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TESTIMONY

FEDERAL REGULATION OF FOOD SAFETY

RICHARD A. WILLIAMS, PhD
Director, Regulatory Studies Program, Mercatus Center at George Mason University

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Hearing: From Crop to Craft Beer: Federal Regulation's Impact on America's Food and Agriculture

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Chairman Johnson, Ranking Member Carper, and members of the committee, thank you for inviting me to testify on the impact of federal regulations on America's food and agriculture.

Federal regulations affecting food are intended primarily to protect public health by ensuring that food is safe. These regulations affect both the cost of growing and manufacturing food and the ever-changing makeup of the food supply. According to President Clinton's Executive Order 12866, food safety regulations (like all regulations) must be based on "the best reasonably obtainable scientific, technical, economic and other information concerning the need for, and consequences of, the intended regulation."[1] Agencies are also legally responsible for ensuring that the science and analysis within these regulations satisfies quality, objectivity, utility, and integrity requirements.[2] Yet far too often, federal food regulations conform to none of these requirements. As a result, food regulations cost far too much and accomplish far too little, far too often.

My testimony today will touch on these problems with our current food regulation system. I will provide several examples of failed food safety regulations and explain why there are better approaches to solve food safety problems than regulations that try to anticipate every conceivable problem.

FEDERAL FOOD SAFETY MANDATES CAN BE COUNTERPRODUCTIVE

One example of how food safety regulation can cost a lot but deliver little is the most recent expansion of a process control approach called hazard analysis critical control points, or HACCP. The food industry invented this

1. Exec. Order No. 12866, 3 C.F.R. 638 (1993).
2. Office of Management and Budget, "Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies," effective October 1, 2001. The guidelines were mandated by the Consolidated Appropriations Act, 2001, Pub. L. No. 106-554 § 515, 114 Stat. 2763A-154 (known as the Data Quality Act) (2001).

For more information or to meet with the scholar, contact
Robin Bowen, 703-993-8582, rbowen@mercatus.gmu.edu
Mercatus Center at George Mason University, 3434 Washington Blvd., 4th Floor, Arlington, Virginia 22201

approach 50 years ago for NASA to use in the space program.[3] HACCP is a system of preventive controls that relies on monitoring and recordkeeping at critical points where contaminants can be detected and eliminated. Following its use in the space program, HACCP was used extensively by food manufacturers before the government got involved. Over the decades before federal involvement, HACCP was successfully implemented where it was needed, but today most food safety failures in processing plants are due to problems with cleaning, sanitation, or management.[4]

Nevertheless, in 2011 Congress passed the Food Safety Modernization Act (FSMA), which "aims to ensure the U.S. food supply is safe by shifting the focus from responding to contamination to preventing it." In fact, regulations promulgated by the Food and Drug Administration (FDA) and the US Department of Agriculture (USDA) have always focused primarily on prevention. FSMA now requires the entire food industry to implement HACCP. [5]

But because HACCP is now a government-run program, it is no longer a firm-run food safety tool. It is now a bureaucratic mandate that generates massive amounts of paperwork that can be reviewed by FDA. In fact, prior to FSMA, FDA and USDA had already mandated HACCP in three different industries.

HACCP REGULATIONS HAVE FAILED IN THREE INDUSTRIES

These three industries are case studies of failed government regulations using HACCP. The first industry FDA imposed HACCP on was the seafood industry. When FDA implemented the first HACCP regulation for seafood in the mid-1990s, the major health hazard related to seafood involved raw shellfish, particularly contaminated oysters from the Gulf of Mexico.[6] The problem for FDA was that there is no "control point" where the contamination can be reduced or eliminated. The HACCP approach failed to reduce seafood contamination because it did not work on products served raw—in fact, despite the regulation, illnesses from oysters in the United States virtually doubled by 2011.[7] Since all sellers of seafood (i.e., fish and shellfish) had to use HACCP regardless, it was mostly a waste of resources.[8] This is an example of why it makes no sense to require everyone in the food industry to use HACCP.

