Comments

The Center for Progressive Reform

Standards for the Growing, Harvesting, Packing and Holding of

Produce for Human Consumption

Docket ID No. FDA-2011-N-0921

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EXECUTIVE SUMMARY

We applaud the FDA's efforts to establish, for the first time, a comprehensive set of food safety standards for produce farms. In recent years, contaminated produce has been responsible for a number of devastating outbreaks, from *Listeria*-tainted cantaloupes that killed up to 43 people in 2011 to a *Cyclospora* outbreak that sickened 631 people in 25 states this past summer, not to mention millions of illnesses that likely go undiagnosed or unreported. The proposed rule would address some of the most likely sources of contamination on farms, including tools and equipment; water used in agricultural activities; worker health and hygiene; animals in the growing area; and animal-based soil amendments.[1]

In the preliminary regulatory impact analysis (PRIA), the FDA finds that the rule is easily justified on economic grounds, estimating annual benefits of $1.04 billion—representing 1.75 million avoided illnesses in the United States—and annual domestic costs of $460 million.[2]

Nevertheless, produce farm organizations and anti-regulation think tanks have tried to undermine and delay the rulemaking—downplaying the scope of the public health crisis, predicting financial ruin for farms across the nation, and urging the FDA to weaken or drop crucial safeguards and expand the rule's already-sizable exemptions.[3] A major trade association for the produce industry is now insisting that the agency release a second round of proposed rules and is lobbying Congress to set a longer timetable for FSMA implementation.[4] House Republicans, for their part, have demanded that the agency conduct additional, time-consuming "scientific and economic analysis" before finalizing any of the food safety rules.[5]

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[1] Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption; Proposed Rule, 78 Fed. Reg. 3504 (proposed Jan. 16, 2013) (to be codified at 21 C.F.R. pts. 16 & 112), *available at* http://www.regulations.gov/#!documentDetail;D=FDA-2011-N-0921-0001.

[2] FDA, Analysis of Economic Impacts – Standards for the Growing, Harvesting, Packing and Holding of Produce for Human Consumption 52 (Jan. 16, 2013), *available at* http://www.fda.gov/downloads/Food/GuidanceRegulation/FSMA/UCM334116.pdf [hereinafter Final Draft PRIA].

[3] *See, e.g.,* MERCATUS CENTER, REGULATORY REPORT CARD ON THE FDA'S PROPOSED PRODUCE RULE, Aug. 2013, http://mercatus.org/sites/default/files/Farm-standards_rc_100113.pdf (calling the rule ineffective, unnecessary, unfocused, and onerous); SOFIE E. MILLER & CASSIDY B. WEST, GEORGE WASHINGTON UNIV. REG. STUDIES CTR., PUBLIC INTEREST COMMENT ON THE FDA'S PROPOSED PRODUCE RULE, Aug. 12, 2013, *available at* http://research.columbian.gwu.edu/regulatorystudies/sites/default/files/u41/FDA_2011_N_0921_Miller_West.pdf (claiming the rule imposes unnecessary costs on society); CORNUCOPIA INST., FOOD SAFETY THEATER 9, 11-13, Sep. 19, 2013, http://www.cornucopia.org/FoodSafety/FoodSafetyWhitePaper.pdf (warning that the FDA will be able to target small farms one-by-one and put them out of business, and claiming that the FDA overstated the public health threat to justify its "massive intrusion onto the nation's produce farms"); Farm & Ranch Freedom Alliance, Analysis of FDA's Proposed Food Safety Regulations, Sep. 12, 2013, http://farmandranchfreedom.org/fda-proposed-food-safety-regulations-2013/#benefits (doubting that contaminated produce could be responsible for the number of unreported illnesses suggested in the FDA's analysis).

[4] Dan Flynn, *Produce Association Joins Call for Makeover of FSMA Rules*, FOOD SAFETY NEWS, Oct. 3, 2013, http://www.foodsafetynews.com/2013/10/produce-association-also-wants-makeover-for-fsma-rules.

[5] Helena Bottemiller, *House Clears Portion of Farm Bill with Provision Aimed at Delaying FSMA*, FOOD SAFETY NEWS, July 12, 2013, http://www.foodsafetynews.com/2013/07/house-clears-portion-of-farm-bill-with-provision-aimed-at-delaying-fsma.

Contrary to these distortions, the rule is an excellent deal for both the public and the industry. Not only will it substantially prevent many of the wide-ranging harms associated with contaminated produce, but it will do so at a reasonable cost, with ample exclusions and extended compliance dates for small and low-risk farms. **In fact, the rule's benefits will be even more significant, and its costs considerably smaller, than the FDA suggests in its analysis.**

The FSMA Calls for "Minimizing the Risk," not a Cost-Benefit Standard

While we support the FDA's conclusion that the rule's benefits justify its costs, the Food Safety Modernization Act (FSMA) does not call for the use of a cost-benefit standard.

The FSMA requires that the rule set forth procedures, processes, and practices that "*minimize the risk* of serious adverse health consequences or death, *including* [those] that the Secretary determines to be *reasonably necessary* to prevent the introduction of known or reasonably foreseeable biological, chemical, and physical hazards."[6] The FSMA balances this requirement by requiring the FDA to "provide *sufficient flexibility* to be *practicable* for all sizes and types of businesses."[7]

Given this statutory mandate ("minimize the risk"), the FDA should base the rule's standards on the best available methods for preventing contamination of produce. This is the primary test under the statute, and while the FDA is additionally instructed to "includ[e]" those procedures, processes, and practices that are "reasonably necessary"—implying the need to take cost into consideration—the agency is not limited to those that are reasonably necessary if other methods are available and necessary to minimize the risk.

And even the "reasonably necessary" language requires only that the overall cost of such measures remains reasonable—in other words, that the rule as a whole remains "practicable." This language does not require the FDA to adopt a cost-benefit standard, involving an intricate balancing of costs and benefits in which the agency seeks to maximize "net benefits" (benefits minus costs).[8] While we recognize that the FDA is required by Executive Orders 12866 and 13563 to prepare a cost-benefit analysis for informational purposes, ultimately the agency must

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[6] Food Safety Modernization Act, Pub. L. No. 111-353, sec. 105(a), § 419(c)(1)(A), 124 Stat. 3885, 3901 (2010) (codified as amended at 21 U.S.C. § 350h (2010)), *available at* http://www.gpo.gov/fdsys/pkg/PLAW-111publ353/pdf/PLAW-111publ353.pdf (emphases added).

[7] Food Safety Modernization Act, sec. 105(a), § 419(c)(1)(B), 124 Stat. at 3901 (emphasis added).

[8] In *Amer. Textile Mfrs. Inst. v. Donovan* [*Cotton Dust*], the U.S. Supreme Court upheld the Occupational Safety and Health Administration's (OSHA) rule on cotton dust, holding that the "reasonably necessary and appropriate" language in the agency's authorizing statute did not require OSHA to conduct a cost-benefit analysis when setting standards on toxic substances. The Court concluded that Congress defined the basic relationship between costs and benefits by including a "feasibility" standard, which required OSHA to issue a standard that protected worker health to the maximum extent unless it was not capable of being done. The Court also found it significant that the statute placed worker health above all other considerations except feasibility. 452 U.S. 490, 508-13 (1981).

The FSMA strikes a similar balance between costs and benefits by requiring the FDA to set standards for produce safety that "minimize the risk" of serious illness or death as long as they "provide sufficient flexibility to be practicable for all sizes and types of businesses." Indeed, "practicable" is essentially a synonym of "feasible," meaning "able to be done." Moreover, the statute places the benefit to public health above general cost considerations (which are not mentioned at all), tempering it only by the need for overall practicability. Thus, the *Cotton Dust* decision lends support to the view that the FSMA does not call for the use of a cost-benefit standard.

promulgate standards that satisfy its statutory mandate, not an artificial cost-benefit test superimposed on top of it.

We believe cost-benefit analysis is a deeply flawed tool for evaluating and crafting regulatory policies. Among other things, it systematically overestimates the costs of regulation while leaving out benefits that are not easily monetized, it obscures the value choices and assumptions that lie behind the numbers, and it imparts a misleading sense of precision to estimates that are speculative at best.[9] In many cases, a cost-benefit standard interferes with the agency's discretion to adopt the level of protection intended by Congress.

Nevertheless, to the extent the FDA continues to use the cost-benefit analysis presented in the rule's PRIA, either as a decisionmaking tool or as a way of expressing the rule's likely impacts, the analysis should at least be made as comprehensive and accurate as possible. Currently, the PRIA includes a number of errors, omissions, and false assumptions that have kept the expected benefits artificially low and inflated the expected costs.

Flaws in the PRIA Underestimate the Rule's Benefits and Overstate Its Costs

In general, the PRIA (like many cost-benefit analyses before it) counts every nickel and dime that might conceivably be construed as a cost of the rule—literally, down to the 47 cents in "lost productivity" every time a farm worker washes her hands, even after going to the bathroom—but takes an exceedingly narrow view of the rule's benefits. Of the many benefits that would result from food safety improvements on produce farms, the PRIA considers only the cost of illnesses that would be avoided—and even that estimation minimizes the scope and impact of produce-related illnesses.

Some of the problems in the PRIA were introduced or exacerbated during review by the White House Office of Information and Regulatory Affairs (OIRA).[10] In several cases, OIRA changed the agency's estimations without explaining why it was necessary to do so. Other problems were apparent in the FDA's original submission, although the fact that they remained in the PRIA even after OIRA's rigorous extended review—which held up the proposed rule for more than a year beyond its statutory deadline—speaks poorly of the quality of OIRA's review process.[11]

Flaws in the Benefits Estimation

The following are several of the most noteworthy flaws (explained in greater detail in the body of this comment) that contribute to undervaluing the rule's benefits.

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[9] *See, e.g.,* FRANK ACKERMAN & LISA HEINZERLING, PRICELESS: ON KNOWING THE PRICE OF EVERYTHING AND THE VALUE OF NOTHING (2004).

[10] OMB Review of Preliminary Regulatory Impact Analysis for Proposed Rule on Standards for the Growing, Harvesting, Packing and Holding of Produce for Human Consumption (Apr. 12, 2013), *available at* http://www.regulations.gov/#!documentDetail;D=FDA-2011-N-0921-0072 (click on "Tab B Preliminary Regulatory Impact Analysis") [hereinafter OMB Redlined PRIA].

[11] The FSMA required the FDA to propose the produce rule by January 4, 2012. The agency finally released the proposal on January 16, 2013, after almost 13 months at OIRA.

- ***Errors and Omissions***: In one case, the agency failed to correct numbers that were vestiges of an earlier, rejected approach. In another, the FDA neglected to consider deaths resulting from illnesses due to unidentified pathogens, even though the agency's data source clearly suggested a death rate. After correcting these mistakes, the benefits of the rule rise to $1.66 billion—a 60-percent increase over the PRIA's estimate.

- ***Underestimated Cost of a Foodborne Illness***: The reductions in quality of life associated with various foodborne illnesses are based on subjective judgments about how the average person would feel, which are in many ways unrealistic and minimize the impact of illness. For example, a non-hospitalized gastrointestinal illness is assumed to cause fever, cramps, and diarrhea that is "often bloody," but the PRIA assumes that the victim "would not be anxious or depressed."[12]

  The PRIA determines the magnitude of an illness' impact with reference to a "health baseline" that is supposed to represent the average, already-imperfect state of health of the U.S. population. But this baseline value reflects only the health of the *adult* population, so the PRIA fails to account for the much more dramatic loss faced by child victims of food poisoning. In fact, foodborne illness disproportionately affects children, who made up 36 percent of all confirmed cases in 2012.[13]

  The PRIA attempts to incorporate the long-term complications of foodborne illness, which are often much more devastating than the acute infection itself. But it neglects to include some of the most serious and well-documented complications—like fetal complications due to *Listeria* in pregnant women (which can cause miscarriages, premature labor, and lifetime neurological problems) or post-infectious irritable bowel syndrome (which can impair a person's productivity and quality of life indefinitely).

  The FDA's analysis ignores other significant costs of illness, from the days that an ill individual's parent or loved one has to take off work in order to care for the person, to the costs of laboratory analysis and pharmaceuticals. A recent study provides pathogen-specific estimates that account for some of the missing costs.[14] Using these more comprehensive figures, the benefits of the proposed rule would be $2.90 billion—a 180-percent increase over the FDA's original estimate.

- ***Underestimated Incidence of Produce-Related Illnesses***: Based on its own outbreak database, the FDA estimates that 7.4 percent of all foodborne illnesses are attributable to produce. But the FDA's database is far from complete, including only those outbreaks in which the FDA became involved in the investigation and was able to trace the source to contamination during food production. As a result, the database is skewed toward the largest outbreaks at the expense of the more frequent, smaller outbreaks investigated by state and local health departments.

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[12] *See* Final Draft PRIA, *supra* note 2, at 379-80.

[13] *See* CDC, Tables and Figures – 2012 Preliminary Data, http://www.cdc.gov/foodnet/data/trends/tables-2012.html.

[14] Robert L. Scharff, *Economic Burden from Health Losses Due to Foodborne Illness in the United States*, 75 J. FOOD PROTECTION 123 (2012), *available at* http://www.marlerblog.com/uploads/image/s18.pdf.

The Centers for Disease Control and Prevention (CDC), on the other hand, provide a much more complete database of foodborne illnesses, although it would overestimate the number of illnesses due to on-farm contamination to some extent because it includes illnesses linked to retail or consumer mishandling. (The FDA acknowledges, however, that some of these cases may have a root cause at the farm level). According to this database, produce is responsible for somewhere around 24 percent of all illnesses. A recent study offers a particularly useful perspective on CDC data, augmenting it with attribution estimates from experts.[15] Using this study in combination with the more comprehensive cost estimates described above, we estimated potential benefits of $6.68 billion.

Because the true number of illnesses caused by on-farm contamination probably lies somewhere between both databases, we propose that the FDA use the figures derived from its own database as a lower bound and the figures derived from the CDC database as an upper bound. **Thus, we suggest the rule would have an approximate range of avoided-illness benefits from $2.90 billion to $6.68 billion, instead of the $1.04 billion estimated in the PRIA.**

- *Omission of Other Kinds of Benefits from the Discussion*: Food safety improvements on produce farms would bring a number of additional benefits, both to the industry and to the public, completely apart from the cost of avoided illnesses. In fact, the FDA originally included well-reasoned, qualitative discussions of some of these benefits in the draft PRIA that it sent to the White House for review, but OIRA deleted them entirely.[16]

  Reductions in contamination would reduce the number of recalls over time and thus prevent some of the far-reaching costs associated with a recall. Raw produce and fresh-cut produce were the most frequently recalled commodities from fall 2011 to fall 2012.[17] These frequent recalls are incredibly damaging to a farm's bottom line and its long-term reputation. In fact, their negative impacts often spread to other, innocent farms that grow the same commodity, or even to farms that grow a different commodity that is mistakenly implicated in an outbreak. When tomatoes were thought to be linked to the *Salmonella* Saintpaul outbreak of 2008 (later determined to be caused by raw peppers), it cost the U.S. tomato industry up to $200 million.[18]

  Other benefits completely missing from the analysis include: (1) avoided costs of

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[15] Michael Batz et al., *Ranking the Disease Burden of 14 Pathogens in Food Sources in the United States Using Attribution Data from Outbreak Investigations and Expert Elicitation*, 75 J. FOOD PROT. 1278, 1279-83 (2012), *available at* http://www.marlerblog.com/uploads/image/Michael%20Batz%20article.pdf [hereinafter Batz Journal Study].

[16] *See* OMB Redlined PRIA, *supra* note 10, at 33-37.

[17] FDA, THE REPORTABLE FOOD REGISTRY: TARGETING INSPECTION RESOURCES AND IDENTIFYING PATTERNS OF ADULTERATION THIRD ANNUAL REPORT: SEPTEMBER 8, 2011 – SEPTEMBER 7, 2012, at 5, 12-13 (2013), http://www.fda.gov/downloads/Food/ComplianceEnforcement/RFR/UCM349856.pdf [hereinafter 2011-2012 Reportable Food Registry].

[18] THE PEW CHARITABLE TRUSTS & SAFE TABLES OUR PRIORITY, STATE SURVEILLANCE OF FOODBORNE ILLNESS 2 (2009), *available at* http://www.pewhealth.org/uploadedFiles/PHG/Content_Level_Pages/Reports/PSP-RPT_Surveillance_STOP_Survey.pdf [hereinafter STATE SURVEILLANCE OF FOODBORNE ILLNESS].

investigating and responding to produce-related outbreaks, which are mostly borne by severely underfunded state and local health departments; (2) avoided panic felt by people who have eaten produce later recalled for contamination, even if they do not ultimately get sick; (3) avoided costs of lawsuits that inevitably follow major produce-related outbreaks; (4) the protection and promotion of U.S. export sales, which may be disrupted by contamination events—or alternately, encouraged by safer practices; and (5) the psychological benefits to consumers of having a safer supply of fresh produce.

Flaws in the Cost Estimation

The PRIA also significantly overstates the rule's cost in a number of ways:

- ***One Quarter of the Rule's Total Cost is Attributed to a Hand Washing Requirement***: The PRIA estimates that worker hand washing required under the rule—before work, after a break, and after using the bathroom—would cost farms a total of *$113.5 million* in "lost productivity" (the single largest cost of any standard in the rule). In other words, the workers could be handling raw produce instead of washing their hands, and this represents a financial loss to the farm.

  The FDA originally estimated it would take workers an average of one minute each time to walk to the hand-washing facility and wash their hands, worth 23 cents in lost productivity and totaling $56.8 million when multiplied against all the workers at roughly 40,000 covered farms every day. But OIRA inexplicably increased it to two minutes (47 cents) per hand-wash, *doubling* the total cost to the current estimate of $113.5 million.[19]

  The estimation is at odds with common sense: hand washing, a universally recognized safety measure, has such obvious and compelling benefits that its advantages need not be weighed against its opportunity costs—and few consumers would agree that the labor of workers with unwashed hands represents any kind of "productivity" to be lost.

  Just as important, most farms are already required under an Occupational Safety and Health Administration (OSHA) rule to allow their workers "reasonable use" of hand-washing facilities throughout the work day, and even to encourage them to wash their hands at some of these same points.[20] It is incongruent for the FDA to then assume that every minute a worker spends away from the work station practicing good hygiene is time that the employer was entitled to. Indeed, worker hand washing will likely be folded into the regular course of everyday activities on produce farms, at minimal extra cost.

- ***OIRA Exaggerated the Cost to Exempt Farms***: Originally, the FDA estimated that farms exempt from the rule would spend five minutes every two weeks preparing a piece of poster board with the farm's name and address, to comply with the rule's minimal disclosure requirement, at a total cost of $341,000 ($101 per farm). After OIRA was through with the PRIA, it assumed inexplicably that farmers would spend an *hour* every

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[19] *See* OMB Redlined PRIA, *supra* note 10, at 162-64.
[20] 29 C.F.R. § 1928.110(c)(4).

two weeks preparing that sign, bringing the cost up to $3.82 million ($1,134 per farm).[21]

- ***The Cost of Testing Agricultural Water***: The PRIA assumes that laboratory analysis of water samples would cost $87.30, adding up to thousands of dollars per farm every year. But given the extended compliance dates for the rule's water requirements (up to six years beyond the rule's effective date for very small farms), it is almost inevitable that the requirement will drive technological innovations, spurring the development of low-cost testing kits that can be used with little training "on farm," and increasing competitiveness among suppliers of testing products and services. These developments, already in the making in some ways, will make testing more affordable for small farms.

- ***Double Counting in the Estimation of Worker-Monitoring Costs***: The second-largest cost in the rule is attributed to monitoring farm workers' compliance with food safety training ($79 million). But the FDA mistakenly relied on cost data that instead represents the monitoring of fields for animal intrusions—which the agency already included in its estimation of the rule's animal requirements.

Regulatory Options

The FDA has proposed that farms with less than $25,000 in annual sales be exempt from the rule, but it is also requesting comment on other potential cutoffs, from $50,000 to $500,000. The agency should keep the small-farm cutoff at $25,000 because the FDA estimates that tens of thousands of additional illnesses would occur with any of the higher thresholds. The FSMA requires the agency to set standards that minimize the risk of illness or death, and this cutoff is most consistent with that statutory objective.

