Disease Control and Prevention that occurred between 2003 and 2008 might be due to "handling or storage at retail establishments, restaurants or homes."[34] Because the regulation (1) does not cover any of these facilities, (2) is based on data that are six years old, (3) does not provide any evidence of the percentage of cases caused in food manufacturing, and (4) provides no information on the current practices at food manufacturing plants, the FDA should reconsider

[32] Ricardo Carvajal, "Court Rejects FDA's 'Target Timeframes' for FSMA Regulations and Orders Publication by June 30, 2015," *FDA Law Blog* (Hyman, Phelps & McNamara, P.C.), June 30, 2013, http://www.fdalawblog.net/fda_law_blog_hyman_phelps/2013/06/court-rejects-fdas-target-timeframes-for-fsma-regulations-and-orders-publication-by-june-30-2015.html.
[33] FSMA Supplemental Notice of Proposed Rulemaking for Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food, Docket No. FD-2011-N-0920, Preliminary Regulatory Impact Analysis, p. 6.
[34] Ibid., 14.

the requirements to minimize the costs within the limits of the FSMA (absent congressional intervention). In addition, the FDA should limit the rule to larger businesses only.

The FDA offers three options for the definition of "very small businesses" (qualified facilities) that would limit the activities with which these firms would have to comply under newly written section 418. Given the explicitness of the law as written, the FDA does not appear to have much more flexibility. Finally, both Congress and the FDA should consider what is likely to be a more effective way to incentivize firms to exercise due diligence in food manufacturing: ex post monitoring of food safety outbreaks with published determination of root causes.[35]

Produce Rule

The FDA has more flexibility to exempt farms that are not problems than to exempt manufacturing plants. However, as mentioned earlier, the FDA has explicitly rejected excluding commodities that have never been shown to pose risks. Without offering any evidence, the FDA states, "It is likely that at least some commodities that currently have never been implicated in an outbreak have a positive probability of being implicated in a future outbreak."[36] This argument, if followed to its logical end, would not allow exemptions for any product for any health or safety rule ever. The FDA's analysis shows that the vast majority of "predictable" outbreaks from produce come from sprouts and leafy greens.[37] The analysis notes that covering other produce that had only one outbreak makes it "considerably more difficult to project the

[35] Richard A. Williams, "A New Role for the FDA in Food Safety" (Mercatus Working Paper, Mercatus Center of George Mason University, Arlington, VA, November 2010).
[36] "Standards for the Growing, Harvesting, Packing and Holding of Produce for Human Consumption, Proposed Rule," 79 Fed. Reg. 58433, 58444 (September 29, 2014, FDA).
[37] Id. at 58458–60.

extent to which benefits will be derived . . . because . . . they are unpredictable."[38] For smaller firms, the FDA's own analysis shows that net benefits would be maximized by setting the threshold for a covered farm between $50,000 and $100,000, an option also preliminarily rejected in the proposed rule.[39] Instead, the FDA has proposed a shotgun approach targeting all covered foods rather than one that focuses on those foods or farms that pose the greatest risks."[40] In short, the FDA needs to carefully craft exemptions where significant risks have not been documented.

Animal Feed Rule

An examination of the information presented in the PRIA and the preamble to the rule indicates that the only possible way to get net benefits on this rule would be to apply it to pet foods only.[41] "A pet food–only rule would apply to about six to seven percent as many facilities, but it would still achieve almost all of the benefits of the regulation covering all animal food facilities. Since no data indicate that non-pet animal food has been related to human salmonellosis, a pet food–only rule would lose none of the human-health benefits."[42] Otherwise, if the FDA covers everything it has proposed, calculations by Ellig and me suggest that, at best, benefits would be about $30 million. The FDA estimated that costs would be between $87 million and $129 million.[43]

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[38] Id. at 58461.
[39] Id. at 58444.
[40] Michael Marlow, "Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption" (Public Interest Comment, Mercatus Center at George Mason University, Arlington, VA, 2013), 2.
[41] Jerry Ellig and Richard Williams, "Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Food for Animals" (Public Interest Comment, Mercatus Center at George Mason University, Arlington, VA, March 4, 2014), 13.
[42] Ibid, 13.
[43] Ibid, 11.

