MERCATUS CENTER
George Mason University
Bridging the gap between academic ideas and real-world problems

PUBLIC INTEREST COMMENT

Focused Mitigation Strategies to Protect Food against Intentional Adulteration
Docket ID: FDA-2013-N-1425

Richard A. Williams
Vice President, Policy Research, Mercatus Center at George Mason University

Department of Health and Human Services, Food and Drug Administration
RIN: 0910-AG63
Submitted June 30, 2014
Comment period closes June 30, 2014

INTRODUCTION

The Regulatory Studies Program of the Mercatus Center at George Mason University is dedicated to advancing knowledge about the effects of regulation on society. As part of its mission, the program conducts careful and independent analyses that employ contemporary economic scholarship to assess rulemaking proposals and their effects on the economic opportunities and social well-being available to all members of American society.

This comment addresses the efficiency and efficacy of this proposed rule from an economic point of view. Specifically, it examines how the proposed rule may be improved by more closely examining the societal goals the rule intends to achieve and whether this proposed regulation will successfully achieve those goals. In many instances, regulations can be substantially improved by choosing more effective regulatory options or more carefully assessing the actual societal problem.

SUMMARY

The proposed "Focused Mitigation Strategies to Protect Food against Intentional Adulteration" rule is intended to supplement four previous bioterrorism rules to reduce the probability of a successful terrorist act involving processed food.[1] Congress mandates an essentially redundant regulation while paying no attention to the identified threat of intentional contamination through the mechanism of foot and mouth disease, which could cost the US economy in excess of $10 billion.

1. US Food and Drug Administration, "Focused Strategies to Protect Food Against Intentional Adulteration," proposed rule, December 24, 2013, https://www.federalregister.gov/articles/2013/12/24/2013-30373/focused-mitigation-strategies-to-protect-food-against-intentional-adulteration.

For more information, contact:
Robin Bowen, (703) 993-8582, rbowen@mercatus.gmu.edu
Mercatus Center at George Mason University
3434 Washington Boulevard, 4th Floor, Arlington, VA 22201

The ideas presented in this document do not represent official positions of the Mercatus Center or George Mason University.

Apparently extending the reasoning of other parts of the Food Safety Modernization Act, which uses Hazard Analysis Critical Control Point (HACCP) principles to address non-intentional contamination of food, Congress instructed the FDA to apply HACCP principles to terrorism. The FDA discusses four relevant points about this rule:

1. Between the FDA and the food industry, there have been massive efforts to address food terrorism in the recent past.[2]

2. The FDA is "further challenged by the paucity of the data on the extent to which facilities have already implemented programs to mitigate this risk . . . "[3]

3. This type of rule is "without precedent."[4]

4. The FDA provides evidence that there have been previous cases of intentional contamination of food, but there have been no large, terrorist-inspired intentional contamination events that this rule would address.

Given the uncertainty of the underlying risks that remain after all these efforts, the uncertainty as to which preventive controls are already in place, and the uncertainty about whether this rule might be effective in any fashion, this seems to be a case where it makes more sense to find out what the industry is doing and to test the design requirements (if necessary) before going forward to a final rule. Otherwise, given the massive expenditures and completely uncertain benefits, this rule can at best be characterized as "speculative precaution." At a minimum, the FDA should put forward the least burdensome, most targeted regulation possible until there is more information.

The options discussed below would call for a much more targeted regulation to high-value food industries, particularly larger facilities that make non-shelf-stable foods (so that much of them would be consumed before detection).

THE FOOD SAFETY MODERNIZATION ACT

After the terrorist attacks on September 11, 2001, Congress passed the Public Health Security and Bioterrorism Response Act of 2002 to prevent terrorist attacks on the food supply. The 2002 law required the FDA to issue four regulations; three required food facilities to register with the FDA, to keep records of incoming and outgoing shipments, and to give the FDA prior notice of shipments of imported food, and one allowed the FDA to put shipments of food on administrative detention if it believed that it had credible information that the food presented a threat of serious adverse health consequences or death to humans or animals. The FDA issued these four final regulations fulfilling the congressional mandate in 2004, 2005, and 2008.

In the Food Safety Modernization Act of 2011, Congress required the FDA to issue a new regulation to address terrorism relating to the food supply and the intentional contamination of food. In general, the 2011 law covers the same products and producers as the 2002 law.