Furthermore, the proposed rule already provides sufficient flexibility for small and low-risk farms. Even without raising the threshold, the rule would exempt 79 percent of all U.S. farms and significantly extend compliance dates for those small farms that are still covered by the rule. Vigorous opposition from small farms gives the impression that they would be financially overwhelmed by the rule, but there is evidence that some may be overreacting out of mistrust and uncertainty, misjudging just how broad these exemptions really are. In a survey of farmers from this past fall, some of the respondents who made the most negative comments about the rule and suggested it would put them out of business actually turned out to be exempt.[22] Increasing the FDA's outreach efforts and clarifying points of confusion would be more effective (and protective of public health) than further expanding the exemptions.

Finally, the FDA should include in the final rule all the standards presented in the proposed rule. One group has suggested that the standards for equipment, tools, buildings, and sanitation (ETBS) be eliminated because they are supposedly the least cost-effective standards in the rule. But the FDA's figures on the standards' effectiveness were skewed due to data limitations, as the agency admitted. In fact, the ETBS standards are absolutely essential: improperly designed, un-

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[21] *See* OMB Redlined PRIA, *supra* note 10, at 60-61.
[22] Michael Bulger, Produce Safety: Regulations, Local Food Systems, and the Tester Amendment, Appendix B (May 14, 2013) (unpublished M.A. thesis, New York University) (included as Appendix B of this comment).

cleanable facilities and equipment were likely responsible for *Listeria* contamination of cantaloupes in 2011, the deadliest food outbreak in almost a century.[23]

Recommendations

Because it is hard to predict how effective the rule will be in reducing illnesses, recalls, and other negative impacts of contamination, the FDA should consider using "breakeven analysis" to justify the rule. The agency could estimate how large the rule's benefits would have to be before they would plausibly justify its costs, instead of trying to quantify all the rule's benefits.[24] The FDA originally relied on a breakeven analysis in the draft that it submitted to OIRA.[25]

In addition, the FDA should take into account that by preventing foodborne illnesses, the produce rule would also protect values that are inherently "non-quantifiable," like dignity, liberty, and fairness. It is damaging to a person's dignity and liberty to be unwittingly "poisoned" from eating contaminated produce, to have to undergo invasive medical tests and procedures, and to suffer long-term complications that impair one's quality of life. And the impacts of foodborne illness are not evenly distributed, but disproportionately strike the weak and the vulnerable: they are most serious for very young and very old individuals, those who have compromised immune systems, and pregnant women and fetuses.[26] Executive Order 13563 instructs agencies to consider such values and distributive concerns qualitatively, since these kinds of benefits cannot be adequately expressed in a cost-benefit analysis.[27]

We respectfully urge the FDA to:

1. **Finalize the proposed rule as quickly as possible in its strongest, most protective form**, keeping the cutoff for the small-farm exemption at $25,000 and retaining all the proposed standards in the final rule;

2. **Correct errors and assumptions** in the PRIA that understate the rule's benefits and exaggerate its costs, and reverse any changes made by the OIRA that have compounded these flaws;

3. **Use more comprehensive estimates** for the cost of illnesses attributable to produce;

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[23] FDA, Environmental Assessment: Factors Potentially Contributing to the Contamination of Fresh Whole Cantaloupe Implicated in a Multi-State Outbreak of Listeriosis, Oct. 19, 2011, *available at* http://www.fda.gov/Food/RecallsOutbreaksEmergencies/Outbreaks/ucm276247.htm [hereinafter FDA Cantaloupe Outbreak Assessment].

[24] *See* OMB, Circular A-4: Regulatory Analysis 2 (2003), *available at* http://www.whitehouse.gov/sites/default/files/omb/assets/omb/circulars/a004/a-4.pdf (encouraging breakeven analysis when it is difficult to monetize all the rule's important benefits and costs).

[25] OMB Redlined PRIA, *supra* note 10, at 38-40.

[26] FDA, Foodborne Illness: Especially Dangerous for the Vulnerable, June 4, 2013, http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm354783.htm.

[27] Exec. Order No. 13,563 § 1(c), 76 Fed. Reg. 3821, 3821 (Jan. 18, 2011), *available at* http://www.gpo.gov/fdsys/pkg/FR-2011-01-21/pdf/2011-1385.pdf.

4. **Include in the PRIA a qualitative discussion of the rule's benefits** that could not be quantified or monetized, and restore the sections on avoided recalls and consumer peace of mind that were deleted by OIRA.

BENEFITS OF THE PRODUCE RULE

The FDA estimates that the rule will reduce the amount of produce contamination that occurs on covered farms by about 65 percent, based on interviews with experts from the agricultural industry and academia about the effectiveness of the various preventive measures included in the proposed rule.[28] As a result, the rule is estimated to prevent 1.75 million illnesses every year. According to the FDA, these avoided illnesses would have cost society $1.04 billion.[29]

Errors and Omissions

The PRIA's calculations suffer from a number of errors and omissions that underestimate the severity of the public health risks addressed by the rule and thus make the benefits of the rule appear much smaller than they are.

The number of illnesses estimated to be caused by "fresh-cut produce" (753,958) is artificially low because it relies on erroneous values for CDC-reported illnesses. These numbers are vestiges of an earlier draft, and the FDA ultimately rejected them because they reflected false assumptions and underestimated the proportion of illnesses caused by produce.[30] Both the FDA and OIRA failed to notice that these rejected values were still being used in the fresh-cut analysis.[31] When the correct values are used, this calculation shows that fresh-cut produce is responsible for an additional 37,000 illnesses per year.[32]

Even more significantly, the PRIA estimates that nearly 3 million produce-related illnesses are caused annually by "unidentified" foodborne pathogens (those that are just emerging or are not

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[28] Final Draft PRIA, *supra* note 2, at 75-78.

[29] *Id.* at 52 tbl.11. Included in this estimate are the benefits of avoided illnesses due to "fresh-cut produce." These illnesses may have been caused by contamination either on the farm or at the processing facility. The produce rule applies only to the activities that occur on the farm, while the processing facility may be subject to the FDA's rule on preventive controls for human food. But because the FDA cannot determine which outbreaks could be linked to farm-level contamination and which could be linked to problems at the processing facility, it includes all illnesses related to fresh-cut produce in the estimated benefits for the produce rule. To avoid double counting, the FDA excludes these illnesses from its benefits estimation in the preventive-controls rule. *Id.* at 64.

[30] The old values failed to account for the possibility that illnesses not associated with a food vehicle in the CDC database may nevertheless have been caused by FDA-regulated foods. *See* OMB Redlined PRIA, *supra* note 10, at 10-12 (calling the numbers in Table 3 "much more plausible" than the numbers in Table 2, which are the ones mistakenly reproduced in the fresh-cut analysis).

[31] There is another mathematical flaw in Table 18 of the PRIA (page 64) that contributes to the underestimation of illnesses due to fresh-cut produce: for "unidentified" agents, the value in the sixth column is supposed to be the product of the entries in the fourth and fifth columns (1.82% * 39,099,360 = 711,608), but instead it is 693,812, which underestimates the number of illnesses by about 18,000. Apparently, this flaw is another leftover from the FDA's earlier draft (when 1.77% was used instead of 1.82%) that was never corrected. *See* OMB Redlined PRIA, *supra* note 10, at 27 tbl.14. We incorporated this correction in the revised estimate given above.

[32] *See* Appendix A *infra* (section on "Fixing the Estimated Number of Illnesses Due to Fresh-Cut Produce").

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easily identified through tests),[33] but it fails to account for any deaths resulting from these illnesses, as it does for most of the other pathogens. The leading study on unidentified foodborne pathogens reports that 1 out of every 22,771 cases leads to death.[34] The FDA incorporated other data from this study into its analysis (*e.g.*, the number of illnesses caused by unidentified pathogens, the rate of hospitalization), but in what appears to have been an enormous oversight, neglected to include the death rate.[35] Fixing this oversight accounts for an additional 127 deaths caused by contaminated produce every year.[36]

With both corrections combined, the benefits of the rule rise to $1.66 billion—a 60-percent increase over the PRIA's estimate.[37]

The PRIA Underestimates the Loss in Quality of Life due to Foodborne Illness

For each pathogen, the FDA estimates an average cost per illness based on an individual's lost quality of life for the average duration of the illness, combined with the average medical costs of treating the illness. But the methodology used to translate illnesses into dollar values does not represent the true cost of an illness. Briefly:

- The estimated losses in quality of life are subjective and in many cases unrealistic;
- The misleading use of a "baseline health index" undervalues the impact of illness;
- The monetary equivalents are based on abstract survey responses that have little bearing on the experience of being ill;
- And the methodology fails to account for serious complications of foodborne illness.

Flawed Judgments about the Impact of Illness

The FDA assigns to each type of illness a "health index" that is supposed to numerically reflect the individual's quality of life during the illness. The index values are designed to incorporate an individual's (1) mobility, (2) ability to perform self-care activities, (3) ability to perform usual activities (such as going to work or school), (4) level of pain and discomfort, and (5) level of anxiety and depression.

After reviewing the medical literature for each pathogen, agency analysts (with the help of a medical professional) tried to determine how the typical symptoms would affect the average person and scored each of those five dimensions along a 3-point scale. For each dimension, a

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[33] The numbers of unidentified-pathogen illnesses given in Tables 17-19 add up to about 2.9 million. *See* Final Draft PRIA, *supra* note 2, at 63-65.
[34] *See* Elaine Scallan et al., *Foodborne Illness Acquired in the United States—Unspecified Agents*, 17 EMERGING INFECTIOUS DISEASES 16, 20 tbl. (2011), *available at* http://wwwnc.cdc.gov/eid/article/17/1/pdfs/p2-1101.pdf (estimating 1,686 deaths out of 38,392,704 illnesses due to unidentified pathogens).
[35] *See, e.g.,* Final Draft PRIA, *supra* note 2, at 387 tbl. (under "Foodborne illness, Unknown Agent," only "nonhospitalized" and "hospitalized" cases are listed, without reference to deaths).
[36] After fixing the figures for fresh-cut produce, an estimated 2.9 million illnesses are caused by unidentified pathogens in produce. If 1 out of 22,771 cases (0.00439%) result in death, then an estimated 127 deaths result from these unidentified pathogens every year.
[37] *See* Appendix A *infra* (section on "Calculating the Benefits after Correcting (1) Fresh-Cut Figures and (2) Deaths due to Unidentified Pathogens").

score of 1 indicates no problems, a score of 2 indicates moderate problems, and a score of 3 indicates extreme problems. So, for instance, a health index of "22221" means that the ill individual would have moderate problems with mobility, self-care, and performing usual activities, and moderate pain and discomfort, but no anxiety or depression. Each index is associated, in a lookup table, with a number between 0 and 1.00 that represents the "quality of life" corresponding to that set of disabilities and discomforts.[38]

Ultimately, however, the agency's judgments are little more than subjective, hypothetical guesses that in many ways minimize the impact of illness. Someone actually suffering from one of these illnesses would likely come to very different conclusions and feel that the agency's analysis is out of touch with the reality of illness.

For example, the PRIA explains that a case of non-hospitalized shigellosis causes fever, stomach cramps, and diarrhea that is "often bloody" but then inexplicably concludes that a person with this illness "would not be anxious or depressed." The agency draws the same conclusion about listeriosis and salmonellosis, both of which present similar anxiety-provoking symptoms.[39] Even more disturbing, *none* of the illnesses or complications is considered to cause "extreme anxiety or depression"—not hospitalized gastrointestinal illness, not long-term disability due to Guillain-Barre Syndrome (an autoimmune disease that causes pain, paralysis, and respiratory failure), and not even end stage renal disease (ESRD).[40]

The analysis also leads to some irrational equivalencies and comparisons between illnesses. The PRIA assumes that ESRD, a complication caused by particularly virulent strains of *E. coli*, reduces one's quality of life to a lesser extent per day than a non-hospitalized gastrointestinal illness.[41] But as those living with ESRD can attest, it is physically and mentally devastating, requiring either a kidney transplant or long-term dialysis. Waiting for a donor kidney can take years, and even after a successful transplant—which lasts only about 10 to 15 years before another one is needed—patients must take immunosuppressive medications for the rest of their lives that cause serious side effects and make them susceptible to infections. Dialysis involves either flushing a chemical bath through an abdominal catheter four to six times a day, or more commonly, going to a facility several times a week for a blood-filtering process that takes three to four hours and causes nausea and cramps. ESRD almost always leads to further complications like bone disease and anemia.[42] It strains credulity to think these highly intrusive, permanent consequences would interfere less with one's daily quality of life than a bout of gastrointestinal illness not requiring hospitalization.

As these flawed judgments illustrate, this over-simplistic scoring system is inadequate to convey the impacts of foodborne illness in a meaningful, informative way. The FDA should devote more of its analysis to a qualitative discussion of produce-related illnesses, rather than burying their

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[38] *See* Final Draft PRIA, *supra* note 2, at 377-80.

[39] *See id.* at 379-80 (the EQ-5D scores for each of these illnesses have a "1" in the final position).

[40] *See id.* at 380-82 tbl.142 (none of the EQ-5D scores for illnesses or complications have a "3" in the final position).

[41] *See id.* (assuming that most non-hospitalized gastrointestinal illnesses cause a loss of 0.181 quality adjusted life days (QALDs) per day, whereas ESRD causes a loss of only 0.162 QALDs per day).

[42] Colin Caywood, *Living with ESRD*, FOOD SAFETY NEWS, Mar. 5, 2010, http://www.foodsafetynews.com/2010/03/living-with-esrd.

true impacts behind misleading numbers.

<u>Misleading Use of a Baseline Health Index</u>

The PRIA states that the average health index of the U.S. population is 0.87 (on a scale from 0 to 1.00), so it determines the loss due to illness only from this baseline, rather than from a state of full health. So, if someone with non-hospitalized gastrointestinal illness has a "quality of life value" of 0.689, the PRIA subtracts that value from the 0.87 baseline, and concludes that the illness would reduce the average individual's quality of life by just 0.181 each day.[43]

But the baseline value used in the PRIA is the average health index of the U.S. *adult* population, reflecting the lost quality of life due to chronic conditions that come with age.[44] The FDA does not disclose this limitation, presenting the baseline as "the average health score based on the U.S. population" and applying it across the board to all estimated foodborne illnesses, not just those affecting adults.[45] The health baseline for children would logically be higher than 0.87, which means that children would suffer a greater loss due to foodborne illness than the FDA estimated.

Foodborne illnesses disproportionately affect children. In 2012, children made up 36 percent of all laboratory-confirmed foodborne illnesses, along with 28 percent of all hospitalizations and 6 percent of deaths.[46] The incidence of *Salmonella* in very young children was significantly greater—affecting 63 out of 100,000 individuals under five years old—than in any other age group (incidences ranging between 11 and 19 out of 100,000). The same is true for infections caused by *Shigella* and Shiga toxin-producing *E. coli* (STEC), among other pathogens.[47] Infections are often more serious in children as well; for example, hemolytic uremic syndrome (HUS) is a relatively rare complication in adults infected with *E. coli* O157:H7, but it occurs in 15 percent of infected children, often leading to kidney failure.[48]

Executive Order 13045 directs each agency to "ensure that its policies, programs, activities, and standards address disproportionate risks to children that result from environmental health risks or safety risks."[49] More specifically, each agency shall provide "an evaluation of the environmental

[43] Final Draft PRIA, *supra* note 2, at 377-79.

[44] *See* Nan Luo et al., *Self-reported Health Status of the General Adult U.S. Population as Assessed by the EQ-5D and Health Utilities Index*, 43 MED. CARE 1078, 1078 (2005) (finding an index score of 0.87 for the "general adult U.S. population" as assessed by the EQ-5D instrument).

[45] Final Draft PRIA, *supra* note 2, at 377.

[46] *See* CDC, Tables and Figures – 2012 Preliminary Data, http://www.cdc.gov/foodnet/data/trends/tables-2012.html. The figures used above are obtained by combining the number of illnesses, hospitalizations, or deaths in children less than five years old, children between five and nine, and children between 10 and 19.

[47] *Shigella* affected 17 out of 100,000 children under five, and 15 out of 100,000 children between five and nine, compared with incidences of 1 to 3 for older age groups. STEC O157 affected 5 out of 100,000 children under five, and non-O157 STECs affected another 5, compared to an incidence of 1 to 2 among older age groups for each pathogen. *See id.*

[48] THE PEW HEALTH GROUP & THE CTR. FOR FOODBORNE ILLNESS RESEARCH & PREVENTION, CHILDREN AND FOODBORNE ILLNESS 2 (2009), http://www.pewtrusts.org/uploadedFiles/wwwpewtrustsorg/Fact_Sheets/Health_and_Human_Services/Children-and-FBI-Factsheet-11-09.pdf?n=8034.

[49] Exec. Order No. 13,045 § 1-101(b), 3 C.F.R. 198, 198 (1997), *reprinted in* 42 U.S.C. § 4321 note (West 2010), *available at* http://www.gpo.gov/fdsys/pkg/FR-1997-04-23/pdf/97-10695.pdf.

health or safety effects of the planned regulation on children."[50] **By using a health baseline that reflects only adults, the FDA neglects to consider the full impact of foodborne illness on children and thus ignores its obligations under the Executive Order.**

Even for adults, the use of this baseline has disturbing implications. Health states cannot be simply added and subtracted from each other, as if they were measured in the same units, representing the same kinds of disability and discomfort. People are concerned not only with their ability to perform certain functions or their general level of "discomfort," but also with the unique set of symptoms they experience. Surely the onset of vomiting and diarrhea would be at least as troubling to someone already suffering from limited mobility and chronic pain, as it would for a person in full health. If anything, preexisting health problems would make it more difficult to cope with the added strain of a foodborne illness, and vice versa, perhaps resulting in an even greater loss in quality of life than a healthy person might suffer.

Some individuals may already have a quality of life lower than the health state associated with a foodborne illness. The FDA's methodology of subtracting the latter from the former would suggest—illogically—that such individuals experience a negative reduction (in other words, an increase) in their quality of life after the illness.

To avoid these problematic implications, and to properly account for children, the FDA should use a baseline of 1.00 in its calculations, representing not necessarily a state of perfect health, but at least a state that is free of the specific, debilitating effects of foodborne illness. This is the only assumption that accounts for the serious impact that foodborne illness has on everyone's quality of life, regardless of age or other health conditions.

<u>Quality-of-life Values Reflect Abstract Surveys, not Experience of Illness</u>

A casual reader of the PRIA might assume that the quality-of-life values associated with various health states—ranging from 0 to 1.00—were given by individuals suffering from foodborne illness, reflecting their actual experiences. To the contrary, researchers surveyed about 7,500 random individuals, asked them abstract questions about a small sample of health states, and then filled in the values for the rest through statistical modeling and extrapolation.[51]

Primarily, the researchers conducted "time trade-off" (TTO) exercises, in which they asked respondents to imagine living for 10 more years with vague levels of disability and discomfort— "no problems," "some problems," or "extreme problems" in each of five general domains. They then asked respondents to decide how many of those years they would sacrifice (dying earlier) in order to live in full health instead. The answers formed the basis for estimating the quality-of-life values associated with each health state.[52]

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[50] *Id.* § 5-501(a).

[51] *See* James W. Shaw et al., *US Valuation of the EQ-5D Health States Development and Testing of the D1 Valuation Model*, 43 MED. CARE 203, 206 (2005), *available at* http://www.tree4health.org/distancelearning/sites/www.tree4health.org.distancelearning/files/readings/US%20Valuation%20of%20EQ5D%20Health%20States.pdf, *cited in* Final Draft PRIA, *supra* note 2, at 378 n.55.

[52] *See id.* at 204-05. *See also* EUROQOL GROUP, EQ-5D-5L USER GUIDE: BASIC INFORMATION ON HOW TO USE THE EQ-5D-5L INSTRUMENT 22 (2011), *available at*

Such hypothetical exercises push against the limits of human cognition. To the extent the questions are even answerable, it is doubtful that people can conceptualize these time preferences with any level of precision.[53] Moreover, their responses are far removed from the lived-in experience of someone actually suffering from days, months, or years of pain and disability, and even more so from the specific symptoms and complications of foodborne illness.

While this tool has become common practice in economic analysis of health interventions, the FDA should at least describe how these values were obtained and acknowledge the uncertainty inherent in such estimations.

<u>Serious, Well-Documented Complications Missing from FDA's Analysis</u>

The PRIA claims to incorporate the costs of secondary complications of foodborne illness, which tend to be much more severe and long-lasting than the acute infection. The FDA compiled a list of 11 complications associated with various pathogens, including Guillain-Barre Syndrome, reactive arthritis, and end stage renal disease. The agency then estimated the reduction in quality of life that each would cause (depending on its symptoms and duration), and incorporated it into the overall cost for the pathogen, based on the likelihood that the complication would arise.[54]

But the FDA's list of complications only scratches the surface. Some of the most serious and well-documented complications remain unaccounted for in the analysis, resulting in costs-per-pathogen that underestimate their true impacts.

