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Public Interest Comment¹ on

The Food and Drug Administration's Proposed Rule:

Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption

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Sofie E. Miller and Cassidy B. West

The George Washington University Regulatory Studies Center²

The George Washington University Regulatory Studies Center strives to improve regulatory policy through research, education, and outreach. As part of its mission, the Center conducts careful and independent analyses to assess rulemaking proposals from the perspective of the public interest. This comment on the Food and Drug Administration's proposed rule on farming safety standards for specific produce commodities does not represent the views of any particular affected party or special interest, but is designed to evaluate the effect of FDA's proposals on overall consumer welfare.

Introduction

FDA's proposed rule, *Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption*, would establish minimum standards for the safe growing, harvesting, packing, and holding of produce. It includes standards for worker training, worker health and hygiene, agricultural water quality, soil treatment, the presence of domesticated animals on produce fields, equipment, tools, and buildings. The purpose of these standards is to reduce microbiological hazards in food intended for raw human consumption, which can lead to foodborne illness. The standards would apply to both domestic and imported produce, with

¹ This comment reflects the views of the authors, and does not represent an official position of the GW Regulatory Studies Center or the George Washington University. The Center's policy on research integrity is available at <http://research.columbian.gwu.edu/regulatorystudies/research/integrity>.

² Sofie E. Miller and Cassidy B. West are Analysts at the George Washington University Regulatory Studies Center, 805 21st St. NW, Suite 609, Washington, DC. (202) 994-2974. Sofie can be reached at sofiemiller@gwu.edu; Cassidy can be reached at cassidyb@email.gwu.edu. Many thanks to Summer Fellow Tatiana Pino for her research contributions to the *Cost Effectiveness of Preventive Controls* section of this comment.

exemptions for farms smaller than \$25,000, direct-marketing farms, foods that are rarely consumed raw, foods for personal or on-farm consumption, and produce that receives commercial processing that reduces the presence of microorganisms. The exemption for farms smaller than \$25,000 encompasses 62 percent of all non-organic farms and 66 percent of all organic farms, with a total of 149,426 farms exempted from the rule.

FDA estimates that the proposed regulation will prevent 1.75 million foodborne illnesses that result from all covered produce consumed each year; or sixty-five percent of the total illnesses associated with produce covered by the rule. It estimates annual costs of the proposed rule to be \$459.56 million for domestic farms and \$170.62 million for foreign farms, for a total of \$630.18 million. FDA estimates benefits of \$1.04 billion from the rule each year, resulting in an estimated \$406.22 million in annual net benefits.

This comment examines FDA’s statutory authority to regulate covered produce and whether the proposed rule as written meets the requirements for regulatory analysis as outlined in Executive Order 12866. We then analyze the effect of FDA’s proposed standards on small businesses, assess the benefits presented by the agency (along with the accompanying uncertainty), and recommend that FDA incorporate retrospective review into the text of its rule.

Statutory Authority

The Food Safety Modernization Act of 2011 (“FSMA” or “the Act”) requires the Secretary of the Department of Health and Human Services³ to issue regulations setting science-based minimum standards for the safe production and harvesting of fruits and vegetables that are “raw agricultural commodities” for which increased regulatory standards could minimize the risk of serious adverse health consequences or death. The Act gives the agency significant flexibility to determine what farms, commodities, and safety provisions will be mandated by the rule. Among other considerations, the agency is required to:

1. Establish (through rulemaking) processes which the Secretary determines are necessary to prevent the introduction of various hazards into the raw agriculture food supply and minimize the risk of death and serious health impacts [§105(c)(1)(A)];
2. Consider differences in risk for different products, while still minimizing the need for separate standards applicable to separate foods [§105(c)(1)(D)];
3. Provide flexibility to all types of businesses, particularly small businesses that may be covered by a promulgated rule [§105(c)(1)(B)];
4. Delay applicability of these rulemakings to small and very small businesses [§105(b)(3)(A – B)].

³ The Food and Drug Administration is an agency within the Department of Health and Human Services.

While the agency has acted to implement these provisions, in some ways the standards proposed in this rule are not science-based, and additional flexibility for small businesses would both increase net benefits and be in line with the requirements of Executive Orders 12866 and 13563.⁴

Compliance with Regulatory Analysis Requirements

Section 1(a) of Executive Order 12866 instructs regulatory agencies to identify the compelling public need that a new regulation seeks to address:

Federal agencies should promulgate only such regulations as are required by law, are necessary to interpret the law, or are made necessary by compelling public need, such as material failures of private markets to protect or improve the health and safety of the public, the environment, or the well-being of the American people. In deciding whether and how to regulate, agencies should assess all costs and benefits of available regulatory alternatives, including the alternative of not regulating.

Without knowledge of what problem any proposed regulation seeks to address, the public (and the agency) would not be well-equipped to know whether the proposed standards are the best approach for addressing the problem or whether they will generate actual societal benefits.

Although FDA is not explicit on this point in the proposed rule, these standards attempt to address the possible problem of asymmetric information between producers and consumers. Consumers may not have the access or knowledge to investigate the accuracy of raw foods' production claims, and may not have adequate information to judge which practices could ensure the safety of raw agricultural commodities. Approaches to address this market failure could either ensure consumers have reliable information, or obviate the need for consumers to obtain specific information by making agricultural practices uniform and reliable; the proposed rule takes the latter approach.