At the same time, there has been no congressional attention to possible intentional threats to food regulated by the Food Safety Inspection Service at the USDA.[5] A 2005 report funded by the Department of Justice's National Institute of Justice found foot-and-mouth disease (FMD) to be the most lethal weapon in the agroterrorists' arsenal unanimously identified by agricultural experts.[6]

---

2. Focused Mitigation Strategies To Protect Food Against Intentional Adulteration; Proposed Rule, US Food and Drug Administration, 78 Fed. Reg. 247 (December 24, 2013), http://www.gpo.gov/fdsys/pkg/FR-2013-12-24/pdf/2013-30373.pdf.
3. FDA, Proposed Rule, 78025.
4. Ibid.
5. Although FSIS has not been inactive on this issue. See, for example, FSIS, *Food Defense Plan*, http://www.fsis.usda.gov/wps/wcm/connect/99f95182-0c9e-4214-9762-e98197f54ebf/General-Food-Defense-Plan.pdf?MOD=AJPERES
6. Terry Knowles, et al., "Defining Law Enforcement's Role in Protecting American Agriculture from Agroterrorism" (National Institute for Justice

The FBI echoed this concern in 2012, saying, "Attacks directed against the cattle, swine, or poultry industries or via the food chain pose the most serious danger for latent, ongoing effects and general socioeconomic and political disruption. Experts agree that FMD presents the most ominous threat. The cattle, swine, and poultry industries are regulated by the Food Safety Inspection Service, not the FDA. Adding another FDA regulation on top of the existing four FDA regulations will not in any way reduce the FMD threat. In fact, with rules tightening on other potential targets, it may be possible that remaining targets like the cattle industry increasingly become more likely targets.

Estimates of the impact of a FMD outbreak on the US economy vary but exceed $10 billion. A 2012 study estimated losses to the US economy of $11.7 billion.[7] A 2013 study of the effects of a terrorist attack on the United States using FMD showed an expected loss of between $37 billion and $228 billion, depending on the size and containment of the attack, and for just the short- and medium-term consequences of the attack.[8] These estimates show a vulnerability to the US food supply that Congress has failed to address while doubling up on an area that has not been identified to have the same degree of risk.

Given (1) the tremendous uncertainties in the need for and effectiveness of this rule, (2) the fact that it was required by Congress, and (3) the Office of Management and Budget's identification of this regulation as a major rule for the purpose of congressional review, it would seem like this rule is a major candidate for just such a review.[9]

THE NEED FOR REGULATION

Beyond the fact that this is required by Congress, the FDA discusses a market failure and four events as justification for this rule.

The FDA has produced a standard market failure justification for the regulation to satisfy OMB Circular A-4. The assumption is that profit-maximizing food processors do not have an incentive to invest in security as much as they would if they bore the full cost of an act of intentional contamination because there are externalities associated with an act of intentional contamination (people would get ill or die, and those costs are not factored into the costs of production). Even if this justification is hypothetically reasonable, the FDA does not provide evidence that food companies have in fact underinvested in preventing terrorist attacks. The agency does not provide evidence that the earlier rules failed to properly address this problem or that firms were not in compliance.

Furthermore, processed food has not been associated with a single incident of intentional contamination in the United States that would be addressed by this rule. In the preamble to the regulation, the FDA produces the following incidents as evidence of the need for this regulation:[10]

1. Thirty years ago, members of the Rajneeshee commune in The Dalles, Oregon, spread *Salmonella* bacteria at salad bars at local restaurants and sickened 751 people. Commune members hoped to turn a local election in their favor by making people sick and reducing election turnout.[11]

2. Eighteen years ago, an employee of a hospital laboratory in Dallas, Texas, took *Shigella* bacteria from the lab and used it to contaminate pastries that she then left in the lab break room in order to

Research Report 212280, Washington, DC, June 30 2005), 3, https://www.ncjrs.gov/pdffiles1/nij/grants/212280.pdf.

7. Richard Boisvert, David Kay, and Calum Turvey, "Macroeconomic Costs to Large-Scale Disruptions of Food Production: The Case of Foot-and-Mouth Disease in the United States," *Economic Modeling* 29, no. 5 (September 2012): 1921–30.

8. Gbadebo Oladosu, Adam Rose, and Bumsoo Lee, "Economic Impacts of Potential Foot and Mouth Disease Agroterrorism in the USA: A General Equilibrium Analysis," *Journal of Bioterrorism and Biodefense*, special issue (2013), http://omicsonline.org/economic-impacts-of-potential-foot-and-mouth-disease-agroterrorism-in-the-usa-a-general-equilibrium-analysis-2157-2526.S12-001.pdf.

9. US Food and Drug Administration, "Focused Mitigation Strategies to Protect Food Against Intentional Adulteration," Preliminary Regulatory Impact Analysis, 38, http://www.fda.gov/downloads/Food/GuidanceRegulation/FSMA/UCM378630.pdf.

