



Comments

The Center for Progressive Reform

Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food

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The Pew Charitable Trusts commissioned CPR to evaluate the preliminary regulatory impact analysis (PRIA) that accompanies the FDA’s proposed rule. Our evaluation of the PRIA makes up the majority of this comment, and the portions that reflect this analysis are also included as an appendix to Pew’s own comment on the rule. However, our comment also contains a number of sections that were not commissioned by Pew, specifically: the introductory portion of the Executive Summary, the first subsection within the Executive Summary (“The FSMA Calls for Science-Based Practices ...”), all sections entitled “Regulatory Options,” Recommendations #1 & 2, and the first and last paragraphs of the Conclusion. These portions reflect the views only of the authors of this comment and are not necessarily endorsed by Pew.

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EXECUTIVE SUMMARY

The FDA's proposed rule on preventive controls represents a major step forward for the safety of processed foods. From frozen meals and spices to nut butters and cheeses, processed foods have been responsible for a large number of outbreaks in recent years. Earlier this year, Farm Rich frozen products sickened 35 people with a virulent strain of *E. coli*. And last year, a 42-person *Salmonella* outbreak was linked to Sunland peanut butter—a disturbing echo of the tainted peanut paste that caused 714 illnesses and 9 deaths back in 2009.

The proposed rule is intended to prevent these disasters, as well as millions of foodborne illnesses that go undiagnosed or unreported each year. It would require manufacturers, processors, and warehouses to design a written food safety plan tailored to each facility's products and operations. (The rule would also apply to mixed-type facilities that conduct processing activities on a farm.) In general, facilities would have to identify the potential hazards in their processes and then implement controls to minimize or prevent them.

This system—Hazard Analysis and Risk-Based Preventive Controls, or HARPC—is intended to address microbiological, chemical, physical, and radiological hazards in food processing, as well as undeclared allergens. In many respects, HARPC is nearly identical to HACCP (Hazard Analysis and Critical Control Points), which is currently required for seafood and juice facilities and often adopted by other food companies to satisfy commercial buyers, although HARPC is slightly broader. In addition to the HARPC requirements, the FDA is also proposing certain changes to the current Good Manufacturing Practices (CGMP) regulations.¹

In the rule's preliminary regulatory impact analysis (PRIA), the FDA estimates \$319 - 475 million in annual domestic costs, depending on which cutoff is used for exempting very small businesses. The FDA also estimates that every year, processed foods cause nearly one million illnesses that cost society \$1.94 - \$1.97 billion, a portion of which would be avoided under the rule. The agency concludes that the strongest option proposed (exempting facilities with less than \$250,000 in annual sales) would “break even”—its benefits would justify its costs—if it prevents just 24 percent of these illnesses.²

Nevertheless, the rule has inspired much confusion and alarm among small food processing facilities worried about its costs.³ Some industry groups are trying to undermine and delay the rulemaking: a major trade association for the produce industry is insisting that the agency release a second round of proposed food safety rules and is lobbying Congress to set a longer timetable

¹ Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food; Proposed Rule, 78 Fed. Reg. 3646 (proposed Jan. 16, 2013), *available at* <http://www.regulations.gov/#!documentDetail;D=FDA-2011-N-0920-0001> [hereinafter Proposed Rule on CGMP and HARPC for Human Food].

² FDA, Proposed Rule for Preventive Controls for Human Food: Preliminary Regulatory Impact Analysis 6-12, 21, Jan. 16, 2013, *available at* <http://www.fda.gov/downloads/Food/GuidanceRegulation/FSMA/UCM334117.pdf> [hereinafter Final Draft PRIA].

³ See, e.g., Cookson Beecher, *Proposed Rule for Food Processors Alarms Some, Confuses Many*, July 29, 2013, FOOD SAFETY NEWS, <http://www.foodsafetynews.com/2013/07/proposed-rule-for-food-processors-alarms-some-confuses-many>.

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 And right-leaning think tanks have questioned the need for the regulation and criticized the FDA for not conducting a more extensive, fully quantified cost-benefit analysis.⁶

Contrary to these distortions, this rule is a good deal for both the public and the industry. Not only will it substantially prevent many of the wide-ranging harms associated with contaminated processed foods, but it will do so at a reasonable cost to the food industry, with ample exclusions and extended compliance dates for small facilities. **In fact, the rule’s benefits will be even more significant, and its costs considerably smaller, than the FDA suggests.**

During the rule’s review, the White House Office of Information and Regulatory Affairs (OIRA) eliminated a number of essential provisions that the FDA originally proposed, including requirements for environmental monitoring, finished product testing, supplier controls, and employee training.⁷ These more extensive standards are essential for verifying the effectiveness of the rule’s other standards and filling large gaps in the preventive-control framework. To fully realize the enormous benefits that this rule can provide, the FDA must restore the additional provisions that were deleted (without explanation) by OIRA.

The FSMA Calls for Science-Based Practices That “Significantly Minimize or Prevent Hazards,” not a Cost-Benefit Standard

We believe the rule’s benefits clearly justify its costs, and they would do so even more strongly if the eliminated provisions were restored to the rule. However, the Food Safety Modernization Act (FSMA) does not call for the use of a cost-benefit standard.

The FSMA requires that the rule “establish *science-based minimum standards* for conducting a hazard analysis, documenting hazards, implementing preventive controls, and documenting the implementation of the preventive controls.”⁸ These preventive controls, in turn, are “*risk-based, reasonably appropriate* procedures, practices, and processes that a person knowledgeable about

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>.

⁶ See, e.g., MERCATUS CENTER, REGULATORY REPORT CARD ON THE FDA’S PREVENTIVE CONTROLS RULE FOR HUMAN FOOD, Aug. 2013, http://mercatus.org/sites/default/files/CGMP-FDA-rule_rc_100113.pdf (giving the rule a score of 11 out of 30, and criticizing the FDA for its “crude” assessment of benefits and its belief that this regulation is needed to improve food safety practices).

⁷ OMB Review of Preliminary Regulatory Impact Analysis for Proposed Rule on Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food (April 12, 2013), available at <http://www.regulations.gov/#!documentDetail;D=FDA-2011-N-0920-0016> (click on “Tab B Preliminary Regulatory Impact Analysis”) [hereinafter OMB Redlined PRIA].