In the Preliminary Regulatory Impact Analysis ("PRIA"), FDA does explore the information asymmetry problem, and suggests that it also causes producers to use less safe practices when growing raw agriculture foods. Because the cause of food-borne illnesses cannot always be identified, FDA suggests producers do not have optimal information on the riskiness of current agricultural practices: "This may result in the underestimation by producers of the costs to society from consuming fresh produce and may cause them to discount the value of food safety

⁴ President Obama has reaffirmed the principles and analytical requirements expressed in EO 12866, "Regulatory Planning and Review," which guides executive branch agency rulemaking. In EO 13563, the President stated that "This order is supplemental to and reaffirms the principles, structures, and definitions governing contemporary regulatory review that were established in Executive Order 12866 of September 30, 1993."

practices and to provide less-than-the-socially optimal amount.”⁵ According to FDA, sufficient private incentives to motivate safer practices do not exist.

Given this understanding of the problem, the rule should be evaluated based on whether it reduces information barriers and allows creation of the proper incentives for the production of safe agricultural commodities.

Pursuant to the requirements of Executive Order 12866, the agency also considered a number of alternatives to the proposed rule, as elaborated in the PRIA. The alternatives listed include:

- a. taking no new regulatory action;
- b. excluding commodities not associated with outbreaks from some or all of the provisions of the rule;
- c. requiring less-extensive standards;
- d. requiring more-extensive standards;
- e. establishing a lower threshold to define a covered farm (an average annual monetary value of food sold during the previous three year period of more than \$10,000).

However, FDA has not proposed the alternative that maximizes net benefits, as required by EO 12866 and reinforced by EO 13563, which state:

In choosing among alternative regulatory approaches, agencies should select those approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity), unless a statute requires another regulatory approach.

FDA estimates that its proposed alternative will provide \$406.22 million annually in net benefits, but it presents other regulatory options that it estimates would offer annual net benefits of up to \$526 million. (This issue is discussed below in the section *Proposed Option does not Maximize Net Benefits*.) By neglecting to maximize net benefits, the agency is not conforming to President Obama’s regulatory principles, and is imposing unnecessary costs on society.

Impact on Small Businesses

The language of the FSMA requires FDA to promulgate a rule that provides flexibility particularly to small businesses and that delays applicability of the rule to small and very small businesses:

The proposed rulemaking [shall] provide sufficient flexibility to be applicable to various types of entities engaged in the production and harvesting of fruits and vegetables that are raw agricultural commodities, including small businesses and

⁵ Food and Drug Administration, *Analysis of Economic Impacts – Standards for the Growing, Harvesting, Packing and Holding of Produce for Human Consumption*. Page 3, Need for Regulation.
<<http://www.fda.gov/downloads/Food/FoodSafety/FSMA/UCM334116.pdf>>

entities that sell directly to consumers, and be appropriate to the scale and diversity of the production and harvesting of such commodities[.]⁶

In an attempt to conform to these requirements, FDA proposes to exempt from parts of its rule farms with less than \$25,000 in annual monetary value of all commodities sold, which constitute 60 percent of all covered domestic farms and about 4 percent of domestic produce acreage. However, even with this exemption, small farms are disparately harmed by the provisions of this rule.

FDA proposes the following definitions, based on average annual monetary value of food sold during the previous three-year period on a rolling basis:

Annual Sales	Size Definition
Above \$250,000 and no more than \$500,000	Small Business
Above \$25,000 and no more than \$250,000	Very Small Business
\$25,000 or less	Excluded from coverage

According to FDA’s analysis, implementation of this rule will result in significant compliance costs to all farms, but these costs are borne particularly by those that it defines as “very small.” Twenty-three percent of the farms covered under the rule fall under FDA’s definition of a “very small business.”⁷

Compliance with the proposed standards exhibit economies of scale, which are factors that cause the average cost of producing something to decrease as the volume of its output increases; and thus the compliance costs impose a larger cost burden on smaller farms. FDA’s Table 133, reproduced below from its PRIA, clearly presents the disparate effects of the proposed standards on small and very small farms.

	Very Small	Small	Large	All Farms
Average costs of implementing provisions in the proposed rule	\$4,697.19	\$12,972.36	\$30,566.23	\$11,429.70
Average annual monetary value of food sold	\$75,279	\$320,696	\$2,638,384	\$656,108
Average costs percentage of average annual monetary value of food sold	6%	4%	1%	2%

The agency compares the average costs of implementing the proposed rule as a percentage of food sales for three different farm sizes. This analysis is useful because, although some farms will incur higher or lower compliance costs, the relevant metric is cost relative to farm size in order to determine which farms will be disparately affected, and whether the rule provides “sufficient flexibility to ... small business” as required by FSMA.

⁶ Food Safety and Modernization Act §105(B)(3)(A) *Standards for Food and Produce Safety*.

⁷ Food and Drug Administration, *Analysis of Economic Impacts – Standards for the Growing, Harvesting, Packing and Holding of Produce for Human Consumption*. Page 16, Farms and Produce not Covered.

“Large” farms (which FDA defines as those with sales above \$500,000 per year) have average food sales of \$2.6 million. Their large compliance costs—\$30,566—comprise only 1% of annual sales. For “very small” farms (sales less than \$250,000 per year), and “small” farms, with sales between \$250,000 and \$500,000 per year, FDA expects compliance costs to consume a higher share of annual food sales—6% and 4%, respectively. This puts small and very small farms at a significant competitive disadvantage relative to their larger counterparts.