Fetal complications due to Listeria

The incidence of listeriosis in pregnant women is about 20 times greater than in the general population. *Listeria* is particularly dangerous for pregnant women because its unique intracellular life cycle allows it to cross the placental barrier and infect the fetus, even if the mother shows only mild signs of illness—or none at all. The infection can result in miscarriage, stillbirth, or premature labor; in some cases, babies are born with meningitis and develop lifelong neurological problems. Of 222 maternal infections reported in the literature, 94 infants were also infected; one-quarter of these infants died, and another 13 percent developed long-term complications.[55]

In the 2011 *Listeria* outbreak caused by tainted cantaloupe, one pregnant woman suffered a

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http://www.euroqol.org/fileadmin/user_upload/Documenten/PDF/Folders_Flyers/UserGuide_EQ-5D-5L.pdf (describing the TTO technique).

[53] *Cf.* JOHN ADAMS, THE ROLE OF COST-BENEFIT ANALYSIS IN ENVIRONMENTAL DEBATES 4-6, *available at* http://john-adams.co.uk/wp-content/uploads/2006/The%20role%20of%20cost-benefit%20analysis%20in%20environmental%20debates.pdf (explaining why people cannot provide meaningful answers in contingent-valuation studies, another kind of study that also asks people to assign values to changes in their own welfare and estimate the tradeoffs they would be willing to make to avoid health or environmental risks).

[54] Final Draft PRIA, *supra* note 2, at 376.

[55] Vanitha Janakiraman, *Listeriosis in Pregnancy: Diagnosis, Treatment, and Prevention*, 1 REVIEWS IN OBSTETRICS & GYNECOLOGY 179, 179-81 (2008), *available at* http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2621056/pdf/RIOG001004_0179.pdf.

miscarriage.[56] Another pregnant woman went into labor three months early due to the infection, and her daughter Kendall was hooked up to an incubator for weeks. A year later, Kendall still had to be fed through a stomach tube and may face permanent physical and mental disabilities.[57]

Despite these well-known examples, the FDA makes no mention of fetal complications in the PRIA. Other researchers, however, have incorporated them into their analyses, finding the costs to be very significant. Researchers for the U.S. Department of Agriculture's Economic Research Service estimated the various costs associated with chronic disability from fetal *Listeria*, including lifelong medical care ($43,000 per case), special education ($108,000 per case), continual total care ($506,000 per case), and future lost earnings ($1 million per case).[58]

The impact of medical procedures and their complications

It is not uncommon for victims of foodborne illness to require surgery or other invasive procedures, which bring their own reductions in quality of life and carry additional risks of complications. The FDA included quality-of-life reductions for the duration of "hospitalization" but did not discuss the immediate or long-term consequences of such procedures.

Barb Pruitt ate *Salmonella*-tainted lettuce in 2009. After developing severe incontinence, respiratory complications, and sepsis, doctors determined she had suffered an intestinal perforation and performed two surgeries to remove portions of her small intestine. Once she was home, her large abdominal wound required constant care to avoid infection and rupture:

> Home health came by three times a week. I bawled like a baby every time because I knew they were going to change my dressing. They would turn the machine off and when the suction stopped my incision would throb. You could see all the way down to the muscles. I knew when they would pull the sponge off of the incision it was going to burn and wake up every nerve. I would beg them not to change it. They would give me pain meds and Ativan to calm my nerves but I will guarantee you it did not work. They would peel back the sheet of tape and then start peeling back the sponge out of the deep incision. It was like putting a knife to an open wound and scraping it without numbing medication. I would have to beg them to give me a break because the pain was more than I could take. I endured dressing changes for over two months.

Because she lost part of her small bowel, Barb will need vitamin B12 shots for the rest of her life, and she faces an increased risk of gall stones and bowel obstructions that may require repeat hospitalizations or additional surgeries.[59]

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[56] CDC, Multistate Outbreak of Listeriosis Linked to Whole Cantaloupes from Jensen Farms, Colorado, Aug. 27, 2012, http://www.cdc.gov/listeria/outbreaks/cantaloupes-jensen-farms/index.html.

[57] Scott Bronstein & Drew Griffin, *Third-deadliest U.S. Food Outbreak Was Preventable, Experts Say*, CNN, May 3, 2012, http://www.cnn.com/2012/05/03/health/listeria-outbreak-investigation.

[58] J.C. BUZBY ET AL., USDA ECON. RESEARCH SERV., BACTERIAL FOODBORNE DISEASE: MEDICAL COSTS AND PRODUCTIVITY LOSSES 62-67 (1996), *available at* http://www.ers.usda.gov/ersDownloadHandler.ashx?file=/media/755624/aer741_1_.pdf.

[59] Marler Clark, Real Life Impacts: The Story of Barb Pruitt, http://www.about-salmonella.com/real_life_impacts/salmonella_ibs (last visited Oct. 4, 2013).

In another case, three-year-old Haylee Bernstein was sickened with *E. coli* O157:H7 after eating "triple-washed" mesclun lettuce in 1996. Among many serious complications, including retinal hemorrhages and rectal prolapse, she had to undergo emergency surgery to treat a tennis-ball-sized brain hemorrhage. The surgery left her blind for weeks, and even today at 18 years old, she still has serious vision problems.[60]

Post-infectious irritable bowel syndrome

Irritable bowel syndrome (IBS) is a chronic disorder characterized by abdominal pain and altered bowel habits—diarrhea, constipation, or both. Studies suggest that between 5 and 32 percent of individuals with acute gastroenteritis will develop IBS. A recent review found that the risk of IBS increases six-fold after a gastrointestinal infection and remains high for several years.[61]

The FDA did not include IBS as one of the complications of foodborne illness. However, post-infectious IBS can have devastating effects on one's quality of life. Barb Pruitt, who developed IBS following her *Salmonella* infection, sometimes has to go home from work due to her bowel issues. On a good day, she goes to the bathroom eight times, and on a bad day, up to 20 times:

> Barbara is tearful today. …. She said she feels like she can never quench her thirst, because if she drinks liquids to quench her thirst, it gives her immediate diarrhea. … [S]he is glad to be alive, but on the other hand, sometimes she gets depressed at the thought of having to live the rest of her life like this.[62]

Other complications

The above examples illustrate just a few of the complications that were not considered in the PRIA. For instance, Haylee Bernstein has diabetes and a learning disability as a result of childhood food poisoning.[63] Infections also weaken the immune system, leaving an individual susceptible to other infections; one woman had a recurrence of shingles after contracting *Cyclospora* this summer.[64] Finally, they can cause sepsis, leading to inflammation throughout the body that may cause irreparable damage to all the major organs, from the pancreas and thyroid to the heart and brain—not limited to the kidney failure described in the PRIA.[65]

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[60] Samantha Bernstein, *My Tour with Foodborne Illness Victims Through the Leafy Greens Industry*, FOOD SAFETY NEWS, June 18, 2013, http://www.foodsafetynews.com/2013/06/my-tour-with-foodborne-illness-victims-through-the-leafy-green-industry; Ana Radelat, *Advocates Frustrated with Obama Administration over Food Safety Law*, THE CONNECTICUT MIRROR, Mar. 13, 2012, http://www.ctmirror.org/story/2012/03/09/advocates-frustrated-obama-administration-over-food-safety-law.

[61] Harry HX Xia, *Post-infectious Irritable Bowel Syndrome*, 15 WORLD J. GASTROENTEROL. 3591, 3591-92 (2009), *available at* http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2721231/pdf/WJG-15-3591.pdf.

[62] Marler Clark, *supra* note 59.

[63] Radelat, *supra* note 60.

[64] James Andrews, *Cyclospora Can Cause Weeks of Illness before Being Identified*, FOOD SAFETY NEWS, Aug. 20, 2013, www.foodsafetynews.com/2013/08/cyclospora-can-take-weeks-of-illness-to-identify.

[65] *See* TANYA ROBERTS ET AL., CTR. FOR FOODBORNE ILLNESS RESEARCH & PREVENTION, THE LONG-TERM HEALTH OUTCOMES OF SELECTED FOODBORNE PATHOGENS 4-6 tbl.1 (2009), *available at* http://www.foodborneillness.org/images/stories/cfi_pdfs/CFI_LTHO_PSP_report_Nov2009_FINAL.pdf (displaying a list of health outcomes due to selected foodborne pathogens).

The FDA should provide a more comprehensive list of complications in the PRIA. Where there are reliable statistics on the incidence of a complication, the FDA should try to incorporate them into the cost-of-illness estimations. If reliable data are unavailable, the FDA should discuss the complication and its impacts qualitatively.

Other Significant Costs of Illness Not Captured by FDA's Methodology

Even if the methodology adequately measured what it claims to, there are other major costs of illnesses that would still not be captured at all.

Fear, Stress, and Loss Felt by the Ill Individual's Loved Ones

One of the characteristic flaws of cost-benefit analysis is its exclusive focus on the lost welfare of the person directly affected—in this case, the reduced quality of life of someone suffering from foodborne illness. But foodborne illness can be just as devastating, if not more so, for the family members and friends who have to watch their loved one suffer, have to struggle with agonizing medical decisions, and in the worst cases, lose their loved one to debilitating complications or death.

One mother described the days her five-year-old son spent in the hospital with an *E. coli* O157:H7 infection from lettuce as "the most terrifying experience of my life."[66] In another case caused by the same pathogen in cookie dough, the husband and children of 57-year-old Linda Rivera had to decide whether or not to keep her on life support after she developed severe complications and had to be placed in a medically-induced coma. Though she survived, she was hospitalized almost continuously in subsequent years, and her family was unable to have her around for their school graduations, the birth of her grandchild, or the joys of everyday life.[67]

Family members are often drained from the full-time responsibilities of caring for individuals with long-term complications from foodborne illness. After contracting listeriosis from tainted cantaloupe, a once-independent 86-year-old man became completely dependent on his wife for the remaining two years of his life. As his daughter said, "My mother is totally exhausted from being a caregiver, not a spouse, but a caregiver. She has taken on the responsibility for both of them, the house, the dog, paying the bills, etc. Friends have commented to me on how frail she appears now, and I would concur with them."[68]

The PRIA's narrow cost-benefit analysis fails to account for these kinds of stresses and losses.

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[66] Comment by Charlene Brown, Meeting on the Food Safety Modernization Act (FSMA) in Portland, Oregon, Mar. 27-28, 2013, *available at* http://www.stopfoodborneillness.org/brown-comments.

[67] Eric Burkett, *Linda Rivera: An E. coli Patient's Will to Live* (Parts I and II), FOOD SAFETY NEWS, July 7-8, 2010, *available at* www.foodsafetynews.com/2010/07/linda-rivera-an-e-coli-patients-will-to-live *and* www.foodsafetynews.com/2010/07/an-e-coli-patients-will-to-live-part-ii.

[68] Bill Marler, *Herb Stevens, Yet Another Listeria Cantaloupe Victim, Died Last Night*, Marler Blog (July 24, 2013), www.marlerblog.com/legal-cases/herb-stevens-yet-another-listeria-cantaloupe-victim-died-last-night.

Center for Progressive Reform – Produce Rule Comment
November 15, 2013

Lost Productivity of an Ill Individual's Caregiver

To the extent that the PRIA accounts for the ill person's lost quality of life due to functional disability (*i.e.*, lack of mobility, inability to perform usual activities such as going to work), arguably it also reflects that person's lost productivity (days of missed work and lost income).[69]

However, one or more caregivers may have to take time off work as well (*e.g.*, one or both parents, a spouse, the adult children of an ill parent), and yet the PRIA does not account for this cost of foodborne illness. One researcher concluded that every day a child is sick with food poisoning, there is a 58-percent chance a parent will have to miss work.[70] Considering that 36 percent of all lab-confirmed foodborne illnesses in 2012 were found in children,[71] the number of missed work-days could be very substantial.

A study in Australia offers another illustration: it found that a caregiver had to miss paid work in five percent of all gastroenteritis cases, adding up to 2.7 million days of missed work over a one-year period.[72] The number of illnesses that the FDA estimates would be prevented by the produce rule is roughly 10 percent of the number of gastroenteritis cases in Australia.[73] If U.S. caregivers miss work at a similar rate to Australians, this study suggests that the produce rule could prevent about 270,000 missed days of work per year *by caregivers alone*.

Additional Medical Costs for Laboratory Analysis and Pharmaceuticals

The FDA included the costs of hospital stays, doctor visits, and ER treatment in its estimations of medical costs, but it failed to account for the cost of laboratory analysis of stool samples, or the cost of medication used to treat foodborne illness.[74]

One researcher estimates that about one-third of people who visit a doctor for food poisoning submit a stool sample for analysis, and each test costs $109.[75] Another study reports that 8 percent of individuals with acute diarrhea took antibiotics, and another 34 percent took either prescription or over-the-counter medications.[76] The average cost of the prescription drugs used range from $17 (for doctor visits) to $49 (for hospitalized cases).[77] If the produce rule prevents

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[69] *Accord* Scharff, *supra* note 14, at 125 (2012).

[70] *Id.* Appendix A, at 6, *available at* http://static.ehe.osu.edu/journals/jfp-2011-appendix.pdf [hereinafter Scharff Appendix].

[71] *See* note 46 *supra*.

[72] GILLIAN HALL & THE OZFOODNET WORKING GROUP, AUS. NAT'L UNIV. NAT'L CTR. FOR EPID. & POP. HEALTH, RESULTS FROM THE NATIONAL GASTROENTERITIS SURVEY 2001 – 2002, at 49 (2004), *available at* http://www.ozfoodnet.gov.au/internet/ozfoodnet/publishing.nsf/Content/7BDEF9F8EC3835D9CA257165001AB31 D/$File/WP50.pdf.

[73] The Australian study estimates that there are 17.2 million cases of gastroenteritis every year, and the FDA estimates the produce rule would prevent 1.75 million foodborne illnesses (roughly 10 percent). *Id.* at 31 tbl.7; Final Draft RIA, *supra* note 2, at 52 tbl.11.

[74] *See* Final Draft PRIA, *supra* note 2, at 382-84 (an example of FDA's estimation of medical costs).

[75] Scharff Appendix, *supra* note 70, at 3.

[76] T.F. Jones et al., *A Population-Based Estimate of the Substantial Burden of Diarrhoeal Disease in the United States; FoodNet, 1996–2003*, 135 EPID. INFECT. 293, 296 (2007), *available at* http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2870567/pdf/S0950268806006765a.pdf.

[77] Scharff Appendix, *supra* note 70, at 4.

1.75 million foodborne illnesses, as the FDA predicts, it would represent substantial savings in lab and pharmaceutical costs not acknowledged in the PRIA.

The FDA Should Use More Comprehensive Estimates for the Cost of an Illness

The FDA's analysis would benefit from using more comprehensive estimates for the cost of an illness. For example, a 2012 study by Scharff provides pathogen-specific costs that cure several of the deficiencies of the FDA's analysis.[78]

This study is not mentioned in the PRIA for the produce rule. However, in the PRIA for another proposed rule released the same day (preventive controls for human food), the FDA briefly acknowledged that the study exists and requests comment on its estimates.[79] According to the FDA, it was not able to fully evaluate the study in time for the release of the proposed rule.

The Scharff study improves upon the analysis in the PRIA in several ways. Specifically, the Scharff estimates (1) include the lost productivity costs for parent caregivers of sick children; (2) include the cost of pharmaceuticals;[80] (3) account for newborn complications from *Listeria*;[81] (4) use more comprehensive healthcare costs;[82] (5) and measure illness-related losses against a baseline of 1.00, instead of using the misleading average index for adults.[83]

The Scharff study is still far from a full accounting of the true costs of illness. Indeed, some illnesses are assumed to have a smaller impact on quality of life in the Scharff study than in FDA's analysis.[84] Nevertheless, the study offers a good example of the kinds of additional considerations that are missing from the PRIA.

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[78] Scharff, *supra* note 14, at 126 tbl.2 (listing these cost estimates in the last column, under the heading "Total Cost per Case: QALY").

[79] *See* FDA, Preliminary Regulatory Impact Analysis: FSMA Proposed Rule for Preventive Controls for Human Food 220 (Jan. 16, 2013), *available at* http://www.fda.gov/downloads/Food/GuidanceRegulation/FSMA/UCM334117.pdf [hereinafter Preventive Controls PRIA]. The FDA cautions that the Scharff study does "not measure what we are measuring in this document" because it estimates the economic impact of all foodborne illness associated with all pathogens, while the FDA is only estimating the cost of illnesses due to FDA-regulated foods. It is true that the study's ultimate result is an all-encompassing annual cost of foodborne illness, but in the course of developing that estimate, Scharff assigned to each pathogen a cost-per-illness—exactly like the FDA does in all the FSMA proposed rules—and it is this aspect of his study that is directly transferable to the FDA's analysis here.

[80] Scharff, *supra* note 14, at 125. *See* Scharff Appendix, *supra* note 70, at 4-6 (explaining how pharmaceutical and caregiver lost-productivity costs were estimated).

[81] Scharff, *supra* note 14, at 125.

[82] In addition to accounting for the cost of stool-sample analysis, Scharff also estimated that a physician would charge $127 for an office visit (instead of the FDA's $87) because the level of complexity involved in treating diarrheal illness would justify using a higher CPT code for the visit. *See* Scharff Appendix *supra* note 70, at 3. *See also* Final Draft PRIA, *supra* note 2, at 382-84 (an example of FDA's estimation of medical costs).

[83] Scharff does not mention using an average health index as a baseline, and the values he uses for lost quality of life (0.492 for hospitalized cases, 0.311 for non-hospitalized cases) seem to be the result of subtracting standard EQ-5D weights (0.508 for a health state of 22321, and 0.689 for a health state of 22221) from 1.00 (representing full health), not a baseline health index less than 1.00. *See* Scharff Appendix, *supra* note 70, at 7; Shaw et al., *supra* note 51, at 218 (listing the EQ-5D weights for these health states).

[84] Scharff assigns the same health state to a non-hospitalized illness that the FDA does (22221). But for hospitalized illnesses, Scharff actually assumes that they would have *less* of an impact on one's quality of life than the FDA

We urge the FDA to incorporate these considerations into its own analysis. To illustrate how this might affect the rule's estimated benefits, we applied the Scharff costs to the number of produce-related illnesses estimated by the FDA, making a few adjustments to reflect certain values chosen by the FDA.[85] **Using these more comprehensive estimates for the cost of an illness, the benefits of avoiding illnesses under the produce rule would be $2.90 billion—a 180-percent increase over the FDA's original estimated benefits.**[86]

Underestimated Incidence of Produce-Related Illnesses

Aside from the cost of each illness, the annual incidence of produce-related illnesses is likely much greater than estimated in the PRIA. Based on its own outbreak database, the FDA estimates that 7.4 percent of all foodborne illnesses are due to produce.[87]

But others have arrived at much higher estimates using the CDC's more complete, if less detailed, database.[88] The Center for Science in the Public Interest found that 24 percent of all illnesses from 2001 to 2010 were produce-related, meaning that produce sickened more people than any other single-ingredient food category.[89] Researchers at the CDC went even further, incorporating outbreaks linked to multi-ingredient foods by partitioning their associated illnesses according to the relative likelihood that each component was the source of contamination. Using this method, they estimated that *46 percent* of all illnesses from 1998 to 2008 were caused by produce.[90] Outbreaks in recent years further confirm that produce is a predominant source of contamination. In 2011, fruits, vegetables, and nuts were responsible for 7 out of the 15 major outbreaks of foodborne illness.[91]

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does: Scharff uses 22321—implying only moderate pain or discomfort, and no anxiety or depression—while in most cases, the FDA uses 22332—implying extreme pain or discomfort, and moderate anxiety or depression. *See* note 83 *supra* (identifying the health states used in Scharff's analysis); Final Draft PRIA, *supra* note 2, at 380-82 (the health states used in FDA's analysis).

[85] Scharff used different values than the FDA for the "value of a statistical life" (VSL) and "value of a statistical life-year" (VSLY), so we adjusted the Scharff cost estimates so they would reflect the values selected by the FDA. *Compare* Scharff Appendix, *supra* note 70, at 6-7 (VSL of $7.33 million and VSLY of $356,500) *with* Final Draft PRIA, *supra* note 2, at 382 (VSL of $7.9 million and VSLY of $214,000).