⁸ Food Safety Modernization Act, Pub. L. No. 111-353, sec. 103(a), § 418(n)(1)(A), 124 Stat. 3885, 3895 (2010) (codified as amended at 21 U.S.C. § 350g (2010)), available at <http://www.gpo.gov/fdsys/pkg/PLAW-111publ353/pdf/PLAW-111publ353.pdf>.

the safe manufacturing, processing, packing, or holding of food would employ to *significantly minimize or prevent* the hazards identified under the hazard analysis ... and that are *consistent with the current scientific understanding* of safe food manufacturing, processing, packing, or holding at the time of the analysis.”⁹ The FSMA balances this mandate by requiring the FDA to “provide *sufficient flexibility* to be *practicable* for all sizes and types of facilities.”¹⁰

Given this statutory mandate, the FDA should base the rule’s standards on the best available methods for preventing food-safety hazards, as long as they are justified by current science and address the risks presented by food processing operations. The “reasonably appropriate” 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).¹¹ 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 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.¹² In many cases, a cost-benefit standard interferes with the agency’s discretion to adopt the level of protection intended by Congress.

While we do not believe the statute requires the FDA to demonstrate that the rule’s benefits “justify” its costs in the first place, we are pleased that the FDA has chosen to justify this rule using a “breakeven analysis”—estimating how large the rule’s benefits would have to be before they would plausibly justify its costs—rather than trying to fully quantify all the rule’s benefits. The advantage of breakeven analysis is that it minimizes the difficulty of both quantifying and

⁹ *Id.* sec. 103(a), § 418(o)(3), 124 Stat. at 3896.

¹⁰ *Id.* sec. 103(a), § 418(n)(3)(A), 124 Stat. at 3895.

¹¹ 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 science-based minimum standards for preventive controls that a knowledgeable person would employ to “significantly minimize or prevent” food safety hazards as long as they “provide sufficient flexibility to be practicable for all sizes and types of facilities.” Indeed, “practicable” is essentially a synonym of “feasible,” meaning “able to be done.” Moreover, the statute places the benefit to public health (the prevention of hazards) 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.

¹² See, e.g., FRANK ACKERMAN & LISA HEINZERLING, PRICELESS: ON KNOWING THE PRICE OF EVERYTHING AND THE VALUE OF NOTHING (2004).

monetizing benefits, since it is often hard to predict a rule's effectiveness with any precision, and most benefits cannot be easily reduced to a dollar amount.¹³

Nevertheless, to the extent that the FDA continues to use the economic analysis presented in the rule's PRIA, either as a decisionmaking tool or as a way of expressing the rule's likely impacts, it should at least be made as comprehensive and accurate as possible. Currently, the PRIA suffers from a number of omissions and distortions that have inflated the rule's costs and understated its benefits.

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

Flaws in the Cost Estimation

The PRIA overstates the costs of compliance because, like most cost-benefit analyses, it does not reflect the cost-saving adjustments and innovations that businesses will inevitably adopt (or have already adopted) to make their operations more efficient in light of new requirements.

- ***Outdated, Unrealistic Recordkeeping Costs:*** Recordkeeping activities are estimated to cost \$296 million per year, or 62 percent of the rule's total cost. This estimate is based on a study from ten years ago and reflects the costs of *manual* recordkeeping tasks. But food companies are much more likely to use electronic systems now, which would substantially reduce the amount of work-time spent on maintaining records. In fact, the number of facilities using electronic systems has risen rapidly in recent years; one recent survey suggested around 44 percent use electronic HACCP records.¹⁴ The rule itself is expected to push many more facilities toward modernization—which will not only make recordkeeping easier but also improve efficiency and profitability in other ways.
- ***Other Industries' Experiences with HACCP Suggest Costs Will Be Manageable:*** In the late 1990s, as HACCP regulations were going into effect for the seafood industry, seafood processors had the same concerns about cost that processors of other foods are expressing now. But HACCP was not the financial disaster that many feared it would be, and the industry accommodated the new system without much difficulty—in fact, it made the industry stronger and more secure.¹⁵ A training alliance between the FDA, academics, and industry was integral to the successful transition, and the FDA is already coordinating a similar initiative for this rule. Before long, HARPC will be as routine for these facilities as HACCP has become for seafood and juice companies.

¹³ See *id.*; 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).

¹⁴ Kevin T. Higgins, *State of Food Manufacturing*, FOOD ENGINEERING, Sep. 2012, available at http://digital.bnppmedia.com/display_article.php?id=1172433.

¹⁵ See Gretchen Goetz, *Preventive Controls: Daunting for Some, Standard Procedure for Seafood*, FOOD SAFETY NEWS, Aug. 5, 2013, <http://www.foodsafetynews.com/2013/08/preventive-controls-daunting-prospect-for-some-standard-procedure-for-seafood>.

Flaws in the Benefits Analysis

The rule’s benefits are given in qualitative terms (“fewer illnesses and deaths”),¹⁶ although the PRIA does estimate the total cost of illnesses caused by processed foods every year, some portion of which would be prevented under the rule. This calculation suffers from a number of flaws that underestimate the potential benefits of the rule. Also, many important benefits, aside from avoided illnesses, are not considered in the analysis at all.

- ***A Significant Error:*** 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 this mistake, the estimated cost of illnesses due to processed foods rises to \$2.22 - \$2.25 billion—a 14-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.”¹⁷

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 2012.¹⁸

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.¹⁹ **Using these more comprehensive figures, the cost of illnesses attributable to processed foods would be \$2.95 - \$3.00 billion—a 52-percent increase over the FDA’s original estimate.**

¹⁶ See Final Draft PRIA, *supra* note 2, at 7-12.

¹⁷ See *id.* at 210-11.

¹⁸ See CDC, Tables and Figures – 2012 Preliminary Data, <http://www.cdc.gov/foodnet/data/trends/tables-2012.html>.

¹⁹ 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>.

- ***Underestimated Incidence of Illnesses Due to Processed Foods:*** Based on its own outbreak database, the FDA estimates that only 2.1 percent of all foodborne illnesses are attributable to processed foods. 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.

The Centers for Disease Control and Prevention (CDC), on the other hand, provide a much more complete database of foodborne illnesses, although to some extent it would overestimate the number of illnesses due to contamination during production 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 processing level). According to this database, just a portion of the food categories covered under this rule are responsible for 11 percent of all illnesses (dairy products, breads/bakery products, non-juice beverages, and sauces/dressings/oils),²⁰ and some CDC researchers have even estimated that dairy alone is responsible for almost 14 percent of illnesses.²¹

Because the true number of illnesses caused by contamination at the processing level probably lies somewhere between both databases, we propose that the FDA use figures derived from its own database as a lower bound and figures derived from the CDC database (incorporating as many food categories as it can reasonably assume would fall within the scope of this rule) as an upper bound.