The high compliance costs may also discourage new farms from entering the market.⁸ To avoid the costs of the rule, farmers may choose to grow a commodity not covered by the rule, increase their off-farm income, or limit their sales to within a 275-mile radius in order to be considered “local growers.”⁹ Any of these actions are likely to reduce consumer choices as well as small farmers’ welfare.

In order to mitigate the disparate impact on small farms, the proposed rule allows farmers to develop alternative safety provisions instead of using the ones laid out in the proposed rule, if the alternative provisions provide the same level of public health benefits.¹⁰ While this flexibility and performance focus is good regulatory practice (and less likely to discourage innovation than a one-size-fits-all design standard),¹¹ it is unlikely to provide much relief to the small and very small farms covered by the rule. Large farms will be able to accumulate the necessary knowledge and have the advantage of economies of scale to develop different mechanisms to meet the public health standards. Smaller farms may not be sophisticated enough to take advantage of the flexibility. Therefore, the proposed rule may leave small farmers little option but to comply with the specific provisions in the rule.

Proposed Option does not Maximize Net Benefits

FDA’s analysis predicts \$411 million in annual net benefits from its preferred option (which exempts farms with annual food sales less than \$25,000).¹² However, this exemption would not

⁸ Food and Drug Administration, *Analysis of Economic Impacts – Standards for the Growing, Harvesting, Packing and Holding of Produce for Human Consumption*. Page 318, Cost to Small Entities.

<<http://www.fda.gov/downloads/Food/FoodSafety/FSMA/UCM334116.pdf>>

⁹ Food and Drug Administration, *Analysis of Economic Impacts – Standards for the Growing, Harvesting, Packing and Holding of Produce for Human Consumption*. Page 318, Cost to Small Entities.

<<http://www.fda.gov/downloads/Food/FoodSafety/FSMA/UCM334116.pdf>>

¹⁰ Food and Drug Administration, *Analysis of Economic Impacts – Standards for the Growing, Harvesting, Packing and Holding of Produce for Human Consumption*. Page 318, Number of Small Entities Affected.

¹¹ United States. Office of Management and Budget. *Circular A-4: Regulatory Analysis*. September 17, 2003.

“Performance standards express requirements in terms of outcomes rather than specifying the means to those ends. They are generally superior to engineering or design standards because performance standards give the regulated parties the flexibility to achieve regulatory objectives in the most cost-effective way. In general, you should take into account both the cost savings to the regulated parties of the greater flexibility and the costs of assuring compliance through monitoring or some other means.”

¹² It is unclear why FDA cites annual net benefits (total benefits – (domestic costs + foreign costs)) as \$406.22 in the proposed rule and \$411 in the Preliminary Regulatory Impact Analysis (\$1,032m – (\$460m + \$171m)). However, because we are comparing the values in Table 12, we will use those values consistently for this section of the analysis despite their difference from the values presented in the NPRM.

maximize net benefits, as required by EO 12866 and EO 13563. The agency’s own analysis suggests that extending the exemption to all farms with less than \$100,000 in annual commodity sales would increase the net domestic benefits of this rule by \$75 million annually. In fact, Table 12 of the PRIA indicates that of all the regulatory options FDA considered, its proposed option of limiting the exemption to farms that earn less than \$25,000 annually offers the smallest net benefits.¹³

	< \$25K	< \$50K	< \$100K	< \$250K	< \$500K
Prevented Illnesses (in millions)	1.73	1.69	1.63	1.53	1.42
Additional Illnesses not covered	--	47,000	52,000	99,000	117,000
Covered Farms	40,211	28,253	20,140	12,615	8,500
Exempt or Non-covered Farms	149,426	161,384	169,497	177,022	181,137
Produce acres not covered	14.1%	16.4%	19.0%	23.9%	29.7%
Total Domestic Benefits (in millions)	\$1,032	\$1,004	\$973	\$914	\$844
Total Domestic Costs (in millions)	\$460	\$348	\$316	\$282	\$234
Net Domestic Benefits (in millions)	\$582	\$656	\$657	\$632	\$610
Average Domestic Cost (per farm)	\$11,430	\$12,313	\$15,699	\$22,383	\$27,566
Total Foreign Costs (in millions)	\$171	\$152	\$131	\$112	\$91

As Table 12 shows, FDA considered five different exclusion thresholds for small farms ranging from \$25,000 to \$500,000, and calculated anticipated net benefits for each of these threshold levels. Based on this analysis, the threshold exemption level proposed in this rule provides the lowest net benefits of any considered option. Net benefits are maximized by exempting farms smaller than \$100,000, which would increase the net domestic benefits of the rule by \$75 million—from \$582 million to \$657 million annually.¹⁴ Over a 10 year timeframe, exempting farms smaller than \$100,000 would increase this rule’s anticipated net benefits by \$750 million dollars over the proposed exemption threshold of \$25,000.

Given that FSMA specifically directs the agency to “provide sufficient flexibility to...small businesses” and gives FDA not only the discretion to exempt small farms from the standards in this proposed rule, but to determine what constitutes a “small farm,”¹⁵ FDA’s proposed exclusion threshold appears too low.

This is particularly true since President Obama’s Executive Order 13563 made it clear that agencies should “select, in choosing among alternative regulatory approaches, those approaches that maximize net benefits.” Given the requirements of the statute and the instructions in EOs 12866 and 13563, FDA cannot justify limiting its proposed exemption to farms smaller than \$25,000. In order to satisfy the Executive Orders and the intent of its authorizing statute, FDA

¹³ Note that the values for net benefits in Table 12 apparently do not factor in the foreign cost of these standards, which tallies \$170.62 million annually at the \$25,000 threshold. While FDA factored this cost into the net benefits calculation in the proposed rule, it did not do so in the PRIA or in this table.