[86] *See* Appendix A *infra* (section on "Calculating the Benefits Using More Comprehensive Cost-per-Illness Figures from Scharff"). In this estimate, we incorporated the correct number of illnesses caused by fresh-cut produce.

[87] The FDA estimates that raw produce other than sprouts is responsible for 5.41 percent of all foodborne illnesses, fresh cut produce is responsible for 1.82 percent, and sprouts are responsible for 0.19 percent. Added together, these numbers imply that 7.42 percent of illnesses are due to produce. Final Draft PRIA, *supra* note 2, at 63-65.

[88] The CDC's outbreak database is publicly available and searchable. CDC, Foodborne Outbreak Online Database (FOOD), http://wwwn.cdc.gov/foodborneoutbreaks (last visited Oct. 18, 2013).

[89] CAROLINE SMITH DEWAAL & MARCUS GLASSMAN, CTR. FOR SCI. IN THE PUB. INTEREST, OUTBREAK ALERT! 2001-2010: A REVIEW OF FOODBORNE ILLNESS IN AMERICA 5, 7 (2013), *available at* http://cspinet.org/new/pdf/outbreak_alert_2013_final.pdf.

[90] John A. Painter et al., *Attribution of Foodborne Illnesses, Hospitalizations, and Deaths to Food Commodities by using Outbreak Data, United States*, 1998–2008, 19 EMERGING INFECT. DISEASES 407, 409 (2013), *available at* http://wwwnc.cdc.gov/eid/article/19/3/pdfs/11-1866.pdf.

[91] *See* Linda Larsen, *In 2011, One-Third of Food Poisoning Outbreaks Were Caused by Produce*, FOOD POISONING BULLETIN, Jan. 16, 2012, http://foodpoisoningbulletin.com/2012/in-2011-one-third-of-food-poisoning-outbreaks-were-in-produce.

The FDA's estimation does not seem to reflect the extent of produce-related illness and thus underestimates the benefits of avoiding these illnesses under the proposed rule.

Reliance on an Incomplete Database

For each pathogen, the FDA first determines how many illnesses were linked to produce between 2003 and 2008, then calculates the percentage out of all CDC-reported foodborne illnesses during the same period, and applies that same percentage to the number of illnesses estimated to occur every year, which takes into account under-reporting of illness and unidentified pathogens.

However, the initial estimate of the proportion of illnesses due to fresh produce—7.4 percent—is far too low. It is based on the FDA's outbreak database, which, unlike the CDC's database, contains only those illnesses that could be traced back through an investigation to contamination during food production, as opposed to mishandling by retailers or consumers. But as the FDA acknowledges, illnesses that were supposedly caused by retail or consumer mishandling may still have had a root cause at the farm level: the produce might have been contaminated with dangerous pathogens during or after harvest, and the later mishandling simply allowed the bacteria to grow to a point that it caused illness. Because these illnesses are not included in the database, the FDA database may be missing many cases of bona fide produce contamination.[92]

Also, the FDA's database includes only those outbreaks in which the FDA was involved in the investigation. But as the agency points out, it is not involved in every outbreak investigation. In some cases, state and local health departments wait until the end of the year to report the illnesses to the CDC database, so the investigation is already over by the time the FDA learns about it. And for many of the smaller outbreaks, state and local health departments may not call upon the agency for help.[93] According to the FDA, produce-related outbreaks in its database caused an average of 121 illnesses, whereas all outbreaks in the CDC database caused an average of 20 illnesses. This suggests that the FDA's counts are heavily biased toward only the largest outbreaks, excluding many smaller outbreaks that may have been caused by tainted produce.[94]

By contrast, the CDC database includes many illnesses linked to produce where the cause of contamination may not have been fully or successfully investigated. As a result, it does not specify whether the contamination occurred due to unsafe production or retail/household mishandling.[95] To some extent, the number of produce-related illnesses in the CDC database would overestimate the number of illnesses traceable to on-farm contamination, but it would also include many produce-related outbreaks that are arbitrarily missing from the FDA's database.

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[92] Final Draft PRIA, *supra* note 2, at 69.

[93] *See id.* at 69-70.

[94] *See id.* at 307 n.45. In the draft as well as the final PRIA, the FDA tries in the "Analysis of Uncertainty" section to relax its restrictive assumptions and include all potentially produce-related illnesses in its counts, not just those that were traceable to contamination during production and those where the FDA joined the investigation. However, it is very difficult to make sense of this brief section, due to confusing mistakes in calculation or missing explanations— *e.g.*, why the FDA estimated so few illnesses due to unidentified pathogens (100 illnesses) when they make up the overwhelming bulk of the agency's other estimations (often in the millions), or why the FDA assumed that 47.4 percent of the contamination occurs at the farm level. *See* Final Draft PRIA, *supra* note 2, at 307-08.

[95] *See* Final Draft PRIA, *supra* note 2, at 365, 367-68 (describing the relationship between the FDA and CDC outbreak databases).

Because the true number of illnesses caused by on-farm contamination probably lies somewhere between both databases, we suggest that the FDA use the figures derived from its own database as a lower bound and the figures derived from the CDC database as an upper bound.[96]

Study Offers a Particularly Useful Glimpse at CDC Data on Produce-Related Illnesses

A 2012 study by Batz et al. estimates the annual prevalence of foodborne illnesses for each pathogen and food type. Like the study by Scharff discussed above, the FDA requested comment on this study, acknowledging that it was not able to fully evaluate it in time for the release.[97]

In this study, the researchers not only identified all the produce-related cases in the CDC database from 1999 to 2008, but they also examined certain factors for each pathogen to determine whether the outbreak data is representative of the true prevalence of illness.[98] As they explain, there are many reasons that outbreak data may not present the most accurate picture:

> For the purpose of food attribution, use of outbreak data has limitations. Outbreaks, by definition, reflect unusual occurrences and/or breakdowns in standard prevention approaches. As such, they may not be representative of "normal" transmission patterns for specific pathogens. The intensity with which an outbreak is investigated may be dependent on its size or the presence of some unusual feature: i.e., an outbreak involving 100 persons, particularly if it involves an unusual vehicle, is more likely to be investigated than one involving three persons in which a "usual" vehicle is suspected. The completeness of investigations is also highly dependent on the interest (and time availability) of local health department investigators and the diagnostic capabilities of the local laboratories.[99]

Where the researchers determined that the outbreak data are not representative, they relied on expert elicitation to estimate the proportion of illnesses caused by that pathogen.[100]

After accounting for produce-related illnesses due to unidentified pathogens (which were not estimated in the study by Batz et al.), this method of attribution suggests that 9.95 million illnesses are attributable to produce every year, more than three times the amount estimated using the FDA's outbreak database (3.15 million).[101] The FDA assumes that the proposed rule

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[96] This may be similar to what the FDA was trying to achieve in its original draft, in the "Upper Estimation" section. *See* OMB Redlined PRIA, *supra* note 10, at 29-31 ("In truth the actual illnesses attributable likely lie somewhere in between the previous estimates and the ones presented below.") However, it is unclear whether the FDA simply used a broader definition of what constituted a produce outbreak in its own database, or whether it was relying on the CDC database to determine the proportion of illnesses due to produce.

[97] *See* Preventive Controls PRIA, *supra* note 79, at 220.

[98] Batz Journal Study, *supra* note 15, at 1279-83.

[99] MICHAEL BATZ ET AL., RANKING THE RISKS: THE 10 PATHOGEN-FOOD COMBINATIONS WITH THE GREATEST BURDEN ON PUBLIC HEALTH 32 (2011), *available at* https://folio.iupui.edu/bitstream/handle/10244/1022/72267report.pdf [hereinafter Batz Report].

[100] *See* Batz Journal Study, *supra* note 15, at 1281-83.

[101] Final Draft PRIA, *supra* note 2, at 65.

would prevent roughly 56 percent of all produce-related illnesses,[102] so based on this estimate the rule would prevent a maximum of 5.54 million illnesses.

When multiplied by the cost-per-illness figures taken from Scharff above, these estimates would yield $6.68 billion in benefits—over six times the PRIA's original estimate.[103] The FDA should use this figure (or one obtained through a similar methodology) as an upper bound on the cost of produce-related illnesses that would be avoided. Table 1 displays the approximate range of avoided-illness benefits that we suggest: $2.90 billion to $6.68 billion.[104]

Table 1: Our Suggested Lower and Upper Bounds for Annual Avoided-Illness Benefits*

	Method for Estimating the Proportion of Foodborne Illnesses Attributable to Produce**	
	FDA Database (Lower Bound)	Batz et al. - CDC Database/experts (Upper Bound)
Number of Illnesses Attributable to Produce	3.15 million	10.28 million
Number of Illnesses Prevented under the Rule	1.75 million	5.72 million
Benefits, using cost-per-illness figures from Scharff	**$2.90 billion**	**$6.68 billion**

* These figures were obtained by multiplying the number of illnesses by the estimated cost of an illness; they do not incorporate any of the other suggestions we have made for improving the comprehensiveness of the agency's benefits estimations, beyond those that were included in the Scharff cost-per-illness figures. The actual benefits of the rule would likely be much greater than these figures suggest because they would reflect several additional costs of an illness, as identified above, and they would incorporate other kinds of benefits (beyond the cost of avoided illnesses) as we describe in the next section.

** There are some incongruities between the two methods displayed here—for example, although both methods estimate the annual incidence of foodborne illness due to produce, the FDA method draws on data from 2003 to 2008, while the Batz et al. study draws on CDC data from 1999 to 2008. If the FDA were to adopt this model for its benefits estimation, the agency could instead compile CDC data from the same time period as its own data.

Risk of Produce-Related Illness Will Be Even Greater Without Crucial Safety Net

Produce-related illnesses are likely to increase in years to come because the U.S. Department of Agriculture's Microbiological Data Program (MDP) was officially shut down at the end of 2012.[105] Created in 2001, the program was responsible for 80 percent of all public testing of fresh produce for dangerous pathogens. It detected contamination on many occasions:

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[102] *See id.* at 52.

[103] *See* Appendix A *infra* (section on "Calculating the Benefits Using Both (1) Cost Figures from Scharff and (2) Attribution Data from Batz et al.").

[104] The lower bound, $2.90 billion, is the number we derived in the text accompanying footnote 86, *supra*.

[105] Helena Bottemiller, *MDP Shuts Down; USDA Testing of Produce for Pathogens Halted*, FOOD SAFETY NEWS, Jan. 3, 2013, http://www.foodsafetynews.com/2013/01/mdp-officially-shut-down-pathogen-testing-for-produce-halted.

> From 2009 to 2012, MDP found Salmonella 100 times, E. coli O157:H7 twice, and
> Listeria monocytogenes 8 times. Over the same time period, the program sparked 23
> Salmonella recalls, 2 E. coli O157:H7 recalls, and 5 Listeria recalls. Of the pathogens the
> program identified during that time, 39 Salmonella isolates were matched to human
> illnesses — as were both E. coli O157:H7 and all 8 Listeria isolates.[106]

State laboratories participating in the MDP uploaded results to the CDC database, helping other
states crack unsolved outbreaks. The MDP's resources also helped expand the testing capacity of
these labs. For example, the state of Washington received $400,000 to conduct produce testing
for the MDP. State officials said they would probably have to cut staff now that the program has
ended, which would impact the effectiveness of their food surveillance.[107]

Groups representing the produce industry argued that the program was intended merely to
monitor pathogens and collect data, but that instead the results were triggering recalls and
hurting business. These groups lobbied for years to cut funding for the MDP, until the Obama
Administration eliminated the $5 million program from its FY 2013 budget.[108] (One of these
same groups, the United Fresh Produce Association, is now attempting to slow down the FDA's
rulemaking effort, urging the agency to release a second round of proposed rules and lobbying
Congress to set a longer timetable for FSMA implementation.)[109]

Without this crucial piece of the food safety net, the need for—and the benefits of—the produce
rule will be even more significant than the FDA estimates.[110]

Other Kinds of Benefits Not Accounted for in the PRIA

The FDA's analysis captures just one kind of benefit—the avoided costs of illnesses—but this
rule will bring other major benefits as well, both to the public and to the food industry. The
additional benefits described here may be difficult or even impossible to quantify, but they at
least warrant a qualitative discussion in the final RIA.

OIRA Blocked Discussion of Some of These Benefits

In the FDA's original draft of the PRIA, the agency did in fact discuss several of the benefits that
we describe below, specifically: (1) the benefits of avoided recalls, and (2) the psychological
benefits to consumers of having a safer food supply. The discussions were well-reasoned and, if

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[106] Helena Bottemiller, *USDA Budget Cut Could Slash 80 Percent of Produce Testing*, FOOD SAFETY NEWS, July 10,
2012, http://www.foodsafetynews.com/2012/07/usda-budget-cut-could-slash-80-percent-of-produce-testing.
[107] Helena Bottemiller, *The Fight Over the Microbiological Data Program*, FOOD SAFETY NEWS, Feb. 23, 2012,
http://www.foodsafetynews.com/2012/02/the-fight-over-the-microbiological-data-program.
[108] *Id.*; Monica Eng, *U.S. Could Drop Screening for Deadly Strain of E. coli*, CHICAGO TRIBUNE, July 4, 2011,
http://articles.chicagotribune.com/2011-07-04/news/ct-met-pathogen-program-20110704_1_pathogens-coli-fda.
[109] Dan Flynn, *Produce Association Joins Call for Makeover of FSMA Rules*, FOOD SAFETY NEWS, Oct. 3, 2013,
http://www.foodsafetynews.com/2013/10/produce-association-also-wants-makeover-for-fsma-rules.
[110] *See* Dan Flynn, *Letter from The Editor: A Year for Fruit & Vegetable Dangers*, FOOD SAFETY NEWS, Aug. 4,
2013, http://www.foodsafetynews.com/2013/08/letter-from-the-editor-13.

anything, modest in their approach, suggesting merely that the rule would offer benefits above and beyond the avoided cost of illnesses, even if the agency was unable to quantify them.[111]

OIRA, however, deleted these sections entirely during its review, without any explanation. By doing so, OIRA made the rule appear less attractive to stakeholders than it actually is. The FDA should restore these sections to its analysis and expand them to include more information on the rule's other benefits.

Benefits of Avoided Recalls

By requiring safer practices, the proposed rule is expected to prevent a substantial amount of produce contamination on covered farms—65 percent according to the FDA's estimates.[112] Logically, the number of recalls due to contamination should also decrease over time.

This is not to say that recalls will be a thing of the past. Greater attention to food safety could lead to more recalls, at least initially, as farms begin monitoring for additional contamination risks and detecting problems they might have missed before. Indeed, the California Leafy Green Marketing Agreement (LGMA) prescribes standards that are in many ways even more stringent than those in the FDA's proposed rule, and its member growers continue to issue recalls after detecting dangerous pathogens.[113]

But once farms have fully transitioned into compliance with the proposed rule, the reduced risk of contamination should result in fewer recalls. This benefit of the rule should make it particularly attractive to members of the produce industry, many of which have witnessed or experienced the devastating economic impacts of recalls caused by inadequate safety measures. According to an FDA report, raw produce and fresh-cut produce were the most frequently recalled commodities from September 2011 to September 2012, responsible for 33 and 23 recall events, respectively—each number significantly higher than in the two years previous, which likely reflects both the high levels of contamination and improvements in pathogen detection. All the recalls were due to contamination from either *E. coli* O157:H7, *Listeria*, or *Salmonella*.[114]

Recalls vary in their financial impact, depending on the scope of the contamination and the size of the company, but the total costs are often very substantial. In a survey of 36 large companies (86 percent of which were food companies), more than half had been affected by a product recall in the past five years. Of those affected, 29 percent estimated a financial impact of between $10 million and $30 million, while another 23 percent estimated even higher costs.[115]

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[111] *See* OMB Redlined PRIA, *supra* note 10, at 33-37.

[112] Final Draft PRIA, *supra* note 2, at 52 tbl.11.

[113] *See, e.g.,* Dan Flynn, *E. coli-Contaminated Lettuce Came from a California LGMA Grower*, FOOD SAFETY NEWS, Jan. 15, 2013, http://www.foodsafetynews.com/2013/01/contaminated-lettuce-came-from-lgma-grower; Scott Horsfall, *Recalls: A Sign the System is Working*, CA LGMA Blog (Aug. 17, 2012), http://www.caleafygreens.ca.gov/blog/recalls.

[114] 2011-2012 Reportable Food Registry, supra note 17, at 5, 12-13.

[115] GROCERY MANUFACTURERS ASSOCIATION, COVINGTON & BURLING, AND ERNST & YOUNG, CAPTURING RECALL COSTS: MEASURING AND RECOVERING THE LOSSES iii, 3(2011), *available at* http://www.ey.com/Publication/vwLUAssets/Capturing_Recall_Costs/$FILE/Capturing_recall_costs.pdf [hereinafter CAPTURING RECALL COSTS].

When a produce company issues a recall, it loses the profit value of the recalled batches, which are taken off store shelves and returned or destroyed rather than sold. Depending on the size of the recall, this loss can be enormous: at the end of 2011, a Texas-based farm recalled 228,360 pounds (114 tons) of spinach after samples tested positive for *E. coli* O157:H7.[116] The company also pays to administer the recall, including transporting and destroying the recalled batches, conducting public relations, and internally investigating the cause. Companies may have to stop operating for a period of time, to allow government investigation or to modify their processes, causing further business interruptions.[117]

But the true costs of a recall lie beyond its short-term expenses. Food companies worry much more about the implications for their brand and the market in general.[118] Stigma associated with recalled produce can persist long after the recall is over: sales of fresh spinach dropped to zero in the week after the 2006 recall, and it took more than a year for consumers to return to their previous buying habits.[119]

Consumers have a long memory when it comes to recalls: in a survey of consumers in ten cities, 83 percent could name a product recalled in the past two years due to safety concerns. Many described how recalls erode their confidence in food safety: 49 percent said they would be less likely to purchase food that had been recalled due to contamination; 63 percent said they would not buy the food again until the cause of contamination were determined and addressed; and 8 percent said they would never buy the food again, period.[120]

The negative impacts of recalls often spread to companies that had nothing to do with the contamination. Consumers commonly avoid products that are similar to the recalled item; for example, sales of bagged lettuce dropped by 10 percent after the spinach recall.[121] And recalls shake the confidence not only of consumers but of investors as well, which leads to falling stock prices across entire sectors of the food industry.[122] Confusion about the source of contamination can also have disastrous effects on the markets for other kinds of produce. In 2008, state and federal officials were struggling to find the cause of an elusive multistate outbreak of *Salmonella* Saintpaul. Under great pressure, the FDA began warning consumers not to eat certain tomatoes, and national retail chains quickly canceled their tomato orders. Even though the FDA ultimately

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[116] James Andrews, *When Should Recalls Be Made Public?*, FOOD SAFETY NEWS, Feb. 28, 2012, http://www.foodsafetynews.com/2012/02/when-should-recalls-be-made-public.

[117] *See* CAPTURING RECALL COSTS, *supra* note 115, at 5-6.

[118] *See id.* at 6.

[119] Amy Schoenfeld, *The Food Cycle: Recall, Forget, Repeat*, THE NEW YORK TIMES, Dec. 4, 2010, http://www.nytimes.com/2010/12/05/business/05metricstext.html (see interactive feature).

[120] Press Release, IBM, Less Than 20% Of Consumers Trust Food They Buy Is Safe and Healthy, IBM Survey Reveals (June 24, 2009), http://www-03.ibm.com/press/us/en/pressrelease/27817.wss.

[121] WILLIAM K. HALLMAN & CARA L. CUITE, FOOD POLICY INSTITUTE, RUTGERS UNIVERSITY, FOOD RECALLS AND THE AMERICAN PUBLIC: IMPROVING COMMUNICATIONS 19 (2009), *available at* http://www.researchgate.net/publication/228694948_Food_Recalls_and_the_American_Public_Improving_Communications/file/3deec51c9aa689e368.pdf.

[122] *See* PABLO GARCIA-FUENTES ET AL., CONSUMER CONFIDENCE IN THE FOOD SYSTEM, MEDIA COVERAGE AND STOCK PRICES OF FOOD COMPANIES: A REGRESSION ANALYSIS 5-6 (2009), *available at* http://ideas.repec.org/p/ags/aaea10/61658.html.

determined that raw peppers from Mexico, not tomatoes, were the source of the outbreak, the tomato industry claims to have lost $200 million due to the incident.[123]

The market impacts of recalls are detrimental to consumers as well. Large recalls reduce the availability of foods enjoyed by consumers, and in the case of produce, they may deprive consumers of the unique health benefits of eating certain fruits, vegetables, and nuts.