10. FDA, Proposed Rule, 78021.

11. Thomas J. Torok et al., "A Large Community Outbreak of Salmonellosis Caused by Intentional Contamination of Restaurant Salad Bars," *Journal of the American Medical Association* 278, no. 5 (August 6, 1997): 389–95, http://www.cdc.gov/phlp/docs/forensic_epidemiology/Additional%20Materials/Articles/Torok%20et%20al.pdf.

sicken 12 of her coworkers.[12]

3. Five years ago, two employees of a restaurant in Lenexa, Kansas, contaminated the restaurant salsa with an insecticide, sickening 49 patrons. The perpetrators wanted revenge against the restaurant owner for suspending one of them.[13]

4. Six years ago, the contaminant melamine was added to milk on a widespread basis in China, sickening 290,000 children. It is suspected that farmers, milk dealers and milk processing companies were all involved in substituting a mixture of melamine and water for much more expensive raw milk.[14]

Again, *none* of the incidents cited by the FDA would be addressed by this regulation. *None* of them affected commercially processed food sold in the United States. *None* of the three incidents that occurred in the United States occurred at or before the processing stage. Regulating US food processors will do nothing to protect Americans from the types of events that the FDA cites as occurring within the United States. And the FDA does not disclose the fact that, although milk in China was contaminated on a widespread basis, and although the United States imports a significant amount of food from China, the Chinese melamine incident did not cause the adulteration of any food sold in the United States. In fact, the Chinese government responded rapidly, as they have sufficient incentives to ensure that they can continue to export.[15]

With four rules that appear to address the problems of an intentional attack on the food supply, no evidence of noncompliance with those rules, and no history of attacks that would be addressed by this rule, there does not appear to be either a government failure (with respect to the FDA) or a market failure. There is simply no evidence given to suggest underinvestment by the private sector in prevention of a terrorist attack.

Further, although the FDA cites the existence of externalities as market failures, the agency does not discuss whether or not these externalities are "inframarginal." An inframarginal externality is one that, although it may in fact be an externality, remedying does not cause any further investments, as private incentives are sufficient to compensate for any purely public incentives. In this case, even though there is a possibility of an externality (i.e., consumers' illnesses and deaths would not be internalized into the cost of food production), it is not clear that the external cost is sufficiently larger than the costs that would be internalized associated with firm losses such that they have not invested an optimal amount in reducing the probability or outcome of a terrorist attack.[16]

As mentioned earlier, the Public Health Security and Bioterrorism Response Act of 2002 and the four regulations that the FDA put in place in response to it play some role in reducing the probability of attack. The Regulatory Impact Analyses accompanying those rules certainly implied that such would be the case. Simply because the FDA has chosen to do a break-even analysis (as opposed to a benefit-cost analysis) does not relieve them of the responsibility to discuss how the baseline probabilities were changed as a result of implementing those four rules.[17] In addition to those rules, the FDA discusses other guidance and industry efforts to reduce the probabili-

---

12. "Hospital Employee Sentenced to 20 years for Poisoning Co-workers," *Abilene Reporter-News*, September 12, 1998, http://texnews.com/1998/texas/poison0912.html.
13. US Department of Justice, "Kansas Woman Sentenced to Prison for Poisoning Salsa at Lenexa Restaurant," February 9, 2011, http://www.fda.gov/ICECI/CriminalInvestigations/ucm242838.htm.
14. Changbai Xiu and K.K. Klein, "Melamine in Milk Products in China: Examining the Factors that Led to Deliberate Use of the Contaminant," Food Policy 35, no. 5 (October 2010): 463–70.
15. "China Executes Two over Tainted Milk Powder Scandal," BBC News, November 24, 2009, http://news.bbc.co.uk/2/hi/asia-pacific/8375638.stm.
16. An example of a positive inframarginal externality is vaccination of children. Even though there is a positive externality for other children who might catch a disease, there is a sufficient incentive for parents to vaccinate their own children to prevent them from getting sick. Hence, no government subsidy is necessary.
17. A break-even analysis asks the question, how much would the benefits (presumed to unknowable) have to be to cover the costs? This is different from a benefit-cost analysis, which estimates benefits and costs of multiple options and highlights the option for which benefits exceed costs by the maximum amount. A break-even analysis requires more imagination, particularly as performed here in order to compare regulatory options, i.e., imagining the number of years that would have to go by without a terrorist attack.

ties of food-related terrorism.[18] If the FDA feels as though it has been unable to enforce their regulations or that industry is willfully ignoring guidance (including its own), it should state that such is the case. Alternatively, the FDA should acknowledge that the regulations and industry guidance work, assess their effectiveness, and let that effectiveness drive this regulation (minimizing the costs if Congress does not alter the law).