¹⁴ Note that Table 12 does not include net benefits, which would include foreign costs, but only net *domestic* benefits.

¹⁵ Food Safety and Modernization Act §105(a)(3)(A)

should exempt all farms smaller than \$100,000 to maximize the net benefits of this proposed rule.

Regulatory Benefits Estimate Uncertain

Because the proposed rule is a large one that affects thousands of entities and incurs millions of dollars in costs, it is essential to critically evaluate the benefits FDA expects to result from these standards.

Baseline Risk and Risk Reduction

FDA recognizes that it “has only limited data that would establish a clear baseline estimate of how contamination occurs and the likely impact of the proposed provisions on that baseline, with respect to causing human illness.”¹⁶ FDA developed a baseline estimate of the total number of illnesses attributable to produce covered by the rule using a combination of its own outbreak data, those of the Center for Disease Control (CDC), and estimates of the total number of domestic foodborne illnesses that occur annually derived from research conducted by Dr. Elaine Scallan and others affiliated with the CDC.¹⁷ Scallan et al. lacked the data to directly link the estimated number of foodborne illnesses to food, and the researchers recognize that some illnesses they attributed to food may actually be a result of other variables, such as improper hygiene, animal handling, or travel.

The Scallan et al. estimate suffers from other weaknesses as well, which make it of questionable reliability for rulemaking, including:

- Data were often lacking, came from a variety of sources, and were of “variable quality and representativeness.”¹⁸
- Scallan et al. used different methodologies to calculate the baseline estimates, making it difficult to compare the baseline to prior estimates and making Scallan et al.’s estimate of illnesses attributable to food suspect.
- The data and methodological limitations affected the baseline estimates used to calculate the benefits to a large degree,¹⁹ and make it impossible to assess the trends in the actual number of annual domestic foodborne illnesses.²⁰

¹⁶Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption (78 FR, 3506), 2013.

¹⁷ Food and Drug Administration, *Analysis of Economic Impacts – Standards for the Growing, Harvesting, Packing and Holding of Produce for Human Consumption*. Page 61, Baseline Risk of Foodborne Illness.

<<http://www.fda.gov/downloads/Food/FoodSafety/FSMA/UCM334116.pdf>>

¹⁸ Scallan E, Hoekstra RM, Angulo FJ, Tauxe RV, Widdowson M-A, Roy SL, et al. Foodborne illness acquired in the United States—major pathogens. *Emerg Infect Dis*. 2011 Jan. <http://dx.doi.org/10.3201/eid1701.P11101>

¹⁹ Scallan E, Hoekstra RM, Angulo FJ, Tauxe RV, Widdowson M-A, Roy SL, et al. Foodborne illness acquired in the United States—major pathogens. *Emerg Infect Dis*. 2011 Jan. <http://dx.doi.org/10.3201/eid1701.P11101>

¹⁹ Scallan et al., 2011

²⁰ Scallan E, Hoekstra RM, Angulo FJ, Tauxe RV, Widdowson M-A, Roy SL, et al. Foodborne illness acquired in the United States—major pathogens. *Emerg Infect Dis*. 2011 Jan. <http://dx.doi.org/10.3201/eid1701.P11101>

In addition to a questionable estimate used to calculate the baseline risk, FDA chose the 2003 – 2008 timespan, which ignores recent food safety data. FDA chose to use the 2003 – 2008 timespan because it is the “most current and comprehensive” data available,²¹ but it recognizes that “2003 and 2008 had unusually high numbers of illnesses caused by produce, relative to illnesses in adjacent years,”²² which may overstate baseline outbreak data. Beyond 2008, “full outbreak data, from CDC, has not been completely collected, sorted, cleaned, and made available for public use.”²³

According to the CDC, the American food supply has become safer since 1998 and the overall occurrence of infection from six key foodborne pathogens has decreased by 22% from 1996 – 2012.²⁴ Likewise, the White House Food Safety Working Group in a 2011 progress report listed several improvements in FDA’s “commodity-specific draft guidance on agricultural practices that can reduce the risk of microbial contamination in the production and distribution of tomatoes, melons, and leafy greens”—three commodities that pose a higher risk of contamination than some other commodities. FDA’s baseline estimates do not consider improvements that have occurred since 2008, nor do they take into account related FDA, CDC, USDA, and other public and private sector food safety policies that are currently being implemented.²⁵

In addition to ignoring recent food safety progress, the FDA concedes that due to the sporadic nature of outbreaks, the time period may be too short to capture the actual number of illnesses associated with produce, and may overstate the baseline riskiness of specific commodities. FDA’s baseline estimate is based on only six years of data, of which two—2003 and 2008—experienced unusually high numbers of illnesses associated with produce relative to adjacent years,²⁶ and excludes food safety initiatives over the last five years. These practices in the PRIA

²⁰ Scallan E, Hoekstra RM, Angulo FJ, Tauxe RV, Widdowson M-A, Roy SL, et al. Foodborne illness acquired in the United States—major pathogens. *Emerg Infect Dis*. 2011 Jan. <http://dx.doi.org/10.3201/eid1701.P11101>

²¹ Food and Drug Administration, *Analysis of Economic Impacts – Standards for the Growing, Harvesting, Packing and Holding of Produce for Human Consumption*. Page 58, Foodborne Illness Attributable to Produce from Microbial Contamination. <<http://www.fda.gov/downloads/Food/FoodSafety/FSMA/UCM334116.pdf>>

²² Food and Drug Administration, *Analysis of Economic Impacts – Standards for the Growing, Harvesting, Packing and Holding of Produce for Human Consumption*. Page 58, Foodborne Illness Attributable to Produce from Microbial Contamination.