The second industry on which FDA imposed HACCP was the fruit juice industry.[9] The director in charge of the regulations pressed hard to have the federal juice HACCP rule cover the little girl in his neighborhood who sold lemonade from her stand. (I attended this meeting.)[10] He lost on that point, but FDA did end up covering all juices even though only apple and orange juice were causing problems. FDA estimated the first-year costs of this rule at $44 million to $58 million and recurring costs at $23 million. The solution was not HACCP, it was pasteurization.

Finally, in 1995, USDA imposed a HACCP rule on the meat and poultry industry.[11] At the time, USDA estimated costs to the industry over 20 years at $2.2 billion. USDA presented a range of benefits and claimed to be "without the knowledge to predict the effectiveness of the requirements in the rule to reduce foodborne illness."[12] Nevertheless,

3. Richard A. Williams, "Regulations Implementing the Food Safety Modernization Act" (Mercatus Working Paper, Mercatus Center at George Mason University, Arlington, VA, August 2015).
4. William H. Sperber, "HACCP Does Not Work from Farm to Table," *Food Control* 16 (2005): 513–14.
5. "FDA Food Safety Modernization Act (FSMA)," Food and Drug Administration, last updated July 13, 2016, http://www.fda.gov/Food/GuidanceRegulation/FSMA/.
6. Procedures for the Safe and Sanitary Processing and Importing of Fish and Fishery Products, 60 Fed. Reg. 65096 (December 18, 1995).
7. 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.
8. For more on this regulation and other food safety regulations, see Richard A. Williams, "A New Role for the FDA in Food Safety" (Mercatus Working Paper, Mercatus Center at George Mason University, Arlington, VA, November 2010).
9. Food and Drug Administration, Hazard Analysis and Critical Control Point (HAACP); Procedures for the Safe and Sanitary Processing and Importing of Juice, 66 Fed. Reg. 6138 (January 19, 2001).
10. Meeting at the Center for Food Safety and Applied Nutrition, Washington, DC, 1998.
11. Department of Agriculture, Food Safety and Inspection Service, Pathogen Reduction; Hazard Analysis and Critical Control Point (HACCP) Systems, 61 Fed. Reg. 38806 (July 25, 1996).
12. Ibid., 38956.

the department concluded that the program would only have to reduce foodborne illness by 14–17 percent to cover the costs. Despite that, a study four years later concluded that the costs of the rule could "plausibly exceed" the benefits.[13]

THE FSMA CONTINUED AND EXPANDED GOVERNMENT REGULATORY FAILURES

Despite the failures associated with the three previously mandated HACCP rules, FSMA expanded the mandate dramatically by requiring HACCP for the rest of the food industry. Three examples show how regulations have not been informed by science or analysis or have missed their mark.

The first example concerns a HACCP-type regulation for animal feed. This rule was proposed in 2013 and finalized in 2015.[14] It covers both pet food and farm animal feed, though FDA's own analysis demonstrates that there is no microbial contamination problem with farm animal feed. My colleague Jerry Ellig and I commented that this rule was not needed for farm animal feed.[15] Rather than address that point, FDA, oddly, relied on experts' opinions about how effective the rule would be at preventing contamination of livestock feed. Despite its failure to find any problems with farm animal feed, FDA imposed the regulation and all its costly recordkeeping and monitoring requirements on both pet food and farm animal feed, needlessly raising the cost of farm animal feed.[16]

Another FSMA example is the supposedly "risk-based" new regulations on produce that might be consumed raw. All fruits and vegetables that might be eaten raw are covered, despite the lack of evidence that most have caused any problem whatsoever. For instance, sweet corn is not considered to be for raw consumption, but bok choy, brussels sprouts, rhubarb, and turnips are covered.[17] FDA's reasoning for covering all these fruits and vegetables is that, although the vast majority of fruits and vegetables have caused no outbreaks, there is always a possibility that they might cause a problem in the future. FDA states,