PRELIMINARY REGULATORY IMPACT ANALYSIS DOCUMENTATION

The FDA has failed to show in the PRIA precisely which industry categories (NAICS or, as the FDA uses, the older SIC codes) will be affected by this rule, although in the past the FDA has produced tables showing this. Such tables are conspicuously absent in this analysis. Given that the FDA produced an analysis of a regulation covering the food-processing sector using the Dun & Bradstreet database, it is clear that the FDA has the ability to do this. This analysis only says that there are 14,260 food facilities affected (99,800 food-processing facilities less farms, retailers, warehouses and firms with less than $10 million of annual revenue).[19] That leaves a number of questions: what types of foods are covered, how many facilities are exempted by the $10 million cut-off, and how many firms will not have actionable steps? A more transparent analysis with this information would allow commenters to make important determinations about who should and should not be covered.

The Analysis of Uncertainty section provides a very clear illustration of problems with documentation and transparency.[20] The FDA notes that, because the rest of the analysis uses and presents only point estimates, it doesn't make clear the significant amount of uncertainty in the estimates. The FDA then tells us that it did a Monte Carlo analysis for the rule, where "many parameters are defined as probability distributions." What are the "many parameters" that the FDA chose to define as probability distributions? Which probability distributions did the FDA choose for the parameters? There are infinitely many to choose from. The FDA only tells us the 5th and 95th percentile of the outcome of the Monte Carlo analysis. This may satisfy the Circular A-4 for analysis, but it is not helpful to stakeholders.

The FDA does not tell us how many of these facilities will be defined as small businesses (fewer than 500 employees); it only tells us how many *firms* (not facilities) will be classified as small businesses.[21] In fact, given that the FDA has concluded that large, brand-name firms are most likely to be the targets of terrorist attacks, it's not clear why any small or very small firms are included in this rule.

With better documentation, stakeholders will have a better idea of who is covered and who is not. This information can help FDA decision-makers as well as stakeholders to more carefully target this regulation to the most vulnerable firms (those who are high-value targets and who have not instituted sufficient controls).

BETTER REGULATORY ALTERNATIVE

Given that the FDA is mandated in Section 106(B) of FSMA to "consider the best available understanding of uncertainties, risks, costs, and benefits associated with guarding against intentional adulteration of food at vulnerable points," the FDA should gather more data about current practices and find the regulatory option that maximizes the difference between the likely benefits (reduced risk) and costs of this rule, primarily to determine when a facility may be a "qualified (exempt) facility and which industries groups are the most likely targets."[22]

The FDA repeatedly states in the preamble 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

18. FDA, Proposed Rule, 78022–23.
19. FDA, Preliminary Regulatory Impact Analysis, 10.
20. FDA, Preliminary Regulatory Impact Analysis, 25–26.
21. FDA, Preliminary Regulatory Impact Analysis, 34.
22. FDA Food Safety Modernization Act of 2011, Pub. L. No. 111-353, 124 Stat. 3885 (January 4, 2011), 106 B., http://www.gpo.gov/fdsys/pkg/PLAW-111publ353/pdf/PLAW-111publ353.pdf.

terrorist organizations to target the product of relatively large facilities, especially those for which the brand is nationally or internationally recognizable."[23] According to the Department of Homeland Security (DHS), "The goals of terrorists are to attract attention, disrupt the economy, create fear, and disrupt the social fabric."[24] While an attack on the food supply may fit some of these goals, it doesn't seem to work as well as, for example, explosions, particularly for packaged food. If contaminated products sit on shelves in warehouses, stores, or consumer pantries, the contamination is likely to be discovered before perhaps the bulk of a product batch is consumed.

The FDA should use this information to narrow the scope of the regulation while still helping to decrease the probability of an attack on the food supply. In addition to excluding farms, retailers, warehouses, and facilities that are part of firms with annual sales in excess of $10 million, the FDA could exclude facilities that only produce shelf-stable products. The potential benefits of such a rule would be almost identical to the proposed rule at much lower cost. This will be discussed in more detail later.

The following table is reproduced from a recent FDA analysis.[25] It provides Dun & Bradstreet data for processed food facilities without regard to the total sales of parent firms. (No facility is excluded because it has sales in excess of $10 million or any other amount.)

23. FDA, Proposed Rule, 78034.
24. Department of Homeland Security, Integrated Rapid Visual Screening of Tunnels, March 2011, ii, http://www.dhs.gov/xlibrary/assets/st-integrated-rapid-visual-screening-tunnels.pdf.
25. FDA, PRIA, "Table 7- Number of FDA-Regulated Domestic Food Facilities Subject to this Proposed Rulemaking Partitioned by 4 Digit SIC Code," 50–51, http://www.fda.gov/downloads/Food/FoodSafety/FSMA/UCM334117.pdf.