<<http://www.fda.gov/downloads/Food/FoodSafety/FSMA/UCM334116.pdf>>

²³ Food and Drug Administration, *Analysis of Economic Impacts – Standards for the Growing, Harvesting, Packing and Holding of Produce for Human Consumption*. Page 58, Foodborne Illness Attributable to Produce from Microbial Contamination.

<<http://www.fda.gov/downloads/Food/FoodSafety/FSMA/UCM334116.pdf>>

²⁴ Morrall, J.F. & Barry, Matt. “Making Healthy Foods Safer: Food and Drug Administration’s Proposed Produce Safety Standards”. Bloomberg Government Regulatory Analysis, 2013. 1 p.

²⁵ Morrall, J.F. & Barry, Matt. “Making Healthy Foods Safer: Food and Drug Administration’s Proposed Produce Safety Standards”. Bloomberg Government Regulatory Analysis, 2013. 1 p.

²⁶ Food and Drug Administration, *Analysis of Economic Impacts – Standards for the Growing, Harvesting, Packing and Holding of Produce for Human Consumption*. Page 58, Quantifying the Benefits of the Proposed Rule. <<http://www.fda.gov/downloads/Food/FoodSafety/FSMA/UCM334116.pdf>>

serve to overstate baseline risks, and thus overstate estimated reductions in risk attributable to the proposed requirements. FDA should be more transparent about the uncertainty in its estimates.

Efficacy of Preventive Controls

The proposed rule's estimated benefits of approximately \$1 billion annually hinge on the rule reducing foodborne illnesses by 1.75 million annually. FDA derived the 1.75 million figure by estimating the likelihood of produce contamination through eight different pathways, such as worker hygiene and agricultural water, and surveyed FDA staff on the estimated efficacy of the proposed standards in reducing contamination through each pathway. From the PRIA:

FDA experts were asked, based on the current state of the produce industry, to estimate how much of the likelihood of contamination associated with each pathway that the proposed rule might be able to mitigate (on a scale of 0 to 100 percent). These individual responses were then compiled into an overall estimate of efficacy of the proposed preventive controls. The results derived from each set of experts are reassuringly corroborative.²⁷

The FDA staff answers ranged from about 42 percent efficacy to 88 percent estimated efficacy for each pathway, which suggests a range in the reduction in annual foodborne illness of between 1.1 million and 2.4 million per year. However, FDA did not incorporate this wide range into its benefit estimate, but rather averaged the FDA staff answers and used these averages as the final point estimates for reductions in contamination. Using this methodology, FDA gives a point estimate for the reduction in foodborne illnesses that are attributable to raw agricultural products of 64.77 percent, or 1.75 million annually. Table 25 below, from the agency's PRIA, shows the estimated efficacy of proposed controls for each of the contamination pathways and the estimated total mean efficacy of the standards.

²⁷ Food and Drug Administration, *Analysis of Economic Impacts – Standards for the Growing, Harvesting, Packing and Holding of Produce for Human Consumption*. Page 76, footnote 21.
<<http://www.fda.gov/downloads/Food/FoodSafety/FSMA/UCM334116.pdf>>

TABLE 25. PERCENTAGE REDUCTION IN THE RISK OF CONTAMINATION

Contamination Pathway	Likelihood of Contamination	Efficacy of Proposed Controls	% Reduction in the Risk of Contamination		
			5th percentile	mean	95th percentile
Agricultural Water (g/h)	16.32%	54.49%	6%	8.89%	12%
Agricultural Water (ph)	14.37%	72.55%	8%	10.42%	13%
Biological Soil Amendments	13.81%	65.62%	6%	9.06%	13%
Worker Health and Hygiene (g/h)	15.62%	66.04%	7%	10.32%	13%
Worker Health and Hygiene (ph)	15.20%	73.50%	9%	11.17%	14%
Domesticated and Wild Animals	14.09%	58.04%	4%	8.18%	13%
Equipment, Tools, Building and Sanitation (g/h)	4.18%	56.71%	1%	2.37%	4%
Equipment, Tools, Building and Sanitation (ph)	6.42%	67.97%	2%	4.36%	7%
Total			42%	64.77%	88%

FDA’s reliance on this point estimate of a 65 percent reduction in produce contamination has several problems. First, to quantify the likely effectiveness of the proposed rule these experts were asked to only respond with estimates concerning the leafy green or tomato industry, and the state of the industry more than three years ago. It is possible that what is effective on lettuce or tomato farms may be more or less effective on a farm growing a different commodity.²⁸ Further, food safety initiatives (both public and private) have increased in recent years, and relative to this new baseline the rule will be considered less effective. Also, many of the questions asked about the effectiveness of the rule do not mirror the provisions in the rule.

Furthermore, an internal survey of agency staff is not a sound method for determining the efficacy of a series of proposed standards. It is especially difficult to justify the use of FDA’s staff survey—particularly given the flawed survey construction—as one of the primary bases of its benefits estimate given that Congress has directed FDA to implement “science-based” standards. However, it is even more difficult to justify the use of a single point-estimate for benefits given the variance in staff responses. While it would be preferable for the agency to rely on existing literature and experiments to gauge the efficacy of the standards, the available data could be improved by using a range of efficacy rather than a point estimate to calculate benefits.