> As discussed in the 2013 proposed rule and the QAR [qualitative assessment of risk], we agree that an approach that relies on outbreak data, or certain commodity characteristics, to make determinations about which produce should be covered would be inconsistent with the prevention-based approach mandated by FSMA and that relying on outbreak data would be insufficient to protect the public because many foodborne illnesses are not linked to an outbreak and the patterns of outbreaks associated with produce commodities change over time. . . .
>
> . . . We conclude that, while different commodities may have different risk profiles at different stages of production, all commodities have the potential to become contaminated through one or more of the routes identified, especially if practices are poor and/or conditions are insanitary.[18]

Think about that for a moment. That is the ultimate regulatory philosophy: there is no identifiable problem, but anything could happen at any time. That philosophy redefines the food safety problem as a *lack of regulation*. Unfortunately, like farm animal feed producers, if you grow oranges, grapes, carrots, celery, cucumbers, or other problem-free produce, you are on the losing team and have to comply with unnecessary rules.

It's not just that FDA is applying its rules to too many products. In some cases, FDA is actually going after the wrong area of the food supply. The third example concerns FDA regulation of packaged food. There is scant

13. 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.
14. Food and Drug Administration, Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Food for Animals, 80 Fed. Reg. 56170–356 (September 15, 2015).
15. Jerry Ellig and Richard A. 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).
16. Williams, "Regulations Implementing the Food Safety Modernization Act."
17. Food and Drug Administration, Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption, 80 Fed. Reg. 74353 (November 27, 2015).
18. Ibid.

evidence that there is a large, systemic problem with packaged food, despite some highly publicized recalls. Nevertheless, FDA imposes its ramped-up HACCP program on packaged food, though this may, according to one industry estimate, cost $18 billion. (FDA estimated initial costs of $1.8 billion and recurring costs of $1.2 billion.)[19] In fact, FDA notes that most food safety problems occur in places are not covered by FSMA: restaurants, other retail establishments, and homes.[20]

FAILED REGULATIONS BURDEN BUSINESSES WHILE FDA EXPANDS ITS OVERREACH

Those who must comply with rules that aren't needed or don't work probably take no solace in the fact that these laws and regulations benefit those who promoted them, by gaining them a competitive advantage, large consulting fees, or—in the case of FDA—a bigger budget. While our country has labored through one of the worst, longest-lasting recessions in its history, FDA has expanded its food-related budget from $457 million in 2007 to $987 million today, an increase of 116 percent (see attached chart).

Maybe the regulatory system would improve if all voices were heard, but they are not. Most of the regulated farmers, manufacturers, retailers, warehousers, packers, and shippers don't participate in the regulatory process. They don't have the time or resources to read the *Federal Register* every day and hire attorneys and experts to try to influence regulations in their favor. They are too busy trying to make payroll, to be competitive, and to feed their families, not to mention the United States and often the world.

Why can't we get better outcomes? It's certainly not because most participants in the regulatory system aren't well intentioned or don't want safe food. But our method of achieving our goals rests on a century-old theory that the way to govern is to assemble a body of experts and give them lawmaking authority. But that theory produces an unoriginal stream of rules, particularly as there is no accountability for failure to produce food safety results. For those who must comply with those rules, the uncertainty associated with more costs would be easier to bear if the regulations actually solved problems.

SOLUTIONS TO FDA'S BURDENSOME REGULATORY OVERREACH

For a start, let's reprogram FDA. First, we are now in a much better position to trace food contamination outbreaks to their sources.[21] Let's task FDA, USDA, and the Centers for Disease Control and Prevention with doing more of that: tracing food safety outbreaks back to their sources, finding out what went wrong, and then posting the results on the Internet.[22] This is a different approach from trying to anticipate every possible problem and regulate food companies into compliance.