- ***Omission of Other Kinds of Benefits from the Discussion:*** Food safety improvements in processing facilities 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.²² Reductions in contamination and undeclared allergens would reduce the number of recalls over time and thus prevent some of the far-reaching costs associated with a recall. Undeclared allergens were responsible for 60 percent of all recalls of FDA-regulated foods in the second quarter of 2013, while microbiological contamination has consistently remained the second-most common reason for recalls.²³

These frequent recalls can be incredibly damaging to a company’s bottom line and its

²⁰ See CAROLINE SMITH DEWAAL & MARCUS GLASSMAN, CTR. FOR SCI. IN THE PUB. INTEREST, OUTBREAK ALERT! 2001-2010: A REVIEW OF FOODBORNE ILLNESS IN AMERICA 14 (2013), available at http://cspinet.org/new/pdf/outbreak_alert_2013_final.pdf. Juice facilities are exempt from this rule because they are already subject to separate HACCP regulations, so we just considered illnesses linked to non-juice beverages here.

²¹ 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, 410 (2013), available at <http://wwwnc.cdc.gov/eid/article/19/3/pdfs/11-1866.pdf>.

²² See OMB Redlined PRIA, *supra* note 7, at 48-51.

²³ *Undeclared Allergens Top Reason for Second-Quarter Recalls*, FOOD SAFETY NEWS, Aug. 21, 2013, <http://www.foodsafetynews.com/2013/08/undeclared-allergens-top-reason-for-second-quarter-recalls>; OMB Redlined PRIA, *supra* note 7, at 48-49 (describing recall data from 1999-2003 and from 2008-2009).

long-term reputation. The cost of a recall is greatly compounded if the recalled product was used as an ingredient in other foods, like whey protein or nonfat dried milk. In 2009, *Salmonella*-tainted peanut paste led to the recall of nearly 4,000 different products.²⁴ A contamination event can easily bankrupt a company, like Sunland Inc., which finally shut down last month after a 2012 outbreak, leaving 100 people without jobs and leaving local peanut growers without anywhere to sell their crop.²⁵ These are some of the unrecognized costs of recalls that could potentially be avoided through enhanced preventive controls.

Other benefits completely missing from the analysis include: (1) avoided costs of investigating and responding to outbreaks linked to processed foods, which are mostly borne by severely underfunded state and local health departments; (2) avoided panic felt by people who have eaten products later recalled for contamination, even if they do not ultimately get sick; (3) avoided costs of lawsuits that inevitably follow major 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 processed foods.

Regulatory Options

The FDA Should Select the \$250,000 Cutoff for Very Small Businesses

The FDA originally proposed that only businesses with less than \$250,000 in annual sales should be exempted from the rule's HARPC requirements as "very small businesses" (VSBs). But OIRA introduced two other "co-proposed" cutoffs—\$500,000 and \$1 million—that would leave large holes in the rule's coverage. Among these three options, we urge the agency to select the \$250,000 threshold.

Because virtually all large facilities already have a HACCP system in place to satisfy buyer requirements, the most substantial benefits of this rule will derive from small- and medium-sized plants adopting preventive controls. Exempting too many of these plants would remove from the rule's coverage precisely those companies whose practices would be most improved by the proposed rule. Also, while the FDA estimates the \$250,000 option would have to reduce illnesses by 24 percent to break even, it would only have to reduce illnesses by 16 percent under our more comprehensive estimate for the cost of illnesses.

With this option, the proposed rule already provides sufficient flexibility for small facilities. Overall, 47 percent of all facilities would be exempt from the HARPC requirements. And among the remaining facilities that would have to establish a food safety plan, 99 percent have fewer than 500 employees and would thus get two years beyond the final rule's publication date before having to comply.²⁶ Finally, some concerns of small- and medium-size farms about the rule will

²⁴ FDA, Peanut Butter and other Peanut Containing Products Recall List, Oct. 28, 2009, <http://www.accessdata.fda.gov/scripts/peanutbutterrecall>.

²⁵ Dan Flynn, *Nation's Biggest Organic Peanut Processor Shuts Down*, FOOD SAFETY NEWS, Oct. 11, 2013, <http://www.foodsafetynews.com/2013/10/nations-biggest-organic-peanut-processor-shuts-down>.

²⁶ See Final Draft PRIA, *supra* note 2, at 7-8 (displaying the number and size of facilities that are exempt or subject to the rule's HARPC requirements).

likely be cleared up in the final rule. For example, many are worried that farm stands and community-supported agriculture (CSA) organizations will be forced to comply with onerous HARPC rules, but the statute requires that they be exempted as “retail food establishments,” something that the FDA will likely clarify in the final rule.²⁷

The FDA Must Restore the Crucial Provisions Eliminated by OIRA

In the draft proposal that the FDA sent to OIRA for review, the agency included well-defined provisions that would do the following:

- (1) Establish sanitation requirements in place of non-binding recommendations in CGMP;
- (2) Establish training requirements in place of non-binding recommendations in CGMP;
- (3) Require review of consumer complaints;
- (4) Require environmental monitoring for pathogens reasonably likely to occur;
- (5) Require finished product testing when appropriate based on risk;
- (6) Require supplier approval and verification programs where appropriate;
- (7) And require review of the records associated with these activities.

In the version that emerged from OIRA’s review, the FDA makes clear that it is not proposing any of these measures at this time but is instead just requesting comment on them. (Meanwhile, all the information prepared by the agency to explain and justify these requirements has been relegated to an appendix at the back of the preamble.)

Industry groups have seized on the technical distinction between “proposing” and “requesting comment.” The Grocery Manufacturers Association and the Food Marketing Institute argue that the FDA should not include these testing and supplier verification requirements in the final rule without providing additional opportunities for comment (*i.e.*, a second proposed rule) because these provisions were not adequately “detailed” in the proposal. Industry attorneys are already threatening litigation if these provisions end up in the final rule, claiming a violation of the Administrative Procedure Act. Of course, since industry groups have access to all the FDA’s original draft documents (the preamble, the proposed rule, and the regulatory impact analysis), they can see exactly how these requirements would fit into the final rule, and have ample opportunity to weigh in on them during this comment period—just like we are.²⁸

According to FDA research, the top factors responsible for tainted processed foods include (1) deficient employee training, (2) poor sanitation, (3) a lack of supplier controls (undetected contamination of ingredients), and (4) a lack of environmental monitoring (undetected contamination of the processing environment).²⁹ And yet the requirements that were specifically designed to address each of these areas were among those eliminated by the White House.