FDA’s approach of applying its midpoint estimate of 65 percent efficacy to its baseline value of all illnesses associated with microbial contamination in covered foods yields an estimated benefit of \$1.04 billion per year. As noted above, both of these key inputs are highly speculative. Nevertheless,

²⁸ Food and Drug Administration, *Analysis of Economic Impacts – Standards for the Growing, Harvesting, Packing and Holding of Produce for Human Consumption*. Page 88, Summary of Assumptions for Benefits Analysis. <<http://www.fda.gov/downloads/Food/FoodSafety/FSMA/UCM334116.pdf>>

using the range provided by FDA’s unscientific internal staff poll of efficacy sheds more light on the likely effects than a single point estimate. If the provisions in the rule have a 42 percent efficacy in preventing illnesses from produce, this rule will prevent 1,130,769 instances of foodborne illness per year, with annual benefits of \$669 million, 64 percent of FDA’s single point estimate for benefits. If the proposed rule has an 88 percent efficacy then the benefits accrued will be \$1.42 billion. Because these percentage reductions are applied to baseline risks that are likely overstated, FDA’s point estimate is better seen as a reasonable upper bound of the likely benefits, but a more transparent presentation of the range of likely benefits would be more informative to policy makers and the public.

Cost Effectiveness of Preventive Controls

The contamination pathways addressed by this proposed rule pose different levels of risk to consumers, and the proposed standards for addressing these pathways will have varying effects on risk reduction. Ideally, FDA’s proposed rule would focus efforts on those contamination pathways that pose the highest risk to human health and where risks could be reduced most cost-effectively. However, an examination of FDA’s analysis and data shows that this is not the case.

Measuring Cost per Illness Prevented by Contamination Pathway Risk Reduction					
Contamination Pathway	Likelihood of Contamination	Efficacy of Controls	% Risk Reduction	Pathway Costs	% of Total Pathway Costs
Agricultural Water (g/h)	16.32%	54.49%	8.89%	\$55,720,485	17.36%
Agricultural Water (ph)	14.37%	72.55%	10.42%		
Biological Soil Amendments	13.81%	65.62%	9.06%	\$19,424,903	6.05%
Worker Health and Hygiene (g/h)	15.62%	66.04%	10.32%	\$138,206,653	43.05%
Worker Health and Hygiene (ph)	15.20%	73.50%	11.17%		
Domesticated and Wild Animals	14.09%	58.04	8.18%	\$37,775,360	11.77%
Equipment, Tools, Buildings, and Sanitation (g/h)	4.18%	56.71%	2.37%	\$69,920,000	21.78%
Equipment, Tools, Buildings, and Sanitation (ph)	6.42%	67.97%	4.36%		
Total			64.77%	\$321,047,401	100.00%

The table above presents the likelihood of contamination by each of the pathways addressed in the proposed rule, along with the risk reduction FDA anticipates will result from the standards and the accompanying cost estimate per pathway standard. This information allows a comparison of the cost-effectiveness of the proposed standards for different pathways in reducing risks to consumers. According to FDA’s analysis:

Worker health and hygiene in postharvest (g/h) [*sic*] activities is estimated to have the most impact on overall contamination, reducing it by an estimated 11 percent. Equipment, Tools, Buildings, and Sanitation in growing and harvest (g/h) activities are estimated to contribute the least, at only about a 2 percent reduction in contamination. In total, we estimate that this rule will reduce total on farm contamination by about 65 percent.²⁹

Despite contributing the least to overall contamination reductions, the standards for equipment, tools, buildings, and sanitation (ETBS) comprise nearly 22 percent of the total pathway costs of this rule, or \$69.9 million. Although the ETBS standards are only expected to reduce raw produce consumption risk by 7.63 percent cumulatively, these standards are the second most costly of all proposed pathway standards.

The pathway standards can also be ranked by the cost incurred per illness avoided. By this metric the most cost-effective standards are the biological soil amendments, at \$79.32 per illness avoided. (This pathway standard also incurs the lowest cost overall at \$19.4 million.) Standards for agricultural water cost \$106.75 per illness avoided, and standards for preventing contamination from domesticated and wild animals cost \$170.83 per illness avoided. In comparison, the ETBS standards will cost farmers and consumers \$384.34 per illness avoided, nearly \$150-per-illness more than the most expensive standards (for worker health and hygiene).

Given this disparity, it is not clear why FDA focuses so much effort on the reduction of relatively low-risk contamination that occurs through equipment, tools, buildings, and sanitation. Because of the relatively high cost and low benefit of ETBS standards, FDA should remove these standards from its rulemaking. FDA and farm resources would be better directed toward standards to reduce more tangible risks, such as worker health and hygiene and agricultural water.