With new information on actual causes of outbreaks, the market will adjust as (where applicable) millions of food companies incorporate those results into their contracts to ensure that they are not the next to lose sales because of Internet publicity, pay for costly recalls, and suffer lawsuits due to contaminated food. This course of action would use the power of markets and market-based contracts and inspections to do what FDA has been unable to do: establish strong incentives for producers to exercise due diligence.

19. Food and Drug Administration, Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food, 80 Fed. Reg. 55908 (September 17, 2015); Comment from the Association of Food, Beverage and Consumer Products Companies to the Food and Drug Administration (Docket No. FDA-2011-N-0920) on Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food, November 22, 2013.
20. FSMA Supplemental Notice of Proposed Rulemaking for Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food (Docket No. FDA-2011-N-0920), Preliminary Regulatory Impact Analysis, p. 6; cited in Williams, "Regulations Implementing the Food Safety Modernization Act," 19.
21. There are both public and private tools. Public tools include PulseNet and FoodNet and private tools include radio frequency identification (RFID) tags, 2-D barcodes, and laser etching.
22. Williams, "New Role for the FDA in Food Safety."

Second, we need to ensure that before enacting laws or regulations that are unlikely to work (except for the well-connected), regulators perform much better risk analysis and benefit-cost analysis. Stakeholders should be able to sue when this analysis is absent, ignored, or just poorly done.

Finally, let's stop trying to penalize new technologies, and instead embrace them. Just as pasteurization enabled massive improvements in food safety when it was first incorporated into the production process, so too does genetic modification promise to be a boon for both nutrition and food safety.[23]

We have relied on anticipatory regulations for too long to solve food safety problems. It's time to go in new directions if we are to make progress reducing foodborne disease.

ATTACHMENT

Richard Williams and Tyler Richards, "More FDA Spending Does Not Necessarily Mean Better Results," Mercatus Center at George Mason University, November 4, 2015.

23. Richard Williams, "GMO Labels Won't Make Foods Safer, Only More Expensive," Tribune News Service, October 29, 2015.

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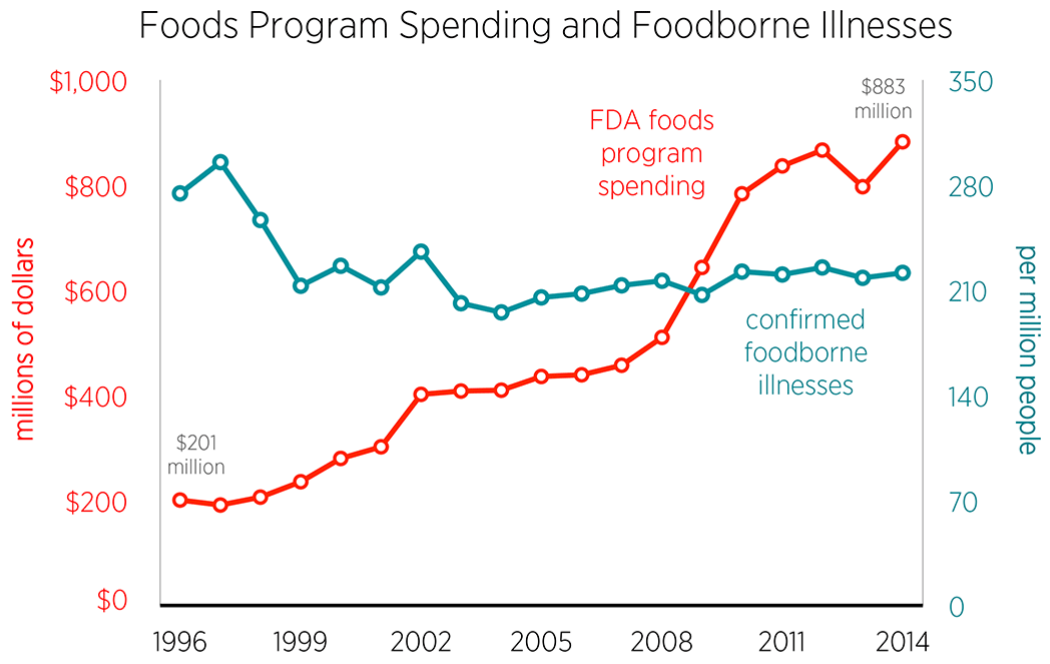
More FDA Spending Does Not Necessarily Mean Better Results