²⁷ See Food Safety Modernization Act, Pub. L. No. 111-353, sec. 102(c)(1), 124 Stat. 3889; Beecher, *supra* note 3 (“FDA’s Jenny Scott said that farm stands and CSAs ... would likely be classified as ‘exempt retail establishments.’”).

²⁸ See Daniel Arrieta, *Docs Outlining OMB's Preventive Control Changes Re-Ignite Testing Debate*, INSIDEHEALTHPOLICY, Mar. 29, 2013, <http://insidehealthpolicy.com/201303292429390/Health-Daily-News/Daily-News/docs-outlining-ombs-preventive-control-changes-re-ignite-testing-debate/menu-id-933.html>.

²⁹ See Final Draft PRIA, *supra* note 2, at 25-26.

Moreover, all these measures are widely recognized as effective by the international food safety community, although many companies only begin to realize their value after they have been the subject of a disastrous outbreak or recall.³⁰ In fact, three of the eliminated provisions (hygiene training, environmental monitoring, and supplier verification activities) were specifically mentioned in the FSMA’s *definition* of “preventive controls,” as paradigmatic examples of the kinds of practices that the FDA should require in its final rule.³¹

The FDA’s analysis suggests that the costs of these provisions would be small compared to the immense gains in food safety they would bring. Each of them would break even with its own cost if it reduced illnesses by less than 1 percent (except for the training requirements, which would have to achieve a 3-percent reduction). Because these measures would significantly enhance the rule’s effectiveness—perhaps to a greater extent than any of the more general, malleable standards that were ultimately proposed—such reductions are more than plausible.

Recommendations

The FDA should take into account that by preventing foodborne illnesses, the Preventive Controls 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 food, 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.³² 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.³³

We respectfully urge the FDA to:

- 1. Finalize the proposed rule as quickly as possible in its strongest, most protective form, selecting the \$250,000 cutoff for very small businesses exempted from the rule;**
- 2. Restore the essential provisions eliminated by OIRA;**

³⁰ See, e.g., Michael Moss, *Food Companies Are Placing the Onus for Safety on Consumers*, THE NEW YORK TIMES, May 14, 2009, www.nytimes.com/2009/05/15/business/15ingredients.html (describing how ConAgra finally decided to adopt supplier controls and finished product testing in the wake of an outbreak linked to its froze pot pies).

³¹ Food Safety Modernization Act, Pub. L. No. 111-353, sec. 103(a), § 418(o)(3), 124 Stat. 3885, 3896 (2010) (codified as amended at 21 U.S.C. § 350g (2010)), available at <http://www.gpo.gov/fdsys/pkg/PLAW-111publ353/pdf/PLAW-111publ353.pdf>.

³² FDA, Foodborne Illness: Especially Dangerous for the Vulnerable, June 4, 2013, <http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm354783.htm>.

³³ 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>.

3. **Correct errors and unrealistic assumptions** in the PRIA that understate the rule’s benefits and exaggerate its costs;
4. **Use more comprehensive estimates** for the cost of illnesses due to processed foods;
5. **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.

COSTS OF THE PROPOSED RULE

In estimating the rule’s cost, the FDA first accounts for the baseline practices of facilities that would be covered under the rule, based on a nationwide survey from 2010. Then, for each provision, the agency assumes no new costs for facilities that already follow the given practice.³⁴

The FDA’s estimated compliance costs vary with the threshold for defining “very small businesses” (VSBs), which would be exempt from the rule’s HARPC requirements. The agency predicts the following annual domestic costs:

- \$475 million (if VSBs are defined as having less than \$250,000 in annual sales)
- \$395 million (if VSBs are defined as having less than \$500,000 in annual sales)
- \$319 million (if VSBs are defined as having less than \$1,000,000 in annual sales)³⁵

But these figures significantly overestimate the rule’s impact. *Ex ante* estimations 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.³⁶ As we explain below, this PRIA is no different.

Recordkeeping Costs Will Be Much Lower Than Estimated

Recordkeeping is central to HACCP-based food safety regimes. More than anything else in the rule, food processors balk at the thought of all the additional paperwork that it will require: a written food safety plan; written procedures for carrying it out; and written records that document every monitoring activity, corrective action, and verification step. In the words of a former FDA official, “According to the FSMA, if it isn’t recorded, it didn’t happen.”³⁷

³⁴ Final Draft PRIA, *supra* note 2, at 27-28.

³⁵ *Id.* at 7-12.

³⁶ 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).

³⁷ David Acheson, *Electronic Documentation Eases FSMA Compliance*, Plex Systems Blog (last visited Oct. 24, 2013), <http://www.plex.com/guest-post-electronic-documentation-eases-fsma-compliance>.

The FDA estimates that these recordkeeping activities will take 3.68 million hours and cost \$296 million each year—62 percent of the rule’s total cost.³⁸ This estimate was based on a study from 2003 (ten years ago) and reflects the costs of *manual* recordkeeping. But as the FDA suggests, food processors are much more likely to use electronic recordkeeping systems now, which would substantially reduce the amount of time required to comply.³⁹ These systems allow processors to automatically monitor and document all their preventive controls. They also organize data into tables, charts, and databases so that companies can easily examine trends in their food safety performance and reevaluate their food safety plans in light of that information.

The number of firms using electronic systems has risen rapidly in the past several years. *Food Engineering* magazine conducted a survey of its readers in 2012, and 44 percent of respondents said that their firms were using electronic HACCP records, up from 31 percent just the previous year.⁴⁰ In another survey of processing facilities, taken in March of this year, only 45 percent of respondents admitted to using manual recordkeeping devices (like spreadsheets) to manage traceability, quality, and inventory issues.⁴¹ The rule itself is likely to induce many of these remaining companies to switch to an electronic recordkeeping system to ease their compliance burden. One-third of the respondents in the *Food Engineering* survey said the FSMA will push them closer to an electronic system.⁴²

When all is said and done, there will be few processors who actually incur the manual-recordkeeping costs estimated in the PRIA. The FDA does acknowledge that its estimates are probably an “upper bound” considering how outdated its estimation may be, but that qualification is likely to be lost on food processors who remain preoccupied with the numerical estimates.⁴³ The FDA should find a way to incorporate this rising use of electronic recordkeeping into its calculations, to give businesses a more realistic idea of what costs they can expect.