Number of FDA-Regulated Domestic Food Facilities Subject to the FDA-Proposed Preventive Controls Rule for Processed Foods, Partitioned by 4-Digit SIC Code

SIC	SIC Description	<20 employees	20-99 employees	100-499 employees	500+ employees	Total
723	Crop preparation	3453	650	210	18	4331
2015	Small game processing	98	13	6	3	122
2021	Butter	139	36	12	0	187
2022	Cheese	842	350	146	11	1349
2023	Milk, condensed & evaporated	436	138	51	9	634
2024	Ice cream	3251	271	97	8	3627
2026	Milk	975	365	287	18	1645
2032	Canned specialties	1365	198	68	23	1654
2033	Canned fruits, vegetables & preserves	1306	322	183	24	1835
2034	Dried fruits, vegetables & soup	594	106	59	5	764
2035	Pickled fruits, vegetables, sauces & dressings	1357	186	85	6	1634
2037	Frozen fruits, vegetables & juices	384	124	91	22	621
2038	Frozen specialties	1118	343	173	26	1660
2041	Flour, grain milling	886	295	77	1	1259
2043	Cereal breakfast foods	321	69	46	8	444
2044	Rice milling	222	62	27	1	312
2045	Flour, blended & prepared	325	92	38	0	455
2046	Wet corn milling	288	46	24	8	366
2051	Bread, bakery products except cookies & crackers	9462	1215	540	45	11262
2052	Cookies & crackers	2118	253	131	32	2534
2053	Frozen bakery products	266	66	56	10	398
2061	Sugar, cane	73	24	14	2	113
2062	Sugar, cane refining	126	15	14	4	159
2063	Sugar, beet	98	19	25	5	147
2064	Candy & confectionery Products	3780	292	125	21	4218
2066	Chocolate & cocoa products	1129	90	40	8	1267
2067	Chewing gum	61	4	15	5	85
2068	Salted & roasted nuts & seeds	242	79	28	5	354
2074	Cottonseed oil mills	82	25	7	0	114
2075	Soybean oil mills	192	82	22	3	299
2076	Vegetable oil mills	134	22	6	0	162
2077	Animal, marine fats & oils (marine only)	659	134	66	3	862
2086	Soft drinks	5207	1228	522	51	7008
2087	Flavoring extracts & syrups	1125	250	60	3	1438
2095	Coffee	1056	136	49	1	1242
2096	Potato chips & similar products	852	244	94	24	1214
2097	Ice	1278	175	1	0	1454
2098	Macaroni, spaghetti & noodles	766	83	39	4	892
2099	Food preparations, NEC	7921	1207	380	31	9539
2869	Industrial organic chemicals, NEC (food additives)	219	80	34	3	336
4221	Farm product warehousing & Storage	3319	178	23	1	3521
4222	Refrigerated warehousing & Storage	3577	702	134	14	4427
5148	Fresh-cut Fruits & Vegetables	323	34	5	0	362
5148	Fresh fruits & vegetables wholesale	19050	1980	301	9	21340
	Total	**80475**	**12283**	**4411**	**477**	**97646**

In the "Costs of the Proposed Rule," the FDA estimates that there are 99,800 facilities that the proposed rule would cover.[26] It finds that of those, 14,260 food-production facilities with more than $10 million in annual sales will have actionable steps. Those 14,260 food-production facilities appear to be governed by 4,624 firms (there are another 47,416 firms with less than $10 million in sales who have to do less).[27]

Comparing that table to the information in the PRIA, it appears that the broader coverage of the intentional contamination rule (e.g., covering seafood and juice products) in comparison to the processed-food preventive-controls proposed rule increases the number of facilities potentially affected from 97,600 to 99,800.[28] Using the data in the table, it appears that excluding farms, retailers, and warehouses reduces the number of facilities covered from 97,646 to 64,027 (removing SICs 723, 4221, 4222, and 5148 fresh fruit & vegetable wholesale)—or a reduction of about 34 percent. Applying that reduction to the total facility number that the FDA claims for the intentional contamination rule (99,800) implies that, before reducing the number of facilities covered for the $10 million very small business cut off, the number of facilities covered without regard to sales is about 65,900. That implies that the $10 million very small business cutoff reduces the number of facilities (with actionable steps) by about 78 percent (from 65,900 to 14,260). Without access to the Dun & Bradstreet database, we can use this information to estimate how covering a narrower set of SICs could further reduce the costs of a modified version of this rule.