Finally, as the FDA originally stated in the draft PRIA that it submitted to OIRA, major recalls can result in the bankruptcy of companies that played any part in the production or distribution of the contaminated product, which can lead in turn to a loss of jobs.[124]

The FDA needs to include a section in the PRIA that describes the potential for reduced recalls under the proposed rule and explores some of the far-reaching costs that would then be avoided.

<u>Avoided Dread and Panic from Exposure to Potentially Contaminated Foods</u>

Even the most comprehensive statistics on food contamination only count those individuals who actually got sick. But outbreaks and recalls also impose substantial costs on potentially exposed individuals—those who are afraid they may have eaten the contaminated food but have not yet fallen ill. These individuals often experience a great deal of emotional stress, and depending on the outbreak, may have to undergo medical screening or vaccination.

This past summer, a 161-person outbreak of Hepatitis A was traced to a blend of frozen berries sold at Costco stores. Costco had sold almost 333,000 packages of the blend, so a third of a million people were potentially exposed to the virus.[125] Because the incubation period can last up to a month, consumers of the berries suffered many sleepless nights wondering whether (or when) they would develop symptoms like fever, nausea, abdominal pain, and jaundice. Many visited their doctors for blood tests, and Costco pharmacies alone administered vaccination shots to more than 10,000 people (county health departments administered thousands more). Some were terrified they had passed along the virus to others, like a woman who had kissed her friend's 2-month-old baby soon after eating the berries.[126] These psychological costs of exposure are very real, but often overlooked.

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[123] STATE SURVEILLANCE OF FOODBORNE ILLNESS, *supra* note 18, at 2. *See* Dan Flynn, *Tomato Growers Want Compensation for Losses in 2008 Outbreak*, FOOD SAFETY NEWS, Aug. 2, 2013, http://www.foodsafetynews.com/2013/08/tomato-growers-want-to-be-compensated-for-losses-in-2008-outbreak.

[124] OMB Redlined PRIA, *supra* note 10, at 34.

[125] Lynne Terry, *Costco Gives Free Hepatitis A Shots in Outbreak Tied to Fairview Processor*, THE OREGONIAN, June 10, 2013, http://www.oregonlive.com/business/index.ssf/2013/06/costco_gives_free_hepatitis_a.html.

[126] James Andrews, *Hepatitis A Vaccination Process Causes Stress, Fear for Many*, FOOD SAFETY NEWS, July 2, 2013, http://www.foodsafetynews.com/2013/07/hepatitis-a-vaccination-process-full-of-stress-fear-for-many; James Andrews, *Thousands Sought Vaccines Following Townsend Farms Hep A Outbreak*, FOOD SAFETY NEWS, June 24, 2013, http://www.foodsafetynews.com/2013/06/thousands-sought-vaccines-following-townsend-farms-hep-a-outbreak.

Avoided Costs of Outbreak Investigation and Response

State and local health departments bear much of the cost of investigating foodborne illness. They are responsible for contacting victims, questioning them about foods they have eaten, analyzing their responses, and performing serotype and DNA analyses that enable them to link cases of illness to one another.[127] While contamination at local retail establishments and restaurants will continue to require their swift investigation, the FDA's proposed rule on produce safety will presumably avoid a number of large outbreaks due to on-farm contamination that have proven burdensome and time-consuming for state and local agencies. For example, the recent multistate *Cyclospora* outbreak, which was linked to an imported salad mix in two states and fresh cilantro in another, has taken months for public health agencies to investigate, and they still have not been able to determine the source.[128]

There is no data on how much agencies actually spend on these investigations. However, contaminated produce was linked to nearly 700 outbreaks solved by state agencies between 1998 and 2008, or about 15 percent of all solved outbreaks (those outbreaks where both the food vehicle and the pathogen were identified).[129] At the same time, nearly all public health agencies are constrained by insufficient budgets. According to a 2010 report, states eliminated $392 million in funding for public health programs in the previous year, and another report found that these budget cuts resulted in deep job losses and the reduction of essential health services. Nine percent of local health departments cut food safety programs specifically.[130] Any meaningful reduction in produce-related outbreaks that require investigation would ease at least some of the burden on public health agencies and free up some of their scarce resources for other activities.

In some cases, outbreaks require public health interventions as well, which are paid for by state and local health agencies. A lawsuit brought by Marler Clark is requesting that Townsend Farms reimburse agencies for the costs of providing thousands of Hepatitis A vaccine shots at clinics during the pomegranate-related outbreak.[131] These costs can be significant: in one restaurant-based outbreak, the Pennsylvania Department of Health spent about $150,000 purchasing immunoglobulin shots to prevent further spread of Hepatitis A.[132]

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[127] STATE SURVEILLANCE OF FOODBORNE ILLNESS, *supra* note 18, at 2.
[128] *See* Sidney Lupkin, *Mystery Continues in Cyclospora Stomach Bug Outbreak*, ABC NEWS, Aug. 6, 2013, http://abcnews.go.com/Health/mystery-continues-cyclospora-stomach-bug-outbreak/story?id=19876091; CDC, Investigation of an Outbreak of Cyclosporiasis in the United States, http://www.cdc.gov/parasites/cyclosporiasis/outbreaks/investigation-2013.html (last visited Oct. 24, 2013).
[129] *See* CTR. FOR SCI. IN THE PUB. INTEREST, ALL OVER THE MAP: A 10-YEAR REVIEW OF STATE OUTBREAK REPORTING 8 fig.4 (2011), *available at* http://cspinet.org/new/pdf/alloverthemap.pdf.
[130] *Id.* at 7.
[131] *Maui Couple Sues over Frozen Berry Mix Linked to Hepatitis Outbreak*, HAWAII NEWS NOW, June 11, 2013, http://www.hawaiinewsnow.com/story/22565249/maui-couple-sues-over-frozen-berry-mix-linked-to-hepatitis-outbreak.
[132] David W. Backcock, *Recouping the Costs of Outbreak Investigations and Prevention*, 68 J. ENV. HEALTH 71, 71 (2006), http://www.marlerclark.com/pdfs/cost-of-outbreak-investigations-jeh.pdf.

Avoided Litigation Costs

Virtually every major outbreak of foodborne illness is followed by lawsuits brought on behalf of victims, often as class actions. These lawsuits are the only recourse victims have to recover some of their losses (medical costs, lost productivity, pain and suffering, death), but they nevertheless have high transaction and information costs. Lawsuits also amplify the reputational losses and other costs incurred by defendant food companies in the wake of an outbreak (*e.g.*, increases in product-liability insurance premiums).[133] By reducing produce contamination, the proposed rule will avoid some of these lawsuits, and thus some of their costs.

Protecting and Promoting U.S. Exports

The FDA analyzes a few potential trade impacts of the produce rule (mainly price effects),[134] but it does not consider that the rule will also protect U.S. export markets. U.S. exports of fruits and vegetables totaled more than $10 billion in 2009.[135] Agricultural economists have said that in the event of an outbreak, "implicated multinational firms are likely to see their exports reduced or banned due to food safety concerns by the importing countries."[136] The proposed rule will provide foreign countries with greater security in the safety of U.S. produce and help to prevent trade disruptions caused by contamination events.

Also, foreign retailers have developed mandatory "GLOBALGAP" standards and practices—on recordkeeping, worker health, fertilizer use, irrigation, and more—that produce growers have to follow (and be certified as following) before doing business with them.[137] A portion of U.S. growers already comply with such standards, but the FDA's proposed rule would raise the bar for all covered farms, bringing them closer to satisfying those kinds of requirements. (The FDA states that the proposed rule is consistent with GLOBALGAP standards.)[138] In other words, the rule could help to expand the amount of U.S. produce that is eligible for export.

Consumer Peace of Mind

In the draft PRIA submitted to OIRA, the FDA stated that "consumers could also derive a psychological benefit from knowing that their food supply is safer, due to this rule."[139] The FDA cited a growing literature on consumers' willingness to pay for a reduction in the probability of foodborne illness. This set of studies found much larger benefits than the FDA's cost-of-illness estimates, presumably because they incorporated some psychological benefits of food safety.[140]

For example, researchers in a 2010 study surveyed 3,511 individuals, offering them differently priced items that presented slightly different amounts of risk. Based on their answers, the

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[133] *See* JEAN C. BUZBY ET AL., USDA ECON. RESEARCH SERV., PRODUCT LIABILITY AND MICROBIAL FOODBORNE ILLNESS 11-12 (2001), *available at* http://ageconsearch.umn.edu/bitstream/34059/1/ae010799.pdf.

[134] Final Draft PRIA, *supra* note 2, at 289-90.

[135] RENÉE JOHNSON, CONG. RESEARCH SERV., THE U.S. TRADE SITUATION FOR FRUIT AND VEGETABLE PRODUCTS 1 (2012), *available at* http://www.fas.org/sgp/crs/misc/RL34468.pdf.

[136] GARCIA-FUENTES ET AL., *supra* note 122, at 5.

[137] JOHNSON, *supra* note 135, at 10-11.

[138] Final Draft PRIA, *supra* note 2, at 289, 292.

[139] OMB Redlined PRIA, *supra* note 10, at 34.

[140] *Id.* at 35.

researchers estimated how much money people would be willing to pay for incremental improvements in food safety. They concluded that American consumers, as a whole, would be willing to pay $305 million for a 10-percent reduction in the risk of *E. coli* contamination in supermarket hamburgers. One of the features of this approach is that it focuses not just on the costs incurred by those who get sick, but on the desire of all consumers to avoid eating risky foods, taking into account their level of worry.[141]

As the FDA explained in its original draft, these studies imply that the value of safer produce would be between $3.6 billion and $24.1 billion. The FDA did not suggest that these figures replace its avoided-illness estimates; in fact, it admitted they were not "directly applicable" to this rule. Instead, the FDA merely used these studies to illustrate that the rule's true benefits are likely much greater than the agency's own estimates suggest.[142] Because OIRA removed this section of the analysis, the final version of the PRIA does not present this alternative perspective and makes no mention of "psychological benefits."[143]

COSTS OF THE PRODUCE RULE

The FDA estimates the annual cost of compliance with the proposed rule to be $460 million. Table 2 below illustrates how the agency breaks down the costs, some of which do not hold up under close scrutiny.

For each provision in the proposed rule, the FDA estimates how many produce farms might already be in compliance and thus would incur no new costs. To account for the industry's baseline food safety practices, the FDA identifies the number of farms that are members of identifiable food safety agreements, like the California and Arizona Leafy Green Marketing Agreements (LGMAs), or those that have been verified by the USDA's Agricultural Marketing Service as following federal guidance on "good agricultural practices" (GAPs). The agency concludes that 1,117 farms in total have one of these food safety programs in place.[144]

Because the FDA lacks data on how many farms may be complying with other food safety programs, or how many are required by their buyers to adopt certain practices, the agency tries to account for these farms using information from a number of agricultural surveys from 1999 to 2008.[145] This is likely the best available data that the FDA can obtain, at least without undertaking costly and time-consuming information collection activities. But it is worth pointing

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[141] Mario F. Teisl & Brian E. Roe, *Consumer Willingness-to-Pay to Reduce the Probability of Retail Foodborne Pathogen Contamination*, 35 FOOD POLICY 521 (2010), *available at* http://www.sciencedirect.com/science/article/pii/S0306919210000813. *See* Emily Caldwell, *Study: Consumers Value Safer Food More Than Current Analyses Suggest*, OHIO STATE UNIVERSITY RESEARCH NEWS, Feb. 8, 2011, http://researchnews.osu.edu/archive/saferfood.htm (summarizing the study).

[142] OMB Redlined PRIA, *supra* note 10, at 35-36.

[143] The final PRIA does retain from the original draft a brief discussion of a willingness-to-pay study in the section on "Analysis of Uncertainty," but it differs from the deleted section: it mentions only one of the studies on the subject; does not present the range of alternative valuations originally included in the draft; and does not explain that these studies attempt to incorporate the psychological benefits of a safer food supply, whereas the FDA's estimates do not. *See* Final Draft PRIA, *supra* note 2, at 308-09; OMB Redlined PRIA, *supra* note 10, at 381-82.

[144] *Id.* at 29-38, 42.

[145] *Id.* at 39-41.

out that the number of farms that have already adopted some of the proposed requirements is probably greater today than it was in 2008, given the increasing importance of food safety to consumers and retailers.[146] For these farms, the rule would be less burdensome than predicted.

Table 2: FDA's Summary of Annual Costs (in millions) (7% discount rate over 7 years)[147]

Cost Sections	Not Covered	Very Small	Small	Large	Total
Administrative cost to learn the rule	$10.06	$11.82	$5.38	$9.53	$36.79
Health and Hygiene	$0.00	$27.18	$15.06	$95.97	$138.21
Agricultural water	$0.00	$27.45	$7.09	$14.00	$48.55
Biological soil amendments of animal origin	$0.00	$1.11	$1.04	$7.06	$9.20
Domesticated and wild animals	$0.00	$10.32	$5.96	$21.50	$37.78
Growing, harvesting, packing, and holding activities	$0.00	$0.17	$0.09	$0.16	$0.42
Equipment, tools, buildings, and sanitation	$0.00	$11.38	$8.22	$39.27	$58.87
Sprouting operations	$0.00	$0.75	$0.71	$6.07	$7.53
Personnel Qualifications and training	$0.00	$19.60	$12.84	$58.98	$91.42
Corrective steps	$0.00	$0.59	$0.28	$1.23	$2.09
Variances	$0.00	$0.00	$0.00	$0.00	$0.10
Recordkeeping	$0.00	$16.19	$4.21	$8.19	$28.60
Total Costs (annual in millions)	$10.06	$126.56	$60.88	$261.96	**$459.56**
Average Cost per farm	$88.33	$4,697.19	$12,972.36	$30,566.23	$11,429.70
Total Cost to Foreign Farms					$170.62

OIRA Exaggerated the Cost to Exempt Farms

The FDA estimates that 75,716 farms would be eligible for a "qualified exemption" from the rule because they have average annual sales of less than $500,000 and more than half of their sales are from direct marketing to consumers or to local establishments. These farms would not be subject to any of the rule's standards for growing, harvesting, packing, or holding produce; instead, they would only have to comply with a minimal labeling requirement. Farms that sell

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[146] *See, e.g., Wegmans To Require Best Food Safety Practices From All Produce Growers*, FOOD SAFETY NEWS, Sep. 24, 2013, http://www.foodsafetynews.com/2013/09/wegmans-to-require-best-food-safety-practices-from-all-produce-growers; Cookson Beecher, *Greens Grower and Whole Foods Team Up for HACCP Certification*, FOOD SAFETY NEWS, July 22, 2013, http://www.foodsafetynews.com/2013/07/greens-grower-and-whole-foods-team-up-for-haccp-certification; *Costs of Food Safety Proposals Causing Concern*, THE HERALD-DISPATCH, Jul. 7, 2013, http://www.herald-dispatch.com/news/briefs/x1410677563/Costs-of-food-safety-proposals-causing-concern ("[The] leader of the fresh fruit and vegetable safety team at the Ohio Agricultural Research and Development Center in Wooster[] says many farms already submit voluntarily to audits or inspections required by companies buying their produce. He says most audits probably would be prompted more by customers than by regulators ….").
[147] Final Draft PRIA, *supra* note 2, at 299 tbl.123.

direct to consumers must display the farm's name and business address on a label, poster, or sign at the point of purchase (*e.g.*, roadside stands, farmer's markets, pick-your-own operations).[148]

According to the PRIA, the annual cost to exempt farms of complying with this labeling requirement totals $3.82 million, or $1,134 per farm.[149] This cost is not just buried somewhere in the PRIA; the FDA also mentions it specifically in its online summary of the rule.[150] To most readers, it probably appears to be a very significant cost, especially since it will be incurred by farms that are supposed to be *exempt* from the rule's standards.

But closer examination reveals the cost to be greatly exaggerated. The FDA expects that exempt farms will use a "poster board" to display the name and address information, and that this poster board would have to be replaced every two weeks, since it can get "tattered and worn-out." For each new poster board, the FDA estimates the cost of the board itself ($6) and the time it would take for the farmer to buy and prepare it, at a wage rate of $47 per hour. (Fortunately, the FDA stopped just short of estimating the cost of a marker to write with, quite sensibly realizing that the farmer would "use something he has on hand.")[151]

Originally, the FDA estimated that it would take a farm operator *five minutes* every two weeks to buy the poster board and write the information, resulting in a total annual cost of $341,000, or just $101 per farm. But OIRA, during its review, inexplicably changed it to an *hour* every two weeks; this change alone was responsible for bringing the total cost up to $3.82 million ($1,134 per farm).[152] There is simply no basis for concluding that this simple task would take an hour to perform, for a number of reasons:

- In all likelihood, farms that sell directly to consumers already display a variety of information at the point of purchase (*e.g.*, prices, types of produce), and so they are probably accustomed to preparing labels, posters, or signs every once in a while. The time it would take these farms to write one additional sign would be negligible.

- The time it takes to obtain poster material would also be negligible. Farms can buy many poster boards at once, instead of visiting an office-supply store every two weeks, as the PRIA seems to suggest with its one-hour estimate.

- Alternatively, farms can buy affordable but durable signs that do not fall apart so quickly, or repurpose one of their existing signs to include this information. The FDA itself remarks in a footnote, "It is possible that a farm may purchase a permanent banner for marketing purposes, and add their contact info at relatively little additional cost."[153]

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[148] Final Draft PRIA, *supra* note 2, at 18-22.
[149] *Id.* at 23.
[150] FDA, FSMA Proposed Rule for Produce Safety – Fact Sheet, http://www.fda.gov/Food/guidanceregulation/FSMA/ucm334114.htm#summary (last visited Oct. 11, 2013).
[151] Final Draft PRIA, *supra* note 2, at 22-23.
[152] *See* OMB Redlined PRIA, *supra* note 10, at 60-61.
[153] Final Draft PRIA, *supra* note 2, at 22 n.4.

The FDA should consider whether to include this cost at all, considering that it will probably be trivial for most farms. At the least, the FDA should restore its original estimate: $341,000.

The PRIA Overestimates the Cost of Health and Hygiene Standards

The handling of produce by infected workers has been responsible for many major outbreaks involving a broad range of commodities like strawberries, green onions, raspberries, tomatoes, leaf lettuce, and herbs.[154]

The proposed rule includes a number of standards related to the health and hygiene of people who come into contact with produce on the farm. Among other things, the rule would require that (1) ill workers be excluded from working directly with produce; and (2) workers wash their hands at certain times—before work, before putting on gloves, after using the toilet, after a break, after touching animals or animal waste, and at any other time their hands could have become contaminated.[155]

<u>"Lost Productivity" Due to Health and Hygiene Standards</u>

The cost of these standards is stated largely in terms of the "lost productivity" of workers who, under the rule, are excluded from work due to illness or busy washing their hands instead of handling the produce. The FDA first determines the amount of time that workers would be absent from their task for reasons of health or hygiene, and then multiplies it by the average hourly wage rate for farm workers (intended to represent the value of their productivity).[156]

But this should not be considered a cost of the rule. The labor of farm workers who pose obvious contamination risks cannot fairly be considered "productivity," as if it were something of value, a benefit that farm owners are entitled to and that the rule deprives them of. It is this kind of "productivity" that leads to produce that is unsellable because it tests positive for pathogens, or produce that is recalled after contamination is detected, or produce that causes widespread illness and damaging publicity for the farm that grew it.

In another, unrelated section of the PRIA, the FDA declined to estimate any cost for a provision prohibiting sprout producers from using lots of seeds that are known or suspected to be associated with foodborne illness. The agency explained: "The public health benefits of refraining to use lots of seed associated with foodborne illness clearly outweigh any cost of doing so, further justifying our omission of the cost consideration …."[157] The same reasoning applies here: the public health benefits of these standards (*e.g.*, excluding Hepatitis-infected workers from handling produce, or requiring workers to wash their hands after going to the bathroom) are so obvious and compelling that the time they require need not even be estimated, much less weighed against the rule's benefits.

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[154] *See* ROBERT B. GRAVANI, PRODUCE SAFETY PROJECT ISSUE BRIEF: FARM WORKER HEALTH AND HYGIENE 4-5 (2010), http://www.pewhealth.org/uploadedFiles/PHG/Content_Level_Pages/Issue_Briefs/PSP_Worker-1.pdf.
[155] *See* Final Draft PRIA, *supra* note 2, at 101-03.
[156] *See id.* at 101-16.
[157] *See id.* at 246.