Finally, it is worth noting that these electronic recordkeeping systems not only facilitate food safety compliance but also help improve and modernize a processor’s operations as well—an incidental benefit of the rule that would help offset the costs of additional recordkeeping. For example, an automated recordkeeping system can “improve equipment efficiencies, minimize disruptions and reduce waste,” since the same data captured for food safety purposes is often linked to efficiency data.⁴⁴ The extent of these improvements would be difficult to quantify, but the FDA should explain that transitioning to an electronic recordkeeping system will often benefit the company’s profitability at the same time that it eases data collection and reporting.

³⁸ Final Draft PRIA, *supra* note 2, at 192-93.

³⁹ *Id.* at 82.

⁴⁰ Higgins, *supra* note 14.

⁴¹ Sudhakar Kaup, *Processing Companies Still Unsure of FSMA Implications*, FOOD PRODUCT DESIGN, Apr. 22, 2013, <http://www.foodproductdesign.com/articles/2013/04/processing-companies-still-unsure-of-fsma-implica.aspx>.

⁴² Higgins, *supra* note 14.

⁴³ Final Draft PRIA, *supra* note 2, at 82. See Goetz, *supra* note 15 (“It’s these numbers — and the complexity of a HARPC plan itself — that have processors of other FDA-controlled foods, especially smaller ones, worried.”).

⁴⁴ Robert Ralyea et al., *Automated Systems Have a Role in Food Safety*, DAIRY FOODS, Apr. 17, 2013, <http://www.dairyfoods.com/articles/89456-food-safety-the-case-for-environmental-pathogen-sampling>.

Other Industries' Experiences with HACCP Suggest Costs Will Be Manageable

According to a recent article on Food Safety News, the concerns of food processors about the costs of this rule are nearly identical to those voiced by the seafood industry in the late 1990s, as similar HACCP regulations from the FDA were going into effect. In that case, the seafood industry itself had requested the regulations, as a way of assuring European buyers and American consumers that all seafood processors, large and small, were producing safe products. But many small processors feared it would be overly burdensome and put them out of business.⁴⁵

Eventually, though, the industry adjusted to the new system without much difficulty. A leader in the Seafood HACCP Alliance said, “Surprisingly, HACCP has been accommodated, has been implemented in the seafood industry, and it has not had the financial consequences that some feared.” Instead, those in the industry say it made the seafood sector stronger and more secure. Key to its successful implementation was an alliance between academics, government agencies, and industry that trained and supported processors in their efforts to comply with the rule.⁴⁶

The FDA is already coordinating a similar education initiative for this rule: the Food Safety Preventive Controls Alliance, developed in collaboration with the Illinois Institute of Technology.⁴⁷ This program will help food facilities transition to the new requirements at a reasonable cost, and before long, HARPC will be as routine for them as HACCP has become for the seafood and juice industries. The FDA may wish to examine how the introduction of HACCP affected the financial performance of small seafood and juice processors over the years that followed, if the agency is able to compile data on the industries or even a few case studies of individual companies. Such information might be useful in reassuring food processors that they will be able to meet the requirements of the proposed rule without sacrificing their bottom line.

BENEFITS OF THE PROPOSED RULE

Unlike the PRIA for the produce rule, this PRIA merely calculates the burden of illnesses attributable to processed foods every year, without attempting to estimate how effective the rule would be in reducing them. (Presumably this is because the produce rule requires a set of specific controls on farms whereas this rule allows for development of a HARPC system that is unique to the hazards of each food processing operation, which makes it more difficult to predict its effectiveness).

The FDA estimates that foods covered under this rule are annually responsible for 917,118 illnesses and 43,408 allergic reactions that could potentially be prevented by this rule. According to the agency, these illnesses and reactions cost society \$1.95 - \$1.97 billion every year.⁴⁸

⁴⁵ Goetz, *supra* note 15.

⁴⁶ *Id.*

⁴⁷ See FDA, Food Safety Preventive Controls Alliance, <http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm284406.htm> (last visited Nov. 1, 2013).

⁴⁸ Final Draft PRIA, *supra* note 2, at 16, 19, 21.

Effectiveness of Preventive Controls

The FDA states that it was unable to estimate how many illnesses would be avoided because the rule functions as a whole, and much of its success will be determined by factors like attitude and commitment.⁴⁹ But in general, the experiences of other industries operating under similar HACCP programs, including non-meat products similar to those covered by this rule, suggest that preventive controls will be able to significantly reduce contamination levels and illnesses. For example, the agency notes that after the introduction of HACCP at an ice cream factory, one bacterium was no longer detectable in the ice cream and another was significantly minimized; other spoilage markers in the ice cream and the environment were reduced by 20 to 35 percent.⁵⁰

Some might think this rule would not have an impact on companies that have already adopted HACCP systems in order to satisfy the requirements of their commercial buyers. The FDA estimates that 66 percent of all food facilities already have a HACCP system in place, including virtually all facilities with more than 100 employees.⁵¹ But even among these facilities, the proposed rule will help to close safety gaps. Forty-one percent of these facilities do not currently use a third party to evaluate and certify their HACCP plans, suggesting that there is little standardization among food manufacturers, whose plans may vary considerably in their quality and effectiveness.⁵² Those that do use third-party certification may still have deficient plans; after all, third-party auditors have been exposed as rubber stamps on many occasions.⁵³ The rule's enforceable minimum standards, combined with the FDA's additional oversight of food safety plans (at least during agency inspections), may help to strengthen and standardize these preexisting HACCP plans, leading to further reductions in contamination levels and illnesses.

The rule improves upon existing HACCP systems in several other ways, too. The HARPC system may require the facility to implement preventive controls at additional points in the production process, not just at the "critical control points" mandated by HACCP.⁵⁴ And the rule includes separate requirements for allergen controls, sanitation controls, and a recall plan, any or all of which may be missing from current HACCP plans in food processing facilities.

The benefits of the rule as proposed are substantial and worthwhile. However, they pale in comparison to the risk reductions that the FDA could achieve if it restored the more extensive standards that were eliminated by OIRA, as we explain later.