We have added the shading on some SICs to highlight those categories of facilities that make products that are not shelf-stable (i.e., would be consumed quickly). Frozen products may or may not fall into this category. The highlighted products are the products that are most likely to suit the needs of people who would intentionally contaminate the food supply because a great deal more of the product might be consumed before the illnesses became apparent. That is, they appear to satisfy the goals of terrorists as expressed by the DHS "to attract attention, disrupt the economy, create fear, and disrupt the social fabric."[29] Adding up the number of facilities in the shaded SICs (and excluding more SICs than the FDA-proposed rule), a rule that only applied to products that were not shelf-stable would cover only about 15,900 facilities. If setting the very small business cutoff at $10 million has the same effect on the number of facilities covered by our alternative version of the rule as it has on the FDA version of the proposed rule, then a rule that only focused on processors of food that was not shelf-stable would affect only about 3,500 facilities (15,900 x .22). Reducing the number of facilities by that much would reduce the cost of the rule by about 75 percent (1 – (3,500 / 14,260)) to about $92 million annually ($367 million x .25). This targeting will be discussed later on in the section covering benefits of the rule.

In addition, the FDA has noted that terrorists are likely to go after large, branded firms.[30] A $10 million food firm is an extremely small firm. In table 6 of the PRIA, the FDA shows that raising the dollar value for a covered facility to $50 million would reduce the number of facilities covered by 36 percent but only reduce the coverage by 6 percent. According to the FDA's analysis, this would save $62 million. That also would exclude firms that do not seem like high-value targets.

In addition, the FDA notes that there are options to *increase* the coverage and costs of this rule. The FDA suggests in one option that it could require testing to guard against economically motivated adulteration requirements.[31] The logic associated with such a requirement appears to be: (1) manufacturers intentionally add in adulterants; (2) the FDA requires them to test for added adulterants; (3) manufacturers discover that they have intentionally added in an adulterant and stop production. Or not.

Finally, the FDA must keep in mind that no regulation will prevent one type of harm from "intentional contami-

26. Economics Staff, Office of Regulatory Policy and Social Sciences, Center for Food Safety and Applied Nutrition, *Focused Mitigation Strategies to Protect Food against Intentional Adulteration*, "Preliminary Regulatory Impact Analysis, Preliminary Regulatory Flexibility Analysis, Preliminary Unfunded Mandates Reform Act Analysis, and Preliminary Paperwork Reduction Act Analysis," Docket No. FDA-2013-N-142, 9–10, http://www.fda.gov/downloads/Food/GuidanceRegulation/FSMA/UCM378630.pdf.

27. Center for Food Safety and Applied Nutrition, "Preliminary Regulatory Impact Analysis," 10.

28. FDA, Proposed Rule, 78017 does not list seafood or juice producers as exempt.

29. Department of Homeland Security, Integrated Rapid Visual Screening of Tunnels, ii.

30. FDA, Proposed Rule, 78034.

31. FDA, Preliminary Regulatory Impact Analysis, 32.

nation events": false threats. Without any access whatsoever to any food facility, perpetrators could cause major recalls (which the FDA estimates to cost $200 million),[32] erode public confidence in government oversight of the food supply, and adversely affect the image and reputation of US food processors in export markets. Terrorists could enhance the impact of an attack by coordinating a diffuse attack at the retail level with misinformation that the food vehicle was a processed food, along with a claim of responsibility. The proposed rule does not, and likely cannot, address this issue.

PRELIMINARY REGULATORY COSTS SECTION

First, the FDA is to be congratulated for including administrative costs. Not all agencies do. However, some cost estimates, while important to include, are suspect. For example, the FDA estimates that the average cost of a vulnerability assessment is $4,800 per facility.[33] Rather than calculate this by the average number of hours the FDA imagines it would take, it could look at actual estimates. For example, the GAO estimated that for large wastewater facilities the costs of a vulnerability assessment were between $1,000 and $175,000 or a mean of about $80,000.[34] There may be some differences between wastewater plants and food facilities, but it seems like the FDA should account for why its estimate appears to be so low.

The FDA also annualizes its costs, including ones that are not for equipment. This practice hides the true first-year costs of this rule. If the FDA wants to annualize costs (a practice allowed by OMB), it ought to also discuss total first-year costs and recurring costs so that decision-makers can have a full appreciation for how large this rule is.

The FDA mentions that the average adoption rate for facilities with 100 or more employees of complying with the RTI model is 70 percent.[35] There is no footnote; is this an assumption or is it data? It appears to conflict with statements in the preamble about the "paucity of the data on the extent to which facilities have already implemented programs to mitigate this risk."[36]

The FDA received some very specific comments on the costs of HACCP for Human food, unintentional contamination. Those costs, submitted by industry, showed that the costs of HACCP were considerably higher (perhaps twentyfold) than FDA estimates. The FDA should incorporate those comments into this rule as well. If it does so, the costs may be shown to be considerably higher than what is estimated here.