The Cost of Worker Hand Washing

The FDA estimates (based on a national survey) that 91 percent of farm workers do not wash their hands before work or after being away from their work station, and that 25 percent do not wash their hands after using the toilet.

The agency assumes that the proposed rule's hygiene standards would require workers to wash their hands about four times each day: before work, after using the toilet (estimated to occur twice daily), and after being away from the work station. According to the PRIA, each hand-wash would take, on average, two minutes—20 seconds of actual washing plus time to walk to and from the work station. Having estimated that a worker's time is worth $14 per hour, the FDA concludes that *every hand-wash would cost a farm 47 cents in lost productivity* during those two minutes. **Multiplied by roughly 40,000 farms, these 47-cent "hand washing costs" add up to $113.5 million per year—the largest estimated cost of any standard in the entire rule.**[158]

Much of the responsibility for this outrageous estimate lies with OIRA. Originally, the FDA estimated a hand-wash would take approximately one minute (costing 23 cents), but OIRA changed it to two minutes (47 cents)—*doubling* the total cost from $56.8 million to $113.5 million.[159] Despite the enormity of this change, the PRIA gives no explanation as to why OIRA felt it was necessary. (It is also worth noting that OIRA botched its own interference: it doubled the cost of a hand-wash in this section, but neglected to do so in a later section on hand washing after touching animals, where the estimated cost remains 23 cents.)[160]

Aside from OIRA's interference, the estimation suffers from a major lapse in logic. For hand washing after toilet use, as with other kinds of hand washing, the FDA counts the full two minutes of lost productivity—all but 20 seconds of which represent the time it takes to walk to and from the hand washing facility. (Hand washing after toilet use makes up $24.5 million of the total hand-washing costs.)[161] But when a worker uses the toilet, the worker is *already in* the bathroom and would have to walk back to the work station anyway, with or without washing her hands. In other words, the time spent walking cannot fairly be considered a cost of the rule's hand washing requirement, since it would have occurred even without it. At most, the FDA could only count the 20 seconds spent on actual hand washing in this context.

But more importantly, the entire estimation ignores the fact that farm workers already have a legal right to wash their hands at various times throughout the day, for the protection of their own health. Field sanitation requirements issued in 1987 by the Occupational Safety and Health Administration (OSHA) require agricultural employers with 11 or more employees to "notify each employee of the location of the sanitation facilities and … *allow each employee reasonable*

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[158] *See id.* at 6-7 (deriving the $14 per hour figure from a $9.33 hourly wage plus another 50 percent representing fringe benefits and overhead costs), 113-15 (estimating the frequency of hand-washes and the cost of each one), 116 (deriving the total cost of hand washing across all farms), 299 (summary of costs for the produce rule, none of which are larger than the $113.5 million cost of worker hand washing displayed in Table 40 on page 123).

[159] *See* OMB Redlined PRIA, *supra* note 10, at 162-64.

[160] *See* Final Draft PRIA, *supra* note 2, at 118.

[161] *Id.* at 116 tbl.36.

opportunities during the workday to use them" (emphasis added).[162] The OSHA rule further requires employers to inform each employee of the importance of "good hygiene practices" and instruct them specifically to "wash hands both before and after using the toilet" and "wash hands before eating and smoking."[163]

The FDA cannot count lost productivity due to hand washing as a cost of the proposed rule when workers are already entitled to take a reasonable amount of time for good hygiene practices, and farms are already under a legal obligation to permit it. Certainly the four hand-washes per day envisioned by the FDA qualify as "reasonable" use of sanitation facilities. In other words, time spent on hand washing is the worker's time to spend, not the employer's time to lose, whether the washing is motivated primarily to protect the worker's health, the public health, or both (hand washing virtually always serves this dual function).

Finally, the PRIA counts every hand-wash as a new, separate cost incurred by the farm, but they will surely be absorbed into a farm's existing operations at minimal extra cost. The FDA has requested comment on which of the rule's standards "may be folded into the regular course of everyday activates, already implemented on the farm," and these hygiene standards are a prime example of that.[164] One Washington farm, after signing onto a voluntary food safety program, started towing five or six hand-washing stations behind a trailer, moving them around to different fields so they would be easily accessible to farm workers. The new requirements were an adjustment at first, but soon became part of the daily routine: "'What, I have to wash my hands?'" manager Hector Dominguez said, quoting workers. "Sure. So, it takes time to make everybody do that. But now it's pretty simple."[165]

We urge the FDA to eliminate this unfounded and misleading estimation from the PRIA altogether.

The Cost of Testing Agricultural Water Will Likely Be Lower Than Estimated

The proposed rule includes requirements for the quality of agricultural water used for certain purposes. There must be no detectable generic *E. coli* in water that directly contacts produce during or after harvest (as water or ice), and there must be no more than a certain level of generic *E. coli* (235 colony forming units per 100 mL) in water used during pre-harvest growing activities.[166]

These proposed standards use generic *E. coli* as an indicator organism, whose presence above a certain level suggests fecal contamination of the water source and—possibly—the presence of dangerous human pathogens like *E. coli* O157:H7, *Salmonella*, and *Campylobacter*. The FDA

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[162] 29 C.F.R. § 1928.110(c)(4).
[163] 29 C.F.R. § 1928.110(c)(4)(iv)-(v).
[164] *See* Final Draft PRIA, *supra* note 2, at 101.
[165] Ross Courtney, *Coming Food Safety Regulations Worry Farmers, Packers*, YAKIMA HERALD, Oct. 20, 2013, http://www.yakimaherald.com/photosandvideos/latestphotos/1581916-8/coming-food-safety-regulations-worry-farmers-packers.
[166] *See* Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption; Proposed Rule, 78 Fed. Reg. at 3635-36.

settled on generic *E. coli* as the best and most practical indicator organism for farms to test for at this time, adopting the same approach used in the California Leafy Green Marketing Agreement (LGMA). At the same time, the FDA acknowledges, as stakeholders have pointed out, that the research is mixed on whether generic *E. coli* is a good predictor of pathogenic contamination.[167]

Whatever the rule's water standards ultimately look like, they will likely involve farms collecting samples of agricultural water and testing them. Farm organizations have objected to what they believe will be overly burdensome testing standards, which may require testing as frequently as once a week if the farm uses untreated surface water that receives significant runoff.[168] The PRIA does little to reassure them, estimating a testing cost of $87.30 per sample.[169]

But this is likely a dramatic overestimation of the cost of water testing. *Ex ante* cost-benefit analyses typically overestimate compliance costs, in part because (1) they reflect overly conservative, sometimes outdated assumptions about how businesses operate; and (2) they fail to anticipate that the regulation will inspire technological and operational innovations that make it less expensive to comply.[170]

In this case, the PRIA does not take into account that the burgeoning demand for water testing under the rule is almost sure to:

- Spur the development of low-cost testing kits that can be used "on farm" instead of requiring shipment to a lab and professional analysis; and
- Increase competitiveness among suppliers of testing products and services, driving down prices and making testing more affordable for small farms.

A new report on the microbial-testing market predicts rapid growth and innovation, driven partly by new regulation of the food industry: "Given the pace of current breakthroughs, the market is

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[167] *See id.* at 3561-63; TREVOR V. SUSLOW, PRODUCE SAFETY PROJECT ISSUE BRIEF: STANDARDS FOR IRRIGATION AND FOLIAR CONTACT WATER (2010), *available at* http://www.pewhealth.org/uploadedFiles/PHG/Content_Level_Pages/Issue_Briefs/PSP_Water-Suslow-1.pdf (questioning the wisdom of the approach used in the LGMA and later proposed by the FDA).

[168] *See, e.g.,* Farm & Ranch Freedom Alliance, Action Alert: Tell FDA to Give Farmers More Time!, Apr. 11, 2013, http://farmandranchfreedom.org/action-alert-tell-fda-to-give-farmers-more-time-4-11-2013 ("Weekly or even monthly water testing requirements is unnecessary and extremely expensive. Frequent testing is expensive and, in many cases, not practical because there are few companies licensed to do such testing.").

[169] Final Draft PRIA, *supra* note 2, at 136. Indeed, this estimated cost has contributed to farm groups' opposition to the rule. *See, e.g.,* Nat'l Sustainable Agric. Coal., Top 10 Reasons for Farmers, Consumers, and Organizations to Weigh in on Proposed Food Safety Rules, Oct. 11, 2013, http://www.sustainableagriculture.net/blog/food-safety-comments-top-10 ("FDA estimates the typical cost for one water test is $87.30 – which could add up to thousands of dollars for farmers each year.").

[170] *See* Eban Goodstein & Hart Hodges, *Behind the Numbers: Polluted Data*, THE AMERICAN PROSPECT, Nov. 1, 1997, *available at* http://www.prospect.org/cs/articles?article=polluted_data ("[A]nalysts tend to predict future costs statically, as if firms would continue to use existing practices and technologies…. But basing cost predictions on scenarios that assume no technical evolution is guaranteed to produce gross overestimates."); Thomas O. McGarity & Ruth Ruttenberg, *Counting the Cost of Health, Safety, and Environmental Regulation*, 80 TEX. L. REV. 1997 (2002) (finding that *ex ante* cost estimates are much greater than actual costs incurred, even by orders of magnitude).

expected to witness the emergence of several novel procedures and ideas in the years to come."[171]

In addition, two food safety specialists have written about the need to design disposable, stand-alone tests that would require little user training and thus could be easily used on farms. The development of diagnostic tests for use in low-resource settings (like rural India or sub-Saharan Africa) provides a good model, they say, since the testing environment on a farm resembles these settings more than a scientific laboratory.[172]

Lateral flow tests (similar to at-home pregnancy tests) may be a promising low-cost solution for situations where farms simply need a positive or negative result—for example, in the "no detectable *E. coli*" standard for water that contacts produce during or after harvest. Standards requiring a quantitative result (*i.e.*, a count of bacteria colonies below a certain threshold) pose a greater challenge, but these specialists suggest that in the near future smartphones could be equipped with the capability to analyze the results of quantitative microbial assays using their cameras. As an added bonus, smartphones would enable quick, accurate recordkeeping of tests and results.[173] These are just a few examples of the kinds of plausible technological advances that would help to alleviate the burden of frequent water testing on farms.

In the meantime, companies that make pathogen-testing products for use in laboratories, like 3M and Neogen, will have incentives to increase their supply and lower their prices to capture as much of the expanded market as possible. (One publication advises its readers that now would be an excellent time to invest in these companies.)[174] Labs that offer testing services will pass on some of these savings to farms in order to stay competitive, and due to economies of scale, will be able to charge less for their services and offer discounts for higher-volume testing orders.[175]

Significantly, the proposed rule would give farms a considerable amount of time before they have to comply with these water standards— *four years* after the rule's effective date for large businesses (more than $500,000 in sales), *five years* for small businesses ($500,000 or less in food sales), and *six years* for very small businesses ($250,000 or less in food sales).[176] This delayed implementation will give the market even more time to adjust to the new requirements before farms begin mandatory testing.

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[171] *See* Press Release, Global Industry Analysts, Inc., Rising Concerns Over Food Safety Drives Demand for Agricultural and Environmental Diagnostics, According to New Report by Global Industry Analysts, Inc. (Sep. 27, 2013), http://www.prweb.com/releases/agricultural_diagnostics/environmental_diagnostics/prweb11170544.htm.

[172] Amanda Kinchla & Sam Nugen, *Challenges and Innovations for On-Farm Bacterial Testing*, FOOD SAFETY MAGAZINE, Aug./Sep. 2013, *available at* http://www.foodsafetymagazine.com/magazine-archive1/augustseptember-2013/challenges-and-innovations-for-on-farm-bacterial-testing.

[173] *Id.*

[174] Sara Murphy, *FDA's Proposed Food Safety Rules: Investment Implications*, THE MOTLEY FOOL, Jan. 7, 2013, http://www.fool.com/investing/general/2013/01/07/fdas-proposed-food-safety-rules-investment-implica.aspx.

[175] *See* Laurian Unnevehr et al., *New Pathogen Testing Technologies and the Market for Food Safety Information*, 7 AGBIOFORUM 212, 217 (2004), http://www.agbioforum.org/v7n4/v7n4a07-unnevehr.pdf (analyzing the supply and demand for "food safety information," advances in pathogen-testing technology, and how these changes affect the use of laboratory services by food companies).

[176] Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption; Proposed Rule, 78 Fed. Reg. at 3534; Final Draft PRIA, *supra* note 2, at 9-10 (identifying size thresholds for farms).

Double Counting in the Estimation of Worker-Monitoring Costs

The proposed rule requires management personnel to supervise the farm's operations to ensure compliance with the rule's requirements. The FDA estimates that farm supervisors would spend 9.93 minutes per worker per week monitoring workers' compliance with food safety training, adding up to a $79 million cost across all farms—the second-largest cost in the rule, behind the estimated cost of hand washing.[177]

In deriving that 9.93-minute figure, the FDA mistakenly relied on data that does not represent worker-monitoring costs at all. The figure is based on a study exploring the additional time that California farms spent on "field monitoring" after they joined the Leafy Green Marketing Agreement (LGMA), a food safety program with many similarities to the FDA's proposed rule.[178] The FDA assumed that "field monitoring" meant monitoring workers "for compliance with food safety training."[179] But in that study, it appears to refer to the activity of monitoring the fields themselves (*i.e.*, for evidence of animal intrusions), not watching workers in the fields.[180] **In fact, the FDA relied on these same "field monitoring" figures in estimating the costs of preventing contamination by animals (at an earlier point in the PRIA), so using them again here to estimate the cost of monitoring workers is double-counting of the same costs.**[181]

Without relevant data on how long it would take to monitor workers' compliance, the FDA should not estimate such a staggering cost for this provision. Indeed, it will likely be integrated into a farm's everyday activities at little extra cost—as the agency suggests in the text—since the workers are already being monitored for other purposes, like productivity.[182]

Other Costs Overestimated in the PRIA

It is worth pointing out at least two other sections of the PRIA that overstate the costs of the rule's standards.

The PRIA estimates that monitoring for animal intrusion will cost $37 million every year—$378 per very small farm, $1,260 per small farm, and $2,520 per large farm.[183] But the true costs of

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[177] Final Draft PRIA, *supra* note 2, at 272-74.

[178] SHERMAIN D. HARDESTY & YOKO KUSUNOSE, GROWERS' COMPLIANCE COSTS FOR THE LEAFY GREENS MARKETING AGREEMENT AND OTHER FOOD SAFETY PROGRAMS (2009), *available at* http://www.regulations.gov/contentStreamer?objectId=09000064811f34e0&disposition=attachment&contentType=pdf.

[179] Final Draft PRIA, *supra* note 2, at 272.

[180] The study asked growers, "How many hours per week were spent monitoring *fields*?" (emphasis added) and the authors also clarified that "[f]ield monitoring is carried out by general laborers, who are paid $11.39 per hour." (Monitoring workers for compliance with food safety training, on the other hand, would have to be performed by supervisors.) HARDESTY & KUSUNOSE, *supra* note 178, at 8, 16.

[181] *See* Final Draft PRIA, *supra* note 2, at 203.

[182] *Id.* at 274 ("Additionally, it is likely that these estimates may overstate the true burden that will be incurred by industry, as some of these costs could be absorbed in the everyday monitoring of manager on the farm, which are preformed currently.").

[183] *Id.* at 203.

the rule will likely be much smaller. These estimates were taken from the experience of farms that joined the LGMA, but on their face the animal-monitoring provisions in the LGMA are significantly more extensive than those under the proposed rule. The California LGMA requires "a *periodic* monitoring plan" including "Pre Season, Pre Harvest, and Harvest Assessments," while the FDA's proposed rule requires monitoring only "*as needed* during the growing season" and "immediately prior to harvest" (emphases added).[184] The FDA briefly acknowledges that its estimate may overstate the rule's costs "if the frequency of required monitoring in CA LGMA is greater than that implied in the proposed rule"—which is very likely true.[185] The FDA should consider adjusting its estimated cost to account for less frequent monitoring under the rule.

Finally, the total one-time and annual recordkeeping costs for biological soil amendments are each overestimated by $18,000: the wage rates used in the calculation had already been multiplied by 1.5 to account for overhead and fringe benefits, and by mistake the FDA multiplied them by 1.5 again.[186]

REGULATORY OPTIONS

The FDA Should Keep the Small-Farm Cutoff at $25,000

The FDA is proposing that farms with under $25,000 in annual sales not be covered under the rule, and the PRIA's estimates reflect this assumption. But the FDA is also considering other thresholds for this category: $50,000, $100,000, $250,000, and $500,000.[187]

Setting the Cutoff at $25,000 Is Most Consistent with the FSMA

Analysts from the George Washington University Regulatory Studies Center have urged the FDA to exempt all farms that have less than $100,000 in annual sales because that is the option that maximizes "net benefits" (benefits minus costs) according to the FDA's calculations.[188] The FDA estimates that the net benefits of the proposed option are $582 million, whereas the net benefits of raising the cutoff to $100,000 are $657 million (see Table 3).

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[184] *Compare* Calif. Leafy Green Prod. Handler Mktg. Agreement, Commodity Specific Food Safety Guidelines for the Production and Harvest of Lettuce and Leafy Greens 47, Aug. 4, 2010, http://www.regulations.gov/contentStreamer?objectId=09000064811efddf&disposition=attachment&contentType=pdf *with* Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption; Proposed Rule, 78 Fed. Reg. at 3638.

[185] Final Draft PRIA, *supra* note 2, at 203.

[186] Instead of using $47.40 for farm operators (for very small and small farms) and $30.26 for farm supervisors (for large farms), both of which had already been multiplied by 1.5 to account for fringe benefits and overhead costs—the FDA multiplies them again by 1.5 to obtain $71.10 and $45.39 respectively, unlike every other hourly-wage calculation in the PRIA. The FDA estimated one-time and annual recordkeeping costs of $53,556 each, and using the correct wage rates, each cost would instead be $35,303. *See id.* at 6, 195, 198.

[187] *Id.* at 52.

[188] Miller & West, *supra* note 3, at 6-8.

Table 3: FDA's Summary of Costs and Benefits for Different Small Farm Exclusions[189]

	< $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

However, in choosing to propose the $25,000 cutoff instead, the FDA looked not only to the final dollar figures, but also considered what they represent in terms of real-world impact. With the $100,000 cutoff, the public would suffer an estimated *99,000 additional foodborne illnesses per year* that could have been prevented with the lower cutoff. The agency concluded this was simply too great a cost to the public, as it explained in rejecting even a $50,000 cutoff.[190]

Agencies are not mathematically bound to pick the option with the highest net benefits. Former OIRA Administrator Cass Sunstein himself—one of the most prominent advocates for cost-benefit analysis—writes that "[c]ost-benefit analysis is not an algorithm, and it should not … put government in an arithmetic straightjacket."[191] Executive Order 12866 (reaffirmed in President Obama's E.O. 13563) directs agencies to choose regulatory alternatives that "maximize net benefits," but also carves out space for situations where "a statute requires another approach."[192]

The FSMA does not call for the use of a cost-benefit standard. Instead, the language of the statute compels the FDA to adopt the broadest available protections for produce safety ("*minimize the risk* of serious adverse health consequences or death"), as long as the costs are not excessive ("including [those] that the Secretary determines to be *reasonably necessary* to prevent the introduction of known or reasonably foreseeable … hazards").[193] The agency exercised sound judgment in concluding that the option that would prevent an additional 99,000 illnesses was most consistent with its statutory objective.

In addition, using our more comprehensive benefits estimations instead of the FDA's (see Table 4 below),[194] the number of preventable illnesses that would occur under the $100,000 cutoff

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[189] Final Draft PRIA, *supra* note 2, at 53 tbl.12.

[190] *See id.* at 52-53.

[191] CASS R. SUNSTEIN, SIMPLER 150 (2013).

[192] Exec. Order No. 12,866 § 1(a), 3 C.F.R. 638, 638 (1993), *reprinted as amended in* 5 U.S.C.A. § 601 note (West 2010), *available at* http://www.archives.gov/federal-register/executive-orders/pdf/12866.pdf.

[193] Food Safety Modernization Act, sec. 105(a), §§ 419(c)(1)(A), 124 Stat. at 3901 (emphasis added).

[194] These ranges were calculated by repeatedly following the steps given in Appendix A, each time changing the "percentage of acreage exempt from the rule" to correspond with the values given in Table 3 above.

would be between 101,000 and 326,000—potentially three times what the FDA estimated (99,000 illnesses).[195] And the $100,000 cutoff would no longer maximize "net benefits"; instead, the greatest net benefits would be realized with the $25,000 cutoff, at least toward the upper end of our suggested range of benefits. (And considering that the rule has many benefits that even our upper-bound estimate does not account for, it makes sense to assume that the benefits will veer close to this end of the range.)