A Significant Error

The FDA estimates that more than 806,000 illnesses are caused annually by "unidentified" foodborne pathogens (pathogens that are just emerging or are not easily identified through tests)

⁴⁹ *Id.* at 28-29.

⁵⁰ *Id.* at 35.

⁵¹ *Id.* at 27.

⁵² *Id.*

⁵³ See Stephanie Armour et al., *Food Sickens Millions as Company-Paid Checks Find It Safe*, BLOOMBERG, Oct. 11, 2012, <http://www.bloomberg.com/news/2012-10-11/food-sickens-millions-as-industry-paid-inspectors-find-it-safe.html>.

⁵⁴ Proposed Rule on CGMP and HARPC for Human Food, 78 Fed. Reg. at 3660.

in processed foods.⁵⁵ But the FDA 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.⁵⁶ 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.⁵⁷ Fixing this oversight accounts for an additional 35 deaths caused by contaminated processed foods every year.⁵⁸

With this correction, the estimated cost of illnesses attributable to processed foods rises to a total of \$2.22 - 2.25 billion—a 14-percent increase over the PRIA’s estimate.⁵⁹

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 score of 1 indicates no problems, a score of 2 indicates moderate problems, and a score of 3

⁵⁵ Final Draft PRIA, *supra* note 2, at 16.

⁵⁶ 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).

⁵⁷ See, e.g., Final Draft PRIA, *supra* note 2, at 218-19 tbl. (under “Foodborne illness, Unknown Agent,” only “nonhospitalized” and “hospitalized” cases are listed, without reference to deaths).

⁵⁸ If 1 out of 22,771 cases (0.00439%) result in death, then an estimated 35 deaths result from these unidentified pathogens every year.

⁵⁹ See Appendix *infra* (section on “Calculating the Burden of Illness after Accounting for Deaths due to Unidentified Pathogens”).

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.⁶⁰

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.⁶¹ 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).⁶²

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.⁶³ 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.⁶⁴ 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 illnesses related to processed foods, rather than

⁶⁰ See Final Draft PRIA, *supra* note 2, at 209-212.

⁶¹ See *id.* at 210-213 (the EQ-5D scores for each of these illnesses have a “1” in the final position).

⁶² See *id.* at 212-14 tbl.7 (none of the EQ-5D scores for illnesses or complications have a “3” in the final position).

⁶³ 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).

⁶⁴ Colin Caywood, *Living with ESRD*, FOOD SAFETY NEWS, Mar. 5, 2010, <http://www.foodsafetynews.com/2010/03/living-with-esrd>.

burying their true impacts behind misleading numbers.

Misleading Use of a Baseline Health Index

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.⁶⁵

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.⁶⁶ 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.⁶⁷ 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.⁶⁸ 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.⁶⁹ 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.⁷⁰

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.”⁷¹ More specifically, each agency shall provide “an evaluation of the environmental

⁶⁵ Final Draft PRIA, *supra* note 2, at 210-11.

⁶⁶ 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).

⁶⁷ Final Draft PRIA, *supra* note 2, at 210.

⁶⁸ 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.

⁶⁹ *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.*

⁷⁰ 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.

⁷¹ 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.”⁷² **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.

Quality-of-life Values Reflect Abstract Surveys, not Experience of Illness

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.⁷³

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.⁷⁴

⁷² *Id.* § 5-501(a).

⁷³ 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 211 n.47.

⁷⁴ 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.⁷⁵ 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.

Serious, Well-Documented Complications Missing from FDA’s Analysis

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.⁷⁶

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.

Even more troubling, *none* of the complications on the FDA’s list are ultimately incorporated into the estimated burden of illnesses caused by processed foods because (1) the FDA attributes only three different pathogens to processed foods, based on a very incomplete outbreak database (as we describe in more detail later in this comment); and (2) the FDA mistakenly assumes that these three specific pathogens (*Listeria*, *Salmonella*, and *M. bovis*) are not associated with any “chronic complications.”⁷⁷ As the material below demonstrates, these two pathogens (among many others) are in fact associated with a wide range of long-term complications.

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

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

⁷⁵ 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).

⁷⁶ Final Draft PRIA, *supra* note 2, at 209.

⁷⁷ *Id.* at 19 n.6 (“[N]one of the foodborne illnesses with chronic complications are attributed to foods under the scope of this proposed rule-making”), 216-19 tbl.8 (breaking these pathogens only into “hospitalized” and “non-hospitalized” categories, not considering any of their long-term complications).

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.⁷⁸

In 2012, imported ricotta cheese from Italy sickened 22 people with *Listeria*. Nine infections were related to a pregnancy, and three of these were diagnosed in newborns. Ultimately, one woman suffered a miscarriage.⁷⁹ Less than a year later, cheese made in Wisconsin infected six people with *Listeria*, including another pregnant woman who also had a miscarriage.⁸⁰ There is no way of knowing what ongoing complications any of the newborns who survived these outbreaks might have. One pregnant woman who was sickened by *Listeria*-tainted cantaloupes in 2011 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.⁸¹

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).⁸²

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:

⁷⁸ 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.

⁷⁹ CDC, Multistate Outbreak of Listeriosis Linked to Imported Frescolina Marte Brand Ricotta Salata Cheese (Final Update), Nov. 21, 2012, <http://www.cdc.gov/listeria/outbreaks/cheese-09-12/index.html>.

⁸⁰ CDC, Multistate Outbreak of Listeriosis Linked to Crave Brothers Farmstead Cheeses (Final Update), Sep. 24, 2013, <http://www.cdc.gov/listeria/outbreaks/cheese-07-13/index.html>.

⁸¹ 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>.

⁸² 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.aspx?file=/media/755624/aer741_1_.pdf.

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.⁸³

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.⁸⁴

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.⁸⁵

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.⁸⁶

⁸³ 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).

⁸⁴ 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>.

⁸⁵ 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>.

⁸⁶ Marler Clark, *supra* note 83.

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.⁸⁷ 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.⁸⁸ 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.⁸⁹

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.”⁹⁰ 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

⁸⁷ Radelat, *supra* note 84.

⁸⁸ 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.

⁸⁹ 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).

⁹⁰ 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>.

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.⁹¹

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.”⁹²

The PRIA’s narrow analysis fails to account for these kinds of stresses and losses.

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).⁹³

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.⁹⁴ Considering that 36 percent of all lab-confirmed foodborne illnesses in 2012 were found in children,⁹⁵ 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.⁹⁶

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

⁹¹ 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.