Richard Williams [1], Tyler Richards [2] | Nov 04, 2015

The FDA Foods Program recently requested a $1.167 billion budget for fiscal year 2016. If authorized, this budget would amount to an increase of 27.7 percent ($253 million) above the enacted $914 million for fiscal year 2015. This request is the most recent in a number of steps to implement the Food Safety Modernization Act of 2010 (FSMA), which expanded the FDA's authority to regulate imported and domestically produced foods. The FSMA is designed to reduce foodborne illnesses in the US, but if recent history is any guide, increasing spending may not be effective.

Using the Foods Program's yearly budgets, the results of a recent Centers for Disease Control and Prevention report on foodborne illnesses from 1996 to 2014, and a study estimating the proportion of each pathogen-related illness that is attributable to particular food types, we are able to estimate the number of confirmed foodborne illnesses caused by FDA-regulated foods per million people and compare this trend with the FDA's spending to combat foodborne illnesses. The chart below shows the results of this estimation.



[3]

The number of confirmed foodborne illnesses has remained relatively steady for the last 15 years, beginning at 213 illnesses per million people in 1999 and ending at 222 per million in 2014. However, the amount of money spent on the Foods Program has nearly quadrupled over that time.

The only significant drop in foodborne illnesses occurred in the years 1997–1999. This was driven largely by an almost 40 percent decrease in the incidence rate of *Campylobacter*, one of the most common causes of mild foodborne illnesses. However, it is not obvious this decline was the result of FDA actions, since Food Programs spending saw no unusual increase. Spending went up an average of 10.95 percent over these three years, while the average increase for all 19 years of this study was 9.16 percent.

Although the FSMA is geared toward prevention rather than control, the FDA has had little success with a similar approach in the past. The new FSMA regulations closely resemble a system of controls implemented by the FDA and the USDA called Hazard Analysis and Critical Control Points (HACCP). HACCP began in the 1960s to ensure safe food for space expeditions, but many firms privately adopted it where it was thought to be useful to control pathogens.

In the mid-1990s, the FDA decided to mandate HACCP for some industries. One example of the FDA's use of HACCP is a seafood rule. The largest expected benefit was a reduction of illnesses caused by the pathogen *Vibrio vulnificus*. The FDA estimated that the annual number of *Vibrio*-related cases would decline 20 to 50 percent, and this accounted for half of the rule's expected benefits. Instead, the annual number of cases nearly doubled over the next 14 years.

Nevertheless, the FDA and the USDA continued with new HACCP regulations.

The FSMA mandates a HACCP-like approach for all food. There is no evidence that this approach is likely to result in any significant progress in lowering the rate of foodborne illness. In view of the experience of the last 20 years, neither increasing the FDA's resources nor causing the food industry to spend more (in fact, much more) using this approach appears to be the answer.

Notes:

1) Methodology: The Batz, Hoffman, and Morris study estimated the fraction of each pathogen-caused illness that came from particular food groups from 1998 to 2008. Since the USDA also regulates some food products, we reduced the number of foodborne illnesses for each pathogen to match the estimated fraction of illnesses that were caused by FDA-regulated foods.

2) Limitations: This study is limited by the data available on total foodborne illnesses. The figures shown in this chart are estimations based on the best available data from culture-confirmed cases of foodborne illness.

Mercatus Center at George Mason University – 3434 Washington Blvd, 4th Floor, Arlington, VA 22201

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