Most important, though, is that, for *all* these options, the rule's benefits exceed its costs by an enormous amount. Thus, the FDA should choose the option that is most protective of the public health—the $25,000 cutoff—confident that it best fulfills the FSMA's mandate to "minimize the risk" at a reasonable cost.

Table 4: Our Suggested Range of Benefits for Different Small Farm Exclusions*

(The option with the maximum net benefits is shaded dark for both the lower and upper bounds)	< $25K	< $50K	< $100K	< $250K	< $500K
Lower Bound Benefits - Using FDA Outbreak Database and Illness Costs from Scharff					
Prevented Illnesses (in millions) **	1.77	1.73	1.67	1.57	1.45
Additional Illnesses not covered	-	47,487	53,681	101,167	119,749
Total Domestic Benefits (in millions)	$2,904	$2,827	$2,739	$2,573	$2,377
Total Domestic Costs (in millions)	$460	$348	$316	$282	$234
Net Domestic Benefits (in millions)	$2,444	$2,479	$2,423	$2,291	$2,143
Upper Bound Benefits – Using Attribution Data from Batz et al. and Illness Costs from Scharff					
Prevented Illnesses (in millions)	5.72	5.57	5.39	5.07	4.68
Additional Illnesses not covered	-	153,187	173,168	326,356	386,299
Total Domestic Benefits (in millions)	$6,684	$6,505	$6,303	$5,921	$5,470
Total Domestic Costs (in millions)	$460	$348	$316	$282	$234
Net Domestic Benefits (in millions)	$6,224	$6,157	$5,987	$5,639	$5,236

* We have not supplied alternative estimates for the "Total Domestic Costs" estimated in the PRIA, even though (as we explained above) they overestimate the true costs of the proposed rule in many ways. As a result, the net benefits here actually underestimate the extent by which the rule's benefits exceed its costs—the actual net benefits would be significantly greater, both because the costs would be lower and the benefits would incorporate impacts we could not estimate here (additional avoided costs associated with foodborne illness, plus other kinds of benefits including the avoided cost of recalls, avoided legal costs, etc.).
** The reason that we estimate more prevented illnesses than the FDA does in Table 3 above, even though we base these lower-bound benefits on FDA's outbreak database, is that these figures incorporate the fixed numbers for illnesses due to fresh-cut produce, whereas the numbers in the FDA's table include those erroneous figures.[196]

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[195] To estimate the additional illnesses that would arise under the $100,000 cutoff, add together the "additional illnesses not covered" in the $50,000 and $100,000 columns.
[196] *See* notes 30-32 *supra* and accompanying text.

The Proposed Rule Already Provides Sufficient Flexibility to Small Businesses

The FSMA also requires the FDA to "provide sufficient flexibility to be practicable" for all sizes and types of businesses—and this is exactly what the proposed rule already does.[197] The rule provides a number of exemptions and special provisions that ease burdens on certain small and low-risk farms. It exempts:

- Produce that is rarely consumed raw;[198]
- Produce that is destined for further processing certain to kill pathogens;[199] and
- Farms with annual sales less than $500,000 where more than half is from direct sales to consumers or to local restaurants and retailers (in the same state or within 275 miles).[200]

That last exemption, inserted into the statute itself by the Tester amendment, is protective of small farms but also includes direct-marketing constraints that can arguably be tied to public health concerns, however weakly. By limiting the exemption to farms with a strong local sales presence, it seeks to limit the geographical scope of any outbreaks caused by exempt produce, which could then be more easily traced than a multistate outbreak (supposedly).[201] Also, it assumes that the community ties between the farm and its local customers would have a positive influence on the farm's food safety practices, which might be absent with long-distance business relationships.[202] Finally, it furthers a policy of promoting locally grown food, which is seen as beneficial to the economy, the environment, and the quality of the food. On the other hand, raising the threshold for the blanket small-farm exemption beyond $25,000 would exclude many more farms from the rule's coverage but with none of the attendant public-health considerations that theoretically help to justify the statutory exemption.

With all these provisions combined, *79 percent* of all U.S. farms are already exempt from the rule's substantive requirements. (The remaining 21 percent of farms that are covered under the rule represent 86 percent of acres used for growing produce that may be consumed raw and is not destined for kill-step processing.)[203] If the "small-farm" threshold were raised to a level between $50,000 and $500,000, *between 85 percent and 96 percent* of all farms would be exempt—the exemption would truly swallow the rule.[204]

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[197] Food Safety Modernization Act, sec. 105(a), § 419(c)(1)(B), 124 Stat. at 3901.

[198] Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption; Proposed Rule, 78 Fed. Reg. at 3630.

[199] *Id.*

[200] *Id.* at 3632; Food Safety Modernization Act, sec. 105(a), § 419(f), 124 Stat. at 3903-04.

[201] *But see Powerful Coalition Gains Exemption for Small Farmers*, THE CARNEGIE-KNIGHT NEWS21 PROGRAM, Nov. 18, 2011, http://www.foodsafetynews.com/2011/11/powerful-coalition-gains-exemption-for-small-farmers ("[C]onsumer advocates point out that exempted small farms can still sell almost half of what they produce to large distributors – food that can wind up reaching a lot of people. '…. It's a loophole that is going to come back and harm small producers in the long run,' said Bill Marler.").

[202] *But see id.* ("'There's no scientific basis for Tester," said David Plunkett, senior staff attorney for the Center for Science in the Public Interest …. It's an accommodation so that the bill would be able to make its way through the Senate and the Congress and get to the president's desk.'").

[203] Final Draft PRIA, *supra* note 2, at 18-19.

[204] Subtracting the number of covered farms for each cutoff gives the number of exempt farms, which can then be divided by the number of U.S. farms (189,637) for the percentage of farms that would be exempt. *See id.* at 18, 53.

The proposed rule also delays the compliance deadlines for small farms: those with less than $250,000 in annual sales would have four years after the rule's effective date, and farms with between $250,000 and $500,000 in sales would have three years (larger farms would have two years). These delays extend to the agricultural-water standards as well, which begin to apply two years later for each size category.[205]

<u>Small-Farm Concerns May Reflect Uncertainty More Than the Rule's Actual Impact</u>

Despite these broad exemptions and delays, small farmers and their advocacy organizations have mostly opposed the rule, often vigorously, claiming that it would put an undue strain on small-scale, local farms and put many out of business.[206] However, an analysis conducted in the spring of 2013 by Michael Bulger, then a graduate student in New York University's Food Studies program, suggests that much of the opposition from small farmers appears to be due to confusion over just how broad these exemptions already are, or overreaction to the rule's requirements (see Appendix B).[207] He surveyed 134 produce farmers, collecting information about their size and marketing characteristics, their awareness of the rule, their sense of preparedness, their current level of compliance with the proposed requirements, and their general attitudes toward the rule.

Forty-eight farmers left comments about the rule, only two of which were positive and 22 of which were negative (others were not classifiable by attitude). Some farmers claimed in their comments that the rule would damage them or put them out of business, even though Bulger later determined they would actually be exempt from the rule.[208] These kinds of misunderstandings may be responsible, at least in part, for the overwhelmingly hostile response to the rule seen at the FDA's public meetings—like the one in Maine, where the state's own agriculture department estimates that only a very small percentage of farmers would be subject to the rule, and yet the testimony of many local farmers was "decidedly negative."[209]

One of the requirements most often complained about, in the Bulger survey and at the public meetings, is the expense of testing water, which as we explained above, will not be anywhere near as onerous as some farmers believe. Instead of simply exempting more farms, the FDA should respond to these concerns by intensifying its outreach efforts, clarifying points of confusion, and adjusting its cost estimates to better reflect the rule's true impact.

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[205] Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption; Proposed Rule, 78 Fed. Reg. at 3533-34.
[206] *See, e.g.,* Emily Corwin, *Small Farmers In New England Fear New Food Safety Rules*, NPR Blog: The Salt (Sep. 4, 2013), http://www.npr.org/blogs/thesalt/2013/09/04/218642746/small-farmers-in-new-england-fear-new-food-safety-rules; Farm & Ranch Freedom Alliance, Thirty-Nine Organizations Urge Congress to Protect Farmers from New Regulations, Aug. 26, 2013, http://farmandranchfreedom.org/support-benishek-provision-2013-farm-bill; Holly Ramer, *Small Farmers: Rules Could Halt Local Food Trend*, ASSOCIATED PRESS, Aug. 25, 2013, http://www.apnewsarchive.com/2013/Small_farmers%3A_Rules_could_halt_local_food_trend/id-e2664c9239ec4f31a501fc43bd9580a8.
[207] Bulger, *supra* note 22.
[208] *Id.* at e.
[209] *New England Farmers Don't Much Care for Produce Rule*, FOOD SAFETY NEWS, Aug. 22, 2013, http://www.foodsafetynews.com/2013/08/new-englands-growers-dont-like-produce-rule.

Another reason the FDA should not raise the cutoff is that small farms may actually be less likely than large farms to already comply with food safety practices in the absence of regulation. In Bulger's survey, the largest farms earned the highest mean safety score, while those that were exempt under the Tester amendment had lower average safety scores compared to those covered under the rule.[210] Perhaps this is because large farms often sell to large commercial buyers that require food safety audits, or they have greater incentives and resources to invest in food safety to prevent widespread outbreaks. Whatever the reason, expanding the blanket exemption might remove from the rule's coverage precisely those farms whose practices would be most improved by the proposed standards.

The Equipment, Tools, Buildings, and Sanitation Standards Are Essential

The analysts from the GWU Regulatory Studies Center (RSC) have also urged the FDA to drop the standards related to equipment, tools, buildings, and sanitation (ETBS).[211] Among other things, these standards specify that tools and equipment must be designed so they can be cleaned, and must be kept clean, if they are likely to be in contact with produce; thermometers must be accurate and well-maintained; buildings must be properly constructed to facilitate sanitary operations; and farms must provide clean, readily accessible toilet and hand-washing facilities for workers, as well as protect produce from contaminating pests.[212]

The RSC analysts want these standards eliminated because they are supposedly the "least cost-effective" standards in the rule: the ETBS standards make up 22 percent of the rule's total pathway costs but, according to a table in the PRIA, they reduce the risk of contamination by only 6.73 percent.[213]

However, the FDA itself acknowledges that the figures in this table underestimate the risks from dirty tools, equipment, and buildings due to biases and limitations in the FDA's outbreak database.[214] In an alternative analysis, the FDA looked only at outbreaks from 1990 to 2009 to get a more contemporary view (the previous data went back to 1971). This time, ETBS problems were responsible for more outbreaks than any other contamination pathway, except for worker health and hygiene.[215]

But most importantly, both timespans leave out perhaps the biggest equipment-related produce outbreak in history: the 2011 outbreak caused by *Listeria*-tainted cantaloupes that killed up to 43

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[210] Bulger, *supra* note 22, at d-e.

[211] Miller & West, *supra* note 3, at 12-13, 17-18.

[212] Final Draft PRIA, *supra* note 2, at 211-12.

[213] *See id.* at 78; Miller & West, *supra* note 3, at 12 tbl.

[214] The FDA examined outbreak data from 1971 to 2009 to determine how often ETBS problems played a role in produce contamination. But the FDA explains that the number of outbreaks linked to ETBS problems is likely "biased" for several reasons. These problems are often found in outbreaks where other pathways of contamination played a role as well, forcing the illnesses to be split among the different pathways and lowering the share of illnesses attributable to ETBS issues. Also, ETBS problems may have been incorrectly attributed to another pathway, like worker health and hygiene: "It could be that a worker improperly washes their hands or tools because reasonable accommodations were not provided; however, when this outbreaks [*sic*] is recorded, only worker contact is cited as a contamination pathway." Final Draft PRIA, *supra* note 2, at 73-74 n.17.

[215] *See id.* at 97-98.

people.[216] In its investigation, the FDA identified many aspects of poor facility design and unsanitary equipment that were likely causes of the contamination, including a dripping condensation line that allowed *Listeria*-contaminated water to pool on the floor of the packing facility (which was inaccessible for cleaning), un-cleanable pieces of equipment, dirt buildup and corrosion, and a potato-washer used inappropriately for cleaning melons.[217]

The ETBS standards are an absolutely essential component of the FDA's proposed rule, and they should not be eliminated based on a dubious, misleading assessment of their costs and benefits.

CONCLUSION

We have confidence in the FDA's intention to issue a set of stringent standards that will substantially improve food safety practices on produce farms and better protect the American public from the devastating effects and complications of foodborne illness.

But as we have demonstrated, the PRIA—even as it concludes that the rule's benefits exceed its costs—suffers from significant errors, omissions, and false assumptions that sell the rule short, underestimating its benefits and overstating its costs. By misrepresenting the rule's impacts, these distortions help to fuel needless negativity towards the rule, from members of Congress, produce-industry associations, and farmers themselves.

The FDA should remedy these flaws in the RIA that accompanies the final rule and discuss qualitatively any impacts that could not be incorporated into the agency's numerical estimates. More generally, we urge the agency to issue as soon as possible a strong final rule that minimizes the risk of human illness, consistent with its statutory mandate. To that end, the final rule should include at least all the standards described in the proposed rule and should not expand the exemptions beyond what has already been proposed.

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[216] *See* Dan Flynn, *Letter from the Editor: Cause(s) of Death*, FOOD SAFETY NEWS, Oct. 27, 2013, http://www.foodsafetynews.com/2013/10/letter-from-the-editor-causes-of-death (explaining why the death toll for the *Listeria* outbreak is actually 43 instead of the 33 officially reported by the CDC).
[217] FDA Cantaloupe Outbreak Assessment, *supra* note 23.

APPENDIX A: ALTERNATIVE BENEFITS ESTIMATIONS

The following sections demonstrate how we calculated the alternative benefits (cost of illnesses avoided under the rule) given in previous sections of this comment.

Fixing the Estimated Number of Illnesses Due to Fresh-Cut Produce

The number of illnesses estimated to be caused by "fresh-cut produce" (753,958) is artificially low because it relies on erroneous values for CDC-reported illnesses. For each pathogen, the PRIA gives a value for the total number of illnesses (regardless of the source) reported to the CDC between 2003 and 2008—for example, there were 2,452 identified cases of *E. Coli* O157:H7 and 14,709 identified cases of *Salmonella* during this period.[218] Throughout the document, these same numbers are used whenever the FDA attempts to estimate the percentage of reported illnesses caused by certain kinds of produce—*except* in the estimation for fresh-cut produce. Here, the FDA inexplicably uses different values in the "Identified Cases" column: more than 3,000 cases of *E. Coli* O157:H7, and almost 19,000 cases of *Salmonella*.[219] **Using the correct values, this calculation shows that fresh-cut produce is responsible for an extra 37,000 illnesses per year. See Table 5 below.**

Table 5: Estimated Number of Illnesses Attributable to Fresh-Cut Produce (Fixing Errors in FDA's Version of the Table)[220]

Agent	FDA Fresh Cut (2003-2008)	Identified Cases (2003-2008)	Percentage Attributable to Fresh Cut	Scallan, et al. Estimated Annual Foodborne Illnesses	Estimated Illnesses Attributable to Fresh Cut
E. Coli O157:H7	599	~~3,283~~ 2,452	~~18.25%~~ 24.43%	69,972	~~11,978~~ 17,093
Salmonella	846	~~18,836~~ 14,709	~~4.49%~~ 5.75%	1,072,450	~~48,168~~ 61,683
Total Identified	1,445	79,347	1.82%		
Unidentified[221]			1.82%	39,099,360	~~693,812~~ 712,044
TOTAL					~~753,958~~ **790,820**

The difference between this new total (790,820) and the FDA's original total (753,958) is approximately **37,000 illnesses**.

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[218] Final Draft PRIA, *supra* note 2, at 371 tbl.138.

[219] *Compare id.* at 63 tbl.17 (raw produce other than sprouts) *and id.* at 65 tbl.19 (sprouts) *with id.* at 64 tbl.18 (fresh-cut produce).

[220] The original table is taken from the PRIA itself. *Id.* at 64 tbl.18.

[221] For an explanation of why this row also needed a correction, *see* note 31 *supra*.

Calculating the Benefits after Correcting (1) Fresh-Cut Figures and (2) Deaths due to Unidentified Pathogens

Multiplying the death rate for unidentified pathogens (0.00439%)[222] by the value of a statistical life (VSL) used by the FDA ($7.9 million)[223] results in a weighted cost of death per unidentified illness of $347. Adding this to the FDA's "total expected loss per case" for an unidentified pathogen ($214, which only incorporates the reductions in quality of life from either a hospitalized or non-hospitalized gastrointestinal illness) produces a total cost per case for unidentified pathogens of $561, shown in the table below.

After combining both the corrected figures for fresh-cut produce and the deaths due to unidentified pathogens, the benefits of the rule rise to $1.66 billion—a 60-percent increase over the PRIA's estimate. See Table 6 below.

Table 6: Calculating Illnesses from Produce, after Fixing Fresh-Cut Figures and Deaths from Unidentified Pathogens[224]

Pathogen	FDA's Dollar Loss per Case	Burden of Illnesses due to Raw Agricultural Commodities (RACs) Other Than Sprouts		Burden of Illnesses due to Fresh-Cut Produce, After Fixing Erroneous Figures in PRIA		Burden of Illnesses Due to Sprouts	
		Attributable illnesses	Dollar Burden	Attributable illnesses	Dollar Burden	Attributable illnesses	Dollar Burden
Cyclospora	$1,889	13,482	$25,467,498				
E. coli O157:H7	$7,547	3,539	$26,708,833	17,093	$129,000,871	338	$2,550,886
Hepatitis A	$39,195	1,409	$55,225,755				
Salmonella	$4,622	167,914	$776,098,508	61,683	$285,098,826	7,364	$34,036,408
Shigella sonnei	$2,066	12,934	$26,721,644				
Unidentified	~~$214~~ $561	2,115,437	$1,186,760,157	712,044	$399,456,684	74,407	$41,742,327
SUMS		2,314,715	$2,096,982,395	790,820	$813,556,381	82,109	$78,329,621

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[222] *See* Scallan et al., *supra* note 34, at 20 tbl. (estimating 1,686 deaths out of 38,392,704 illnesses due to unidentified pathogens).
[223] Final Draft PRIA, *supra* note 2, at 382.
[224] The numbers in this table are taken from Tables 17-19 on pages 63-65 of the PRIA, except where they have been corrected.

A = Total Number of Illnesses Due to Produce = (# from RACs other than sprouts) + (# from fresh-cut) + (# from sprouts) = 3,187,644
B = Total Cost of Illnesses Due to Produce = ($ from RACs other than sprouts) + ($ from fresh-cut) + ($ from sprouts) = $2,988,868,397
C = Average Cost per Illness = B / A = $938
D = Percentage of Acreage Exempt from the Rule = 14.1% [225]
E = Number of Illnesses Attributed to Covered Farms = A * (1 – D) = 2,738,186
F = Cost of Illnesses Attributed to Covered Farms = B * (1 – D) = $2,567,437,953

G = Number of Illnesses Prevented = E * (64.77% effectiveness) = 1,773,523
H = **Total Benefits** = G * C = **$1,662,929,562**

These benefits ($1,662.93 million) represent a 60-percent increase over the FDA's estimated benefits ($1,036.40 million).

Calculating the Benefits Using More Comprehensive Cost-per-Illness Figures from Scharff

Scharff used different values than the FDA for the "value of a statistical life" (VSL) and "value of a statistical life-year" (VSLY), so we adjusted the Scharff cost estimates so they would reflect the values selected by the FDA:

- Adjusting the VSL: For each pathogen, we multiplied the "Death (VSL)" portion of the Scharff estimate (representing the weighted cost of death per case)[226] by the ratio of the FDA's VSL ($7.9 million) to Scharff's VSL ($7.33 million).[227]

- Adjusting the VSLY: For each pathogen, we multiplied the "Quality of Life" portion of the Scharff estimate (representing lost quality-adjusted life years (QALYs)) by the ratio of the FDA's VSLY ($214,000) to Scharff's VSLY ($356,500).[228]

Then, for each pathogen, we added together the relevant components of Scharff's estimated cost using these adjusted figures.[229]

Using these more comprehensive estimates for the cost of an illness, the benefits of avoiding illnesses under the produce rule would be $2.90 billion—a 180% increase over the FDA's original estimated benefits. See Table 7 below.