⁹² 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.

⁹³ Accord Scharff, *supra* note 19, at 125 (2012).

⁹⁴ *Id.* Appendix A, at 6, available at <http://static.ehe.osu.edu/journals/jfp-2011-appendix.pdf> [hereinafter Scharff Appendix].

⁹⁵ See note 68 *supra*.

⁹⁶ 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/7BDEF9F8EC3835D9CA257165001AB31D/\\$File/WP50.pdf](http://www.ozfoodnet.gov.au/internet/ozfoodnet/publishing.nsf/Content/7BDEF9F8EC3835D9CA257165001AB31D/$File/WP50.pdf).

cost of medication used to treat foodborne illness.⁹⁷

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 \$109.⁹⁸ 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.⁹⁹ The average cost of the prescription drugs used range from \$17 (for doctor visits) to \$49 (for hospitalized cases).¹⁰⁰ If the proposed rule prevents a portion of the approximately one million illnesses caused by processed foods every year, 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.¹⁰¹ In the PRIA, the FDA briefly acknowledged that the study exists and requests comment on its estimates.¹⁰² 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;¹⁰³ (3) account for newborn complications from *Listeria*;¹⁰⁴ (4) use more comprehensive healthcare costs;¹⁰⁵ (5) and measure illness-related losses against a baseline of 1.00, instead of using the misleading average index for adults.¹⁰⁶

⁹⁷ See Final Draft PRIA, *supra* note 2, at 214-16 (an example of FDA's estimation of medical costs).

⁹⁸ Scharff Appendix, *supra* note 94, at 3.

⁹⁹ 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>.

¹⁰⁰ Scharff Appendix, *supra* note 94, at 4.

¹⁰¹ Scharff, *supra* note 19, at 126 tbl.2 (listing these cost estimates in the last column, under the heading "Total Cost per Case: QALY").

¹⁰² See Final Draft PRIA, *supra* note 2, at 220. 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.

¹⁰³ Scharff, *supra* note 19, at 125. See Scharff Appendix, *supra* note 94, at 4-6 (explaining how pharmaceutical and caregiver lost-productivity costs were estimated).

¹⁰⁴ Scharff, *supra* note 19, at 125.

¹⁰⁵ 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 94, at 3. See also Final Draft PRIA, *supra* note 2, at 214-16 (an example of FDA's estimation of medical costs).

¹⁰⁶ 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

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.¹⁰⁷ Nevertheless, the study offers a good example of the kinds of additional considerations that are missing from the PRIA.

We urge the FDA to incorporate these considerations into its own analysis. To illustrate how this might affect the estimated burden of illness, we applied the Scharff costs to the number of processed-food-related illnesses estimated by the FDA, making a few adjustments to reflect certain values chosen by the FDA.¹⁰⁸ **Using these more comprehensive cost estimates, the burden of illnesses attributable to foods covered under this rule would be \$2.95 to \$3.00 billion—a 52-percent increase over the PRIA’s original estimate.**¹⁰⁹

Underestimated Incidence of Illnesses Due to Processed Foods

For each pathogen, the FDA first determines how many illnesses were linked to processed foods 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 total number of illnesses estimated to occur every year, which takes into account under-reporting of illness and unidentified pathogens. The agency concludes that 917,118 illnesses are caused by FDA-regulated processed foods each year.¹¹⁰ However, processed foods are likely responsible for many more illnesses than this estimation suggests.

Different Estimates for the Percentage of Illnesses Attributable to Processed Foods

Based on its own outbreak database, the FDA estimates that just 2.1 percent of all foodborne illnesses are caused by processed foods.¹¹¹

But the FDA would have arrived at a much higher estimate using the CDC’s more complete, if less detailed, database.¹¹² It may not be easy to determine which outbreaks in the database are linked to processed foods within the scope of this rule because the rule encompasses so many

health), not a baseline health index less than 1.00. See Scharff Appendix, *supra* note 94, at 7; Shaw et al., *supra* note 73, at 218 (listing the EQ-5D weights for these health states).

¹⁰⁷ 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 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 106 *supra* (identifying the health states used in Scharff’s analysis); Final Draft PRIA, *supra* note 2, at 212-14 (the health states used in FDA’s analysis).

¹⁰⁸ 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 94, at 6-7 (VSL of \$7.33 million and VSLY of \$356,500) with Final Draft PRIA, *supra* note 2, at 214 (VSL of \$7.9 million and VSLY of \$214,000).

¹⁰⁹ See Appendix *infra* (section on “Calculating the Burden of Illness Using More Comprehensive Cost-per-Illness Figures from Scharff”).

¹¹⁰ Final Draft PRIA, *supra* note 2, at 16.

¹¹¹ *Id.*

¹¹² 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).

different categories of foods. And there is sometimes no way of knowing whether the food indicated in an outbreak had been processed in a facility (subject to the rule) or prepared from raw materials at a retail store or restaurant (not subject). But even looking at just a few food categories that would generally fall under this rule, one can see that processed foods are responsible for a higher percentage of illnesses than the FDA suggests.

Dairy products, breads/bakery products, non-juice beverages, and sauces/dressings/oils are alone responsible for 11 percent of the illnesses in the CDC's database from 2001 to 2010, according to the Center for Science in the Public Interest¹¹³—and this number does not account for outbreaks linked to frozen foods, snack foods, spices, egg products under the FDA's jurisdiction, and an endless variety of other multi-ingredient products. Researchers at the CDC tried to incorporate 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 13.8 percent of all illnesses from 1998 to 2008 were caused by dairy products alone, to say nothing of the many other categories of foods covered by this rule.¹¹⁴

Outbreaks in recent years confirm that processing facilities remain a very significant source of contamination. Earlier this year, Farm Rich frozen food products sickened 35 people with Shiga-toxin producing *E. coli*, and in 2012, a 42-person *Salmonella* outbreak was linked to peanut butter manufactured by Sunland.¹¹⁵ Meanwhile, spice-processing facilities are becoming increasingly recognized as a major source of *Salmonella* infections: the FDA found that imported spices are contaminated at nearly twice the rate of other imports, and two separate outbreaks linked to tainted pepper sickened 370 people in 2009 and 2010.¹¹⁶

Reliance on an Incomplete Database

The agency underestimates the incidence of these illnesses because it extrapolates from an incomplete database. The FDA's outbreak database, unlike the CDC's database, contains only those illnesses that could be traced back through an investigation to contamination at the food facility, 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 manufacturing level: the food might have been contaminated with dangerous pathogens during processing, and the later mishandling simply allowed the bacteria to grow to a point that it caused illness. Because these illnesses are not included, the FDA database may be missing many cases of bona fide processed-food contamination.¹¹⁷

¹¹³ See DEWAAL & GLASSMAN, *supra* note 20, at 14. Juice facilities are exempt from this rule because they are already subject to separate HACCP regulations, so we just considered illnesses linked to non-juice beverages here.