Retrospective Review

Given the uncertainty in the estimated benefits and costs of the rule, FDA should ensure it has the data to evaluate the rule's outcomes after it is implemented. Through a series of Executive Orders, President Obama has encouraged federal regulatory agencies to review existing regulations "that may be outmoded, ineffective, insufficient, or excessively burdensome, and to modify, streamline, expand, or repeal them in accordance with what has been learned." On January 18, 2011, President Obama signed Executive Order 13563, Improving Regulation and Regulatory Review, which reaffirmed the regulatory principles and structures outlined in EO

²⁹ Food and Drug Administration, *Analysis of Economic Impacts – Standards for the Growing, Harvesting, Packing and Holding of Produce for Human Consumption*. Page 78, Produce Rule Model Potential of Risk Reduction. <<http://www.fda.gov/downloads/Food/FoodSafety/FSMA/UCM334116.pdf>>

12866. In addition to the regulatory philosophy laid out in EO 12866, EO 13563 instructs agencies to

consider how best to promote retrospective analysis of rules that may be outmoded, ineffective, insufficient, or excessively burdensome, and to modify, streamline, expand, or repeal them in accordance with what has been learned. Such retrospective analyses, including supporting data, should be released online whenever possible.³⁰

This ex-post review makes it possible for the public—and for the agencies that regulate them—to measure whether a particular rule has had its intended effect. Given that the expected benefits of this rule are both significant and specific, it will be possible for FDA to review the standards once they have been implemented to gauge whether the claimed benefits are substantiated. While FDA references this possibility briefly in the PRIA, the text of the rule itself does not mention retrospective review or hold the agency accountable to a retrospective review schedule. This leaves the public without the information needed to determine whether the proposed rule is accomplishing its intended purpose.

FDA expects the rule will achieve a 65 percent reduction in annual food-borne illnesses from covered produce. Using data that are already compiled by federal agencies, FDA will be able to track the prevalence of food-borne illnesses before and after implementation of the rule to identify the efficacy of the standards in accomplishing their intended goal.

Former Administrator of the Office of Information and Regulatory Affairs, Cass Sunstein, reiterated these points in his implementing memo, which states:

future regulations should be designed and written in ways that facilitate evaluation of their consequences and thus promote retrospective analyses and measurement of “actual results.” To the extent permitted by law, agencies should therefore give careful consideration to how best to promote empirical testing of the effects of rules both in advance and retrospectively.

In its Draft 2013 Report to Congress on the Benefits and Costs of Federal Regulations, the Office of Management and Budget (OMB) states that such retrospective analysis can serve as an important corrective mechanism to the flaws of ex ante analyses. According to that report, the result of systematic retrospective review of regulations:

should be a greatly improved understanding of the accuracy of prospective analyses, as well as corrections to rules as a result of ex post evaluations. A large priority is the development of methods (perhaps including not merely before-and-after accounts but also randomized trials, to the extent feasible and consistent with law) to obtain a clear sense of the effects of rules. In addition, and

³⁰ Exec. Order No. 13563, *Improving Regulation and Regulatory Review*, 76 FR 3821 (2011).

importantly, rules should be written and designed, in advance, so as to facilitate retrospective analysis of their effects.

In line with the requirements of EO 13563, OMB's implementation memo, and OMB's Draft 2013 Report to Congress, FDA should incorporate specific plans for retrospective review into the text of its final rule. FDA should add language into its final rule committing to retrospectively review this rule at two-year increments following its implementation, measured as percent reductions in foodborne illnesses from the agency's rulemaking baseline. Measuring efficacy at two-year increments will provide relevant foodborne illness data without allowing data to be skewed in any single year by a foodborne illness outbreak. FDA should also consider field testing the requirements of the rule (the randomized trials suggested by OMB), perhaps with a focus on the smaller entities covered.

This information will tell both the FDA and the public how accurate the agency's estimates were, and will provide information for future rulemakings on how best to estimate the effects of such standards on foodborne illnesses. If the retrospective reviews indicate that FDA's standards were ineffective, FDA should consider a rulemaking to change the standards to best reflect the lessons learned.³¹ In addition, retrospective review and field-testing may provide information on the appropriate small business exemption to maximize net benefits.

Unintended Consequences

Even with the best of intentions, regulations can often have unintended consequences that can harm public welfare, and can leave some population subgroups worse-off than they were before. The potential unintended consequences that may result from these proposed standards, and the distributional impacts they may have, are explored below.

Effects on Foreign Farms and Consumers

Because this proposed rule applies to all farms that supply fresh produce to U.S. consumers, the standards apply to both foreign and domestic producers of raw agricultural products. Application of these standards to foreign farms that export to the United States could have a significant impact on Americans' access to imported food: FDA estimates that the cost to foreign firms for complying with these standards is approximately \$170 million annually.

Although all foreign producers exporting raw produce to the U.S. will be burdened by this rule, exporters in the developing world are more likely to shoulder the burden of the increased costs. This will disparately harm poorer farmers, exporters, and lower-income consumers in the developing world. According to the FDA's PRIA:

³¹ See Michael Greenstone's testimony and recommendations before the Joint Economic Committee: "Eliminating Unnecessary and Costly Red Tape Through Smarter Regulations", June 26, 2013. http://www.jec.senate.gov/republicans/public/?a=Files.Serve&File_id=00be5708-528d-4fc8-9d2e-a9ccc3ac25b0

Our analysis predicts that at least some foreign farms from all regions of the world, including our largest trading partners, Mexico and Canada, as well as farms of other nations (especially their smaller farms) would have to incur the cost to change at least some of their practices to comply with the proposed rule. Farms located in the developing world are less likely to already be in compliance with the proposed requirements and will incur the costs to comply.³²

Additionally, if foreign exporters change their farming practices to comply with the proposed rule, foreign agriculture prices could rise as well, adversely affecting low-income consumers in developing countries. As FDA goes on to note in the PRIA: “Any price increases that would be incurred as compliance costs are likely to be passed on to both domestic and foreign customers.”