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[225] The proposed rule would exempt 14.1% of acreage, assuming that the small-farm exclusion cutoff is set at $25,000. Final Draft PRIA, *supra* note 2, at 79.
[226] This portion is listed separately in Table 2 of Scharff's study. *See* Scharff, *supra* note 14, at 126 tbl.2.
[227] *Compare* Scharff Appendix, *supra* note 70, at 6-7 (VSL of $7.33 million) *with* Final Draft PRIA, *supra* note 2, at 382 (VSL of $7.9 million).
[228] *Compare* Scharff Appendix, *supra* note 70, at 6-7 (VSLY of $356,500) *with* Final Draft PRIA, *supra* note 2, at 382 (VSLY of $214,000).
[229] To obtain the resulting QALY estimate, we added together the following components: "Medical Care," "Caregiver productivity loss," Qualify of Life," and "Death (VSL)." This is consistent with Scharff's method of estimating the cost-per-illness under his "enhanced model." *See* Scharff, *supra* note 14, at 125-26.

Table 7: Calculating Illnesses from Produce, Using Cost-Per-Illness Figures from Scharff[230]

Pathogen	FDA's Dollar Loss per Case	Scharff Dollar Loss Per Case	Scharff Dollar Loss Per Case (with FDA's VSL/VSLY)	Burden of Illnesses due to Raw Agricultural Commodities (RACs) Other Than Sprouts (using costs from shaded column)		Burden of Illnesses due to Fresh-Cut Produce, After Fixing Erroneous Figures in PRIA (using costs from shaded column)		Burden of Illnesses Due to Sprouts (using costs from shaded column)	
				Illnesses	Dollar Burden	Illnesses	Dollar Burden	Illnesses	Dollar Burden
Cyclospora	$1,889	$1,483	$1,097	13,482	$14,789,350				
E. coli O157:H7	$7,547	$10,048	$10,339	3,539	$36,588,748	17,093	$176,719,828	338	$3,494,489
Hepatitis A	$39,195	$37,073	$38,788	1,409	$54,652,576				
Salmonella	$4,622	$11,086	$8,330	167,914	$1,398,797,741	61,683	$513,846,618	7,364	$61,345,371
Shigella sonnei	$2,066	$9,551	$6,300	12,934	$81,478,464				
Unidentified	~~$214~~ $561	$1,178	$992	2,115,437	$2,098,518,085	712,044	$706,349,190	74,407	$73,811,905
SUMS				2,314,715	$3,684,824,964	790,820	$1,396,915,636	82,109	$138,651,765

A = **Total Number of Illnesses Due to Produce** = (# from RACs other than sprouts) + (# from fresh-cut) + (# from sprouts) = **3,187,644**
B = Total Cost of Illnesses Due to Produce = ($ from RACs other than sprouts) + ($ from fresh-cut) + ($ from sprouts) = $5,220,392,364
C = Average Cost per Illness = B / A = $1,638
D = Percentage of Acreage Exempt from the Rule = 14.1%
E = Number of Illnesses Attributed to Covered Farms = A * (1 – D) = 2,738,186
F = Cost of Illnesses Attributed to Covered Farms = B * (1 – D) = $4,484,317,041

G = **Number of Illnesses Prevented** = E * (64.77% effectiveness) = **1,773,523**
H = **Total Benefits** = G * C = **$2,904,492,148**

These benefits ($2,904,492,148) represent a 180-percent increase over the FDA's estimated benefits ($1,036.40 million).

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[230] The numbers in this table are taken from Tables 17-19 on pages 63-65 of the PRIA, except where they have been taken from Scharff's study and modified.

Calculating the Benefits Using Both (1) Cost Figures from Scharff and (2) Attribution Data from Batz et al.

The study by Batz et al. includes estimations of the proportion of various foodborne illnesses caused by produce. Because the study relies on the CDC's more comprehensive Foodborne Outbreak Online Database (FOOD) database instead of the FDA's database (representing only those outbreaks investigated by the agency), and perhaps also because it covers a broader time period (1999-2008, compared to the FDA's 2003-2008), it attributes produce-related illnesses to a much larger variety of pathogens than the FDA. Also, Batz et al. did estimate their own cost-per-illness figures, but they used a "cost of illness" approach that included only medical costs and lost productivity costs, consistent with the approach used by the USDA's Economic Research Service.[231] We chose instead to use the cost figures from Scharff, which were based on monetized reductions in quality of life, the same approach used by the FDA here.

Where Batz et al. determined that the CDC outbreak data are not representative of the proportion of illnesses caused by a certain pathogen, they relied on expert elicitation. The percentages given for "Batz" in Table 8 below reflect the attribution choices made by Batz et al. in the study: They represent expert estimates for *Campylobacter*, *Cryptosporidium*, *Toxiplasma*, and *Yersinia* only.[232]

Batz et al. did not estimate the percentage of unidentified-pathogen illnesses attributable to produce, so we followed the FDA's approach by assuming that the share of unidentified-pathogen cases attributable to produce is the same as the share of all identified-pathogen cases attributable to produce. Batz and his colleagues only gathered attribution data for 12 or 13 pathogens, not the universe of all identified pathogens, so they did not come up with a total number of produce-related illnesses due to all identified pathogens. We used the attribution percentage estimated by the Center for Science in the Public Interest, which found that 23.7 percent of all identified illnesses (those with an identified pathogen and an identified food vehicle) in the CDC database were linked to produce between 2001 and 2010.[233] Thus, we assumed that produce was also responsible for 23.7 percent of all unidentified-pathogen illnesses. This likely underestimates the actual proportion because it excludes outbreaks linked to multi-ingredient foods that may have been caused by produce ingredients (*e.g.*, salads, sandwiches) and outbreaks linked to nuts (which are covered under the produce rule).

When combined with the cost-per-illness figures taken from Scharff (see Table 7 above), these estimates would yield $6.68 billion in benefits—over six times the PRIA's original estimate. See Table 8.

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[231] *See* Batz Report, *supra* note 99, at 26.

[232] *See* Batz Journal Study, *supra* note 15, at 1283 (listing the attribution choices made by the authors of the study).

[233] CAROLINE SMITH DEWAAL & MARCUS GLASSMAN, *supra* note 89, at 14 (produce linked to 25,222 illnesses out of 106,635 total identified illnesses). This is also consistent with an earlier study by Scharff, where he found that "roughly one quarter" of illnesses were linked to produce between 2003 and 2007—a time period very similar to the one used by the FDA. ROBERT L. SCHARFF, HEALTH-RELATED COSTS FROM FOODBORNE ILLNESS IN THE UNITED STATES 10 (2010), *available at* http://www.pewhealth.org/uploadedFiles/PHG/Content_Level_Pages/Reports/PSP-Scharff%20v9.pdf.

Table 8: Calculating Illnesses from Produce, Using Cost Figures from Scharff and Attribution Data from Batz et al.*

Pathogen	FDA: % Illnesses Due to Produce[234]	Batz: % Illnesses Due to Produce[235]	Scallan: Estimated Annual Foodborne Illnesses[236]	Estimated Annual Foodborne Illnesses Due to Produce (Shaded Entry * Scallan)	Scharff Dollar Loss Per Case (with FDA's VSL/VSLY)	Dollar Burden of Illnesses due to Produce (previous two columns multiplied together)
Campylobacter		5.2%	845,024	43,941	$5,488	$241,149,569
C. perfringens		3.0%	965,958	28,979	$433	$12,549,570
Cryptosporidium		59.5%	57,616	34,282	$2,323	$79,643,011
Cyclospora	96.95%	78.6%	11,407	8,966	$1,097	$9,835,326
E. coli non-O157 STEC		13.3%	112,752	14,996	$1,019	$15,282,925
E. coli O157:H7	32.06%	18.2%	63,153	11,494	$10,339	$118,831,714
Hepatitis A	84.62%	--	1,566	1,325	$38,788	$51,401,654
Listeria		5.0%	1,591	80	$1,354,950	$107,786,264
Norovirus		15.6%	5,461,731	852,030	$583	$496,819,963
Salmonella	22.10%	17.6%	1,027,561	180,851	$8,330	$1,506,566,462
Shigella sonnei	8.40%	12.2%	131,254	16,013	$6,300	$100,874,723
Toxoplasma gondii		7.0%	86,686	6,068	$39,319	$238,585,980
Yersinia enterocolitica		3.2%	97,656	3,125	$8,255	$25,797,156
Unidentified**	7.44%	23.7%	38,392,704	9,080,891	$992	$9,008,263,244
SUMS				10,283,039		$12,013,387,559

* Batz et al. did not estimate the percentage of Hepatitis A infections attributable to produce, so for this pathogen we used the FDA's estimated percentage.

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[234] The FDA percentages (presented here for comparison purposes) were derived by adding together the percentages for each pathogen given in Tables 17-19 on pages 63-65 of the PRIA.

[235] *See* Batz Journal Study, *supra* note 15, at 1282-83 tbls.3-5 (presenting attribution percentages for produce).

[236] *See* Elaine Scallan et al., *Foodborne Illness Acquired in the United States—Major Pathogens*, 17 EMERGING INFEC. DISEASES 7, 11 tbl.2 (2011), *available at* http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3375761/pdf/09-1101p1_finalR.pdf (estimated annual illnesses for all the identified pathogens); Scallan et al., *supra* note 34, at 20 tbl. (38,392,704 illnesses due to unspecified agents).

A = **Total Number of Illnesses Due to Produce** = (# from RACs other than sprouts) + (# from fresh-cut) + (# from sprouts) = **10,283,039**
B = Total Cost of Illnesses Due to Produce = ($ from RACs other than sprouts) + ($ from fresh-cut) + ($ from sprouts) = $12,013,387,559
C = Average Cost per Illness = B / A = $1,168
D = Percentage of Acreage Exempt from the Rule = 14.1%
E = Number of Illnesses Attributed to Covered Farms = A * (1 – D) = 8,833,131
F = Cost of Illnesses Attributed to Covered Farms = B * (1 – D) = $10,319,499,913

G = **Number of Illnesses Prevented** = E * (64.77% effectiveness) = **5,721,219**
H = **Total Benefits** = G * C = **$6,683,940,094**

These benefits ($6,683.94 million) are 6.45 times as large as the FDA's estimated benefits ($1,036.40 million).

APPENDIX B: EXCERPT FROM UNPUBLISHED M.A. THESIS BY MICHAEL BULGER

Produce Safety: Regulations, Local Food Systems, and the Tester Amendment

(Unpublished M.A. Thesis by Michael Bulger,
New York University, May 14, 2013)

<u>Appendix B</u>

To gain a better picture of the readiness, attitudes, and perceptions of farmers, I conducted an online survey. Through this survey, I sought to assess whether farm safety practices were associated with farm size or exemption eligibility. I was also interested in any relationships that might be found between farm safety, awareness of proposed rules, self-assessed preparedness, and attitudes towards FSMA.

Methods

Invitations and a link to the survey were sent to farmers through a number of different online methods. With the encouragement of GrowNYC, operator of New York City's Greenmarkets, personal invitations to participate in the survey were sent to GrowNYC's associated farmers. Notice of the survey was published online by the Cornell Small Farms Program, Food Safety News, and other websites. The survey was also publicized on Twitter and through the Tufts administrated listserv known as Comfood. All invitations and notices, as well as the survey instrument itself, encouraged farmers and others to pass the survey along. In this way, sampling snowballed beyond my initial outreach, and the full range of the survey's distribution is not known.

After the survey had been completed, farms were grouped into five categories based on commonly used USDA size classes.[1] Farm size was measured as a function of total annual sales. Very small farms generated up to $10,000 in sales, while very

large farms farms had sales of $500,000 or more. Table 1.1. explains farm size

grouping.

Table 1.1. Sales-based Farm Sizes

Annual Sales (in dollars)	Farm Size
0 - 9,999	Very Small
10,000 - 99,999	Small
100,000 - 249,999	Medium
250,000 - 499,999	Large
500,000 and above	Very Large

Each farmer answered a series of questions designed to reflect minimum

science-based standards put forth by FDA. Questions were grouped in categories

matching the proposed rule's subsections, and covered equipment, tools, and buildings,

biological soil amendments, domesticated and wild animals, personnel and hygiene,

agricultural water, and the production of sprouts. Respondents' scores were individually

aggregated into functions of 0 to 100. Answering all applicable questions in a manner

suggesting full compliance with the proposed rules would earn a respondent a perfect

score of 100.

Awareness and self-assessed preparedness were measured along Likert scales

and results were treated as ordinal data. Farmers were also provided an open comment

section upon completion of the survey. The space was made available so that they

might freely express any additional points of view, concerns, or other information. Forty-eight respondents elected to leave comments. Each individual comment was later categorized as one of the following three: positive in attitude towards the rules, negative or concerned about the rules, or not classifiable by attitude.

Results

One hundred and thirty-four produce farmers completed the survey. The mean reported monetary value of annual sales was $183,906. The median sales was $22,500, thus indicating that most farmers who responded were below the mean annual sales. The largest farm reported annual sales of $6 million, while over 30 farms reported annual sales of $5,000 or below.

Almost half of farms for whom size was known were small or very small. Thirteen farms were of medium size, and the remaining two categories each contained 12 farms. Sixteen farms did not provide an annual sales figure of $1,000 or more. Missing figures or very low figures were excluded from analysis based on size.

Based on reported farm size and marketing characteristics, 77% of farms surveyed are exempt from the produce rules. Approximately 12% of farms are covered by the rules, and the remaining 10% of farms did not provide enough information to determine if they qualify for exemptions. The Tester amendment exempts 71% of those surveyed, while 46% of those surveyed would be exempt due to annual sales totaling less than $25,000. There is considerable overlap between farms exempted by the

Tester amendment and farms under $25,000 in sales. Only three farms indicated that they do not grow produce other than exempted low-risk produce.

Slightly more farmers reported that they were unprepared to meet new standards, as opposed to prepared to meet new standards. About half of all respondents reported that they were not sure of their farms preparedness. Lack of awareness of the rules and the exemptions was most likely a contributing factor to farmer uncertainty. Most farmers indicated that they were either not aware or somewhat aware of the rules and exemptions. Less than 20% of farmers reported being very aware of the rules and exemptions.

Forty percent of farmers believed they were already in compliance with the proposed safety rules. Among those who did not believe they were compliant, the majority felt that compliance would take them between one and three years to achieve. Over one-third of farmers not yet in compliance reported that they were unsure of how much it would cost to bring their farm into compliance. Other farmers volunteered cost estimations ranging from $100 to $150,000.

The mean safety rating for farms was 80.9, with a median of 78.4. Out of the 134 farms surveyed, 29 received a perfect 100 safety rating. Safety ratings of 50 or below were observed with 11 farms. The highest mean safety score was observed in the very large farm group. At a 90% confidence level, very large farms were significantly safer than very small and medium farms. However, differences between very large farms and small or large farms did not reach statistical significance. There appeared to be no clear relationship between safety and farm size below the very large level. Additionally, raising the confidence level to 95% erased all significance between the groups.

Farms that were determined to be exempt from the safety rules had a lower mean safety rating than non-exempt farms. Once again, the statistical significance of these findings was erased at the 95% confidence level. Lower average safety ratings were observed on farms who earned exemptions based solely on the Tester amendment when compared to farms covered by the rule. This difference was statistically significant at very high level of confidence.

When compared to farmers who reported being mostly aware or very aware, farmers that reported that they were not aware of the rules were more likely to receive lower safety ratings. Significantly higher mean safety ratings were found on farms that were very aware of the exemptions when compared to farms that were not aware. Self-reported preparedness was also positively associated with safety ratings.

Forty-eight farmers left open comments, of which only two could be classified as overtly positive towards the rules. Comments featuring negative attitudes towards FSMA or concerns about its effects were more common. In total, 22 farmers expressed some degree of negativity or concern towards the new rules. These negative comments included farmers who felt that new rules would force them out of business. Multiple farmers pointed to animal exclusion and expensive water testing as examples of unreasonable burdens they believed were included in the rules. Although one farmer commented that no farms should be exempt, the majority of negative comments that involved farm size were defensive of small farms. Several negative comments came from farmers exempt from the rules who nonetheless asserted that they would be unable able to comply and would be damaged or put out-of-business.

Discussion

Farms size distribution in these results do not reflect the national distribution of produce farm sizes as reported by the 2007 Census of Agriculture.[2] Small and very small farms were overrepresented in this survey, so caution should be used when extrapolating the results. Based on reported FDA estimates, farms covered by the proposed rules were underrepresented in this survey.[3]

Over half of surveyed farms that receive an exemption do so because of annual sales that total less than $25,000. There was a significant difference in safety ratings between farms exempted solely under the Tester amendment and covered farms. While the historically low incidences of reported illnesses associated with these farms suggest that safety ratings or compliance might not accurately convey risk, the differences in practices suggest the need to further research and advocate local food system farm safety.

The high average safety ratings of all farms surveyed reflect the proactive attitude that produce farmers have taken in the absence of specific federal safety minimums. An imperfect safety rating in this survey does not necessarily connote increased risk. Safety ratings might have been lowered due to reported lack of record-keeping or survey error.

The correlation between low awareness of the rules/exemptions and lower safety ratings indicates the need for further outreach. Academic institutions, advocacy organizations, industry groups, and FDA should work together to continue to educate farmers on safety rules and good practices. The frequency of concerns regarding

testing of agricultural water highlight the gap in communication. Because of their inability to promote proprietary products, FDA has not drawn a clear line to approved testing products. Farmers concerns about the time and money necessary to test for compliance with the rules might be alleviated if they are made aware of the low cost of required water testing. It can cost less than $2.00 to conduct a FDA-approved test. Tests can be performed over the course of less than 48 hours, with a minimum amount of labor, and without sending samples to a laboratory.[4] [5]

Continued outreach and education regarding the rules will go a long way towards improving farmers' perceptions and compliance in regards to FDA regulations. Farmers exempt from the rules still believe that they are being forced out by policymakers more accustomed to accommodating big business. Disconnects between local food systems and FDA do exist. As an example, FDA officials James Gorny and Erick Snellman mistakenly indicated that CSAs are covered under FSMA.[6] (James Gorny recently left FDA to work for the industry's Produce Marketing Association).[7] In actuality, the law specifically directs FDA to classify CSAs as a retail food establishment, which exempts CSAs from regulation under FSMA.[8]

Despite the continued misunderstandings and mistrust felt by some farmers surveyed, the proposed produce safety rules contain flexibilities and exemptions designed to lessen their impact on small and local food systems. Much of these accommodations are the result of successful small farm lobbying efforts during the passage of FSMA. The FDA has appears to have fulfilled much of their mandate to create exceptions for small farms.

This survey demonstrates that there is an intersection between the proposed standards and the safe practices of a diverse range of farm sizes. Full compliance with the proposed standards is likely attainable by many farms exempt from the rules. Continued improvement in our food supply can best be facilitated by a cooperative effort to disseminate good practices. Simultaneously, increasing support to competitive and open markets, environmentally sound agro-ecological practices, and social connectivity between farmers and consumers, is in keeping with public goals and consumer trends. If farmers wish to produce safe food, opportunities should be made to assist them through grants, educational resources, and other methods. As government asks more of farmers, it must also invest in helping them raise standards.

Limitations

The survey classified a farm as exempt if it met income and geographic criteria, or if the farm specified that it produced only low-risk products. Additional farms within the survey might be exempted if their agricultural products are destined for further processing that would result in the mitigation of risk. For example, a tomato farmer who sells entirely to the canning industry, whereby the tomatoes are effectively pasteurized, would be exempt from the proposed safety rules. However, this survey would not recognize such an exemption.

Safety ratings in this survey are not an exhaustive assessment of a farm's compliance with proposed produce safety rules. Record-keeping, a component of certain provisions in the proposed rules, was not included for all sections of the survey.

Further, the complicated and diverse nature of farming practices across the population preclude a comprehensive picture of any one farm's compliance obtained through this online survey. The proposed rules allow farmers to submit scientific evidence that they achieve food safety through alternative methods, but these methods could not be evaluated here.

Importantly, this survey was conducted exclusively in English and online. Farmers for whom English was not familiar might have been unable to participate. Along the same lines, individuals with low literacy skills may have been unduly excluded. At least one comment was received that indicated the survey language's complexity was a barrier. The online administration of this survey provided the benefits of snowball sampling and easy distribution, but also prevented farmers without internet access from participating in the survey. As such, this survey selected against farmers who might also lack access to information about proposed rules and good practices, as well as opportunities to offer public comment.

1 Robert Hoppe, et. al, *Structure and Finances of U.S. Farms: Family Farm Report, 2007 Edition*, EIB-24, U.S. Department of Agriculture, Economic Research Service, June 2007.

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