Intentional Adulteration Rule

The FDA states that it does not know what industry food defense practices are currently in place. No intentional adulteration issues that would have been prevented by this rule have occurred, and the FDA offers no evidence that this rule will prevent any instances of intentional contamination in the future. If the FDA does not know what the current industry food defense practices are, it is incumbent on the agency to find out before regulating. For example, firms in the industry may have practices that are far superior to FDA regulations. Because they would be legally required to comply with FDA regulations, they may place less emphasis on these practices or even eliminate them. With such a wide variety of plant locations, processing procedures, transportation methods, warehousing options, and food types, effective practices will almost certainly need to vary considerably.

The best solution would be for Congress to reconsider section 106 of the FSMA. Although Congress's stated intent in this section is for the FDA to focus on clear vulnerabilities such as short shelf life,[44] the FDA's rule implementing the section treats all foods equally. This creates unnecessary costs and may be counterproductive.

If Congress does not act, then the FDA should narrow this rule to the most likely targets. Focusing the regulation on the firms that are the most likely targets could be done in several ways:

1. Include only large, branded firms. The FDA notes that "the goal of terrorist organizations is to maximize public health harm and, to a lesser extent, economic disruption. We have tentatively concluded that such goals are likely to drive terrorist organizations to target

[44] FSMA § 106(a).

the product of relatively large facilities, especially those for which the brand is nationally or internationally recognizable."[45]

2. Exclude products that are shelf-stable, for which most of the product would still be sitting on shelves after the contamination has been discovered.[46]
3. Include only products that have a "bow-tied" supply chain, that is, the product could be contaminated at a central point.[47] This approach would apply particularly to products like fluid milk, in which contamination would affect an entire batch.

This kind of targeting can minimize the costs of complying with the congressional mandate.

7. Summary

The Food Safety Modernization Act required the FDA to issue 10 new regulations that, as currently proposed, will cost at least $2 billion per year. (There may end up being a total of about 40 to 50 regulations.) The analysis provided here of four of those regulations shows that there is very little evidence of the significant food safety problems purportedly addressed by some of the regulations and, for others, there is insufficient evidence that the rules will be effective at reducing foodborne risk. Furthermore, both Congress and the FDA seem to have ignored evidence that similar existing rules (HACCP) have failed to meaningfully reduce food safety risks.

Congress has created much of the problem by issuing specific requirements without justifying their need or potential effectiveness at improving food safety. One means of correcting some of the problems could be using the authority under the Congressional Review Act. Absent

[45] "Focused Strategies to Protect Food Against Intentional Adulteration; Proposed Rule," 78 Fed. Reg. 78013 (December 24, 2013, FDA).
[46] Richard Williams, "Focused Mitigation Strategies to Protect Food against Intentional Adulteration" (Public Interest Comment, Mercatus Center at George Mason University, Arlington, VA, June 30, 2014), 14.
[47] Ibid, 19.

that, the FDA should minimize the cost of the rules primarily by limiting the number of facilities and types of products that they cover.

It would be instructive—though not helpful for this set of rules—for an investigator, perhaps one of the congressional research organizations, to examine how the FSMA came into being in the first place. Questions to be addressed would include the following: Who were the primary authors of the law? And why was the law written, given the lack of evidence of a problem or of a viable solution to the problems ostensibly addressed in the legislation? Have the authors of this legislation (if private citizens) benefited from it in any way? Scholars familiar with public choice economics may find that the FSMA offers valuable lessons for future Congresses, perhaps encouraging them to ask these types of questions before voting to expand regulations.