While a price increase for domestic consumers as a result of this rule is to be expected, a potential unintended consequence of this rule will be to increase food prices for consumers in the developing world as well. Increasing the small farm exemption threshold from \$25,000 to \$100,000, as recommended here, will at least to some extent limit the negative price effects of this rule on consumers.

WTO Guidelines

Although the cost of compliance will not severely affect the bulk of produce already exported to the U.S., the rule will leave little room for new producers, particularly those in developing nations, to sell produce to the American market. To be in compliance with WTO Guidelines, “domestic regulations, standards, testing and certification procedures must not create unnecessary regulatory impediments.” While the rule does not necessarily create impediments to trade, the high compliance costs do create a regulatory impediment by creating a barrier to entry to those foreign farms seeking to enter the produce market. Further, any price increases resulting from the rule will likely affect trade. If foreign farmers have to increase their prices significantly to comply with the rule, then the percentage of foreign produce exported to the U.S. may decrease because American consumers will demand the cheaper, domestic produce, further harming these foreign farmers.

Impact on Supply

As a result of increased production costs to farmers resulting from these standards, the supply of covered produce is likely to decrease as farmers, particularly small farmers, exit the market in combination with fewer new farms entering the market. Decreased supply may lead to higher prices for fruits and vegetables which may be transferred to consumers.

³² Food and Drug Administration, *Analysis of Economic Impacts – Standards for the Growing, Harvesting, Packing and Holding of Produce for Human Consumption*. Page 289, Costs for Foreign Entities and Trade Effects. <<http://www.fda.gov/downloads/Food/FoodSafety/FSMA/UCM334116.pdf>>

Behavioral Effects

While FDA acknowledges that any price increases resulting from the compliance costs will ultimately be passed on to consumers, FDA does not consider how the higher prices for fresh produce will decrease consumer demand for covered commodities, which could have negative health implications. Higher prices will lead consumers, especially those on tight budgets, to substitute fresh or frozen produce for a cheaper option not covered by the rule. While canned fruits and vegetables can be a healthy alternative for consumers if they are aware of the higher sugar and sodium levels, inevitably, some consumers will choose canned fruits and vegetables unaware of the sodium or sugar content. In less optimal cases, some consumers may bypass the canned fruits and vegetables altogether and go for an even less healthy yet cheaper substitute, such as potato chips.

Altering consumer behavior in this way could have negative health effects for domestic consumers which are not accounted for by FDA. Although risks related to foodborne illnesses will likely be reduced as a result of these standards, other risks related to dietary changes may be increased. The proposed standards may have some offsetting negative health impacts by directing consumers away from (more expensive) fresh produce and toward (relatively cheaper) processed food items. In its analysis, FDA should acknowledge these risks.

Conclusion

FDA's proposed *Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption* does not meet statutory and executive requirements, and may needlessly harm consumers as well as small farmers domestically and abroad. First, estimates supporting the rule are based on very limited data and unscientific methods. FDA nevertheless relies on point estimates, rather than presenting a range of likely effects. Second, FDA does not consider unintended side effects associated with higher prices for the fresh commodities covered. Third, even accepting FDA's analysis at face value, the selected option does not maximize net benefits as required by presidential Executive Orders 12866 and 13563. The recommendations below would address some of these issues in the proposed rule and analysis.

Exempt Farms with Annual Sales less than \$100,000

FDA is both authorized by the statute to provide small farms with additional flexibility, and instructed via Executive Order to maximize the net benefits of its rule. The exemption threshold proposed in this rule neither provides small farms with this flexibility nor maximizes net benefits. Based on the agency's own analysis, exempting all farms smaller than \$100,000 would maximize net benefits while also providing additional flexibility for small farms.

Remove ETBS Standards

Because of the relatively high cost and low benefit of the standards for equipment, tools, buildings, and sanitation, FDA should remove these standards from its rulemaking. Despite

contributing the least to overall contamination risk, FDA's proposed standards for equipment, tools, buildings, and sanitation have the highest cost per illness avoided. FDA and farm resources would be better directed toward standards to reduce more tangible risks, such as worker health and hygiene and agricultural water.

Use of Ranges Instead of Point Estimates

Despite very significant uncertainty in both the baseline estimate of risk from foodborne illness and the reductions achievable from implementing the measures proposed in this rule, FDA provides single point estimates of benefits and net benefits. Given the limitations regarding data and methodology used in its baseline estimate and limited information regarding how contamination occurs, FDA should be more transparent about the uncertainty underlying the baseline risk of foodborne illness used in this rule.

Reliance on a single point estimate of the efficacy of this rule implies a degree of certainty FDA does not have, and may misrepresent the benefits of the proposed standards. While it would be preferable for the agency to rely on existing literature and experiments to gauge the likely efficacy of the standards, the available data could be improved by using a range of benefits rather than a point estimate. Using its own survey results, FDA should calculate a range of benefits resulting from reducing foodborne illness by between 42 and 88 percent. This range is more likely to contain within it the actual efficacy of the standards than a single point estimate for efficacy and benefits.

Retrospective Review

FDA should add language to its final rule committing to measure efficacy at two-year increments following implementation of the rule, measured as percent reductions in foodborne illnesses. This information will tell both the agency and the public how accurate its estimates were, and will provide information for future rulemakings on how to tailor standards to achieve desired outcomes. In addition, retrospective review efforts may be able to provide information on whether the small business exemption was appropriate for maximizing net benefits. If the retrospective reviews indicate that FDA's standards were ineffective, FDA should consider a rulemaking to change the standards to best reflect the lessons learned.