Finally, the FDA says it is "unable to estimate the costs of reducing the staging time of ingredients."[37] This may be an enormous cost and have implications for the total costs, and the FDA should estimate this before going forward with this rule.

PRELIMINARY REGULATORY IMPACT ANALYSIS BENEFITS SECTION

The FDA assumes that the benefits of this rule are reducing both the probability of an attack in the first place and, if an attack is launched, the probability of that attack's success in harming people. It admits it has no idea what the reductions in either probability might be.[38] This leads the FDA to the idea of presenting a break-even analysis that would suggest how many attacks over time it would have to disrupt to cover the costs. Note that this does not envision a decision that would not only have benefits equal to costs but that would ensure that the option chosen

32. FDA, Preliminary Regulatory Impact Analysis, 23.
33. FDA, Preliminary Regulatory Impact Analysis, 31.
34. US Government Accountability Office, "Securing Wastewater Facilities: Costs of Vulnerability Assessments, Risk Management Plans, and Alternative Disinfection Methods Vary Widely," GAO-07-480: Published: Mar 30, 2007, Publicly Released: Apr 30, 2007, http://www.gao.gov/products/GAO-07-480.
35. FDA, Preliminary Regulatory Impact Analysis, 14–15. On page 15 it says, "We estimate that about 70 percent of facilities already employ this mitigation strategy . . . "
36. FDA, Proposed Rule, 78025.
37. FDA, Preliminary Regulatory Impact Analysis, 15.
38. FDA, Preliminary Regulatory Impact Analysis, 22.

maximizes the total benefits less the costs (net benefits). In that latter scenario, one has to look at different requirements (marginal) of the regulation to see which ones are worthwhile, that is, which requirements (like coverage and required activities) have benefits exceeding costs.

There are several hidden assumptions in the benefits calculated for the scenarios (especially scenarios 2 and 3):

1. The FDA assumes it is only a matter of time before serious attacks happen on the food supply, even though they have never happened before. This appears to be based on some intelligence that such attacks have been contemplated.

2. Particularly for finding the probability of launching such an attack, the FDA assumes terrorists would know about these rules and not attack the US food supply. Alternatively, if they did, food companies would catch them in the act or detect contaminated food faster. This rule is assumed to ensure that 50 percent of the attacks will not cause an attack somewhere else.[39]

3. The consequences of an attack without this regulation are huge (particularly for scenario 3).

We examine each of assumptions below:

Assumption 1

With respect to the first assumption, this appears to be a possibility at this point with no one having any idea what the likelihood actually is. Given that we still have 48 million unintended illnesses from contaminated food, is it wise to deflect many resources away from solving that problem?

Assumption 2

With regard to the efficacy of these regulations, the FDA assumes that terrorists who are thwarted by these rules will only attack other targets 50 percent of the time. This is based on the mean of a uniform distribution (which is a distribution chosen when one knows absolutely anything whatsoever about the issue). That makes this assumption more or less nonsense. The agency has no basis whatsoever to say that people who have enough resources, skill, and motivation to intentionally contaminate the food supply to the extent that it causes a major foodborne outbreak but who are thwarted by the regulation will simply give up using their considerable resources and skills and deny their malevolent intentions at least on average 50 percent of the time. Especially for Scenario 3, it strains credulity to suggest that a group with the resources, skills, and depth of motive to gather enough of a biological or chemical agent sufficient to kill 5,000 people and cause 100,000 other serious illnesses will only use those resources (including the chemical or biological agent) and skills to pursue their motives by some other opportunity half the time. Furthermore, the FDA simply has no idea if any of these requirements will dissuade terrorists or help to discover if a terrorist attack has occurred, particularly more than current efforts.

Assumption 3

Two papers speak to the consequences of the attack. One reference used by the FDA is Stinson.[40] This paper uses "hypothetical data" that imagines what would happen if the baseline growth of GDP drops from 4 percent to 2.5 percent. It is hypothetical, there is no basis for it, and it is not peer-reviewed. This should be dismissed out of hand.

A second citation is from Wein et al.[41] This paper models distributing botulinum toxin into fluid milk or any other product with a "bow-tied" supply chain, that is, one with a central point at which the product could be con-

---

39. FDA, Preliminary Regulatory Impact Analysis, 24.

40. Thomas Stinson, "The National Economic Impacts of a Food Terrorism Event: Preliminary Estimates," *Proceedings of The Institute of Food Technologists' First Annual Food Protection & Defence Research Conference* (Atlanta, GA, November 3–4, 2005), http://www.ift.org/~/media/Knowledge%20Center/Science%20Reports/Conference%20Papers/3Stinson.pdf.

41. Lawrence M. Wein and Yifan Liu, "Analyzing a Bioterror Attack on the Food Supply: The case of Botulinum Toxin in Milk," *Proceedings of the National Academy of Sciences* 102, no. 28 (2005): 9984–89, doi: 10.1073/pnas.0408526102.

taminated. The toxin is introduced into the supply chain and then is mixed at the choke point in the distribution chain. The toxin is assumed to be periodically released at the choke point as well. In their model, they show a large number of people poisoned, perhaps half a million. This paper was published in 2005 and is no doubt well known by the FDA, the DHS and fluid food producers. Nevertheless, the FDA notes that it would only have to stop an attack once every 200–730 years to cover the costs of this rule. That may be true for specific types of food products that are perishable (like milk) and have bow-tied supply chains, but not necessarily for other products with more diffuse supply chains. Again, this suggests this rule should be targeted much more carefully on the most likely targets where terrorists could achieve their ends. And targeting should include knowing the baseline: what are these firms doing now?

The preliminary regulatory analysis uses a break-even approach to address the question of whether the benefits of the rule justify the costs because the FDA claims that it has no information about the rule's effectiveness at preventing intentional contamination or about the likelihood that an attack will be attempted in a one-year period. The FDA describes three attack scenarios:

> Scenario 1 attacks are those that resemble previous acts of intentional adulteration in the United States. There have been several documented cases of intentional adulteration of food for reasons other than profit in the United States, although these attacks were acts of disgruntled employees rather than acts of terrorism. All of these incidents occurred at the retail level, and none of them resulted in fatalities or widespread illness. Scenario 2 attacks are those that resemble past cases of major outbreaks of foodborne illness in the United States. A successful introduction of a contaminant at an actionable process step would cause, at minimum, a Scenario 2 attack. Scenario 3 attacks are those that could be caused by skilled terrorists with advanced knowledge of contaminants and the food supply, and the intention to kill as many people as possible. Such an attack would cause tens or hundreds of thousands of illness cases, and potentially thousands of deaths.[42]

In fact, the FDA does have information about the effectiveness of the rule at preventing Scenario 1 attacks. "There have been several documented attacks on the US food supply, although none of them occurred at an actionable process step in a covered facility. . . . the proposed rule is not intended to cover such attacks."[43] In other words, the effectiveness of the rule at preventing Scenario 1 attacks is zero percent. The three documented attacks on the US food supply (contamination of salad bars and salsa at restaurants and contamination of treats served in a workplace break room) all occurred far beyond the reach of manufacturing facilities covered in this regulation.

Given that there have been so few Scenario 1 attacks over the years, i.e., three of them, the idea that any rule or training will prevent a lot more is just a fantasy. One might also argue that, given that there have been no Scenario 2 attacks in the last 30 years, they also don't provide justification for the rule. That leaves Scenario 3.

The FDA could reduce the costs of this rule by over $100 million if it focused this regulation primarily on larger firms and only on firms that are likely targets of a Scenario-3-type attack.

CONCLUSION

Unfortunately, this regulation responds to a law that may have addressed a nonproblem. Neither Congress nor the FDA knows what actual practices are in place to minimize the risk and outcome of potential terrorist attacks. At this point, the only thing we know is that there has not been a relevant attack that this rule would address. The FDA should, if allowed by Congress, go back and gather the data both on current practices and on the efficacy of applying the HACCP principles to this kind of problem. If this rule is still considered to be necessary after such an exercise, then this rule should be combined with the unintentional contamination rule that also requires HACCP. Besides that, there are ways the FDA can minimize the costs of this rule by carefully targeting the rule to high-value targets: industries that are not shelf stable, have a point in the process where large amounts of product can

42. FDA, Proposed Rule, 78021.
43. FDA, Preliminary Regulatory Impact Analysis, 22.

be contaminated, and have facilities large enough to satisfy the kinds of goals that food terrorists would target. If, after more research, more needs to be done, the FDA can follow this rule up with a separate regulation.

Finally, the FDA is mandated by Congress to propose this rule, but, in addition to the information the FDA is charged with supplying to Congress, perhaps the FDA can also supply Congress with answers to a few more questions:

1. Who benefits from this rule? Will the people who actually wrote this rule end up being consultants for implementation?

2. Why HACCP for terrorism prevention? Is there research that suggests that that is the best method for firms to reduce the probability or outcome of a food attack?

3. Is there a real problem with lack of prevention on the part of the food industry, or is this really just the result of rent seeking (see 1)?