¹¹⁴ Painter et al., *supra* note 21, at 19.

¹¹⁵ CDC, Multistate Outbreak of Shiga toxin-producing *Escherichia coli* O121 Infections Linked to Farm Rich Brand Frozen Food Products (Final Update), May 30, 2013, <http://www.cdc.gov/ecoli/2013/O121-03-13/index.html>; CDC, Multistate Outbreak of *Salmonella* Bredeney Infections Linked to Peanut Butter Manufactured By Sunland, Inc. (Final Update), Nov. 30, 2012, <http://www.cdc.gov/salmonella/bredeney-09-12/index.html>.

¹¹⁶ See Gardiner Harris, *Salmonella in Spices Prompts Changes in Farming*, THE NEW YORK TIMES, Aug. 27, 2013, www.nytimes.com/2013/08/28/world/asia/farmers-change-over-spices-link-to-food-ills.html; FDA, DRAFT RISK PROFILE: PATHOGENS AND FILTH IN SPICES 14-15 (2013), available at <http://www.fda.gov/downloads/Food/FoodScienceResearch/RiskSafetyAssessment/UCM367337.pdf>.

¹¹⁷ *Id.* at 22.

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. According to the FDA, outbreaks linked to processed foods in its database caused an average of 103 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 processed foods.¹¹⁸

Even several highly publicized outbreaks are conspicuously missing from the agency’s analysis, even though they were linked to FDA-registered facilities and occurred during the examined time period—for example, the 2007 outbreaks caused by ConAgra/Banquet frozen pot pies (401 cases) and General Mills/Totino’s frozen pizzas (21 cases).¹¹⁹ Perhaps these outbreaks do not appear in the FDA’s database because the facilities were *also* registered with the U.S. Department of Agriculture (USDA) and the outbreaks happened to be investigated by the USDA instead of the FDA.¹²⁰ Whatever the reason, the omission of these (and however many other) outbreaks that would be within the scope of this rule leads to an artificially low percentage of illnesses attributed to processed foods in the PRIA.

The CDC database, on the other hand, includes many illnesses linked to processed foods 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.¹²¹ To some extent, the number of illnesses linked to what appear to be processed foods in the CDC database would overestimate the number of illnesses traceable to contamination during production, but it would also include many relevant outbreaks that are arbitrarily missing from the FDA’s database.

Because the true number of illnesses caused by contamination at the processing level probably lies somewhere between both databases, we suggest that the FDA use figures

¹¹⁸ See *id.* at 22-23.

¹¹⁹ See Memorandum on Data from the U.S. FDA’s Ctr. for Food Safety & Applied Nutrition Outbreak Surveillance Database 2012, at 3-4, available at <http://www.regulations.gov/contentStreamer?objectId=09000064811f3a1d&disposition=attachment&contentType=pdf> (listing 16 outbreaks linked to FDA-regulated processed foods between 2003 and 2008, which for some reason do not include the outbreaks related to pot pies and frozen pizzas). See also Moss, *supra* note 30 (profiling the pot pie and frozen pizza investigations).

¹²⁰ See CDC, Multistate Outbreak of Salmonella Infections Associated with Frozen Pot Pies --- United States, 2007, Nov. 28, 2008, <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5747a3.htm>; CDC, Investigation of Outbreak of Human Infections Caused by E. coli O157:H7, Nov. 1, 2007, <http://www.cdc.gov/ecoli/2007/october/103107.html> (Totino’s frozen pizzas). See also Registration of Food Facilities under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002; Interim Final Rule, 68 Fed. Reg. 58,893, 58,903 (Oct. 10, 2003), available at <http://www.fda.gov/Food/GuidanceRegulation/FoodFacilityRegistration/ucm081637.htm#IIIId7> (“Facilities that manufacture/process ‘meat food products,’ such as pizzas with meat topping, and other products, such as cheese pizzas, are under both FDA and USDA jurisdiction and must therefore register with FDA.”).

¹²¹ See Final Draft PRIA, *supra* note 2, at 195-98 (describing the relationship between the FDA and CDC outbreak databases).

derived from its own database as a lower bound and figures derived from the CDC database (incorporating as many food categories as it can reasonably assume would fall within the scope of this rule) as an upper bound.

Other Kinds of Benefits Not Accounted for in the PRIA

The FDA's analysis discusses 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 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.¹²²

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

The proposed rule is expected to prevent a substantial amount of contamination during processing—and thus a substantial number of very costly product recalls—by requiring facilities to implement preventive controls for the following hazards:

- **Undeclared allergens**: During the second quarter of 2013, undeclared allergens were the top reason for all food recalls, responsible for 60 percent of all recalls under the FDA's jurisdiction.¹²³ The proposed rule would require facilities to develop controls to protect against cross-contact of food by allergens and to ensure that allergens are properly declared on the label of the finished product. These measures would logically prevent the need for a portion of recalls due to undeclared allergens.
- **Microbiological contamination**: In the original draft, the FDA explained that microbiological contamination was consistently the second most common reason for recalls of processed foods.¹²⁴ Because the proposed rule would require facilities to implement controls designed to prevent microbiological contamination, it will reduce the

¹²² See OMB Redlined PRIA, *supra* note 7, at 48-51.

¹²³ *Undeclared Allergens Top Reason for Second-Quarter Recalls*, FOOD SAFETY NEWS, Aug. 21, 2013, <http://www.foodsafetynews.com/2013/08/undeclared-allergens-top-reason-for-second-quarter-recalls>.

¹²⁴ OMB Redlined PRIA, *supra* note 7, at 48-49 (describing recall data from 1999-2003 and from 2008-2009).

number of pathogen-related recalls as well.

- **Physical and chemical contaminants:** The rule would also require that facilities consider physical and chemical hazards in their analysis and implement any preventive measures necessary to significantly minimize or prevent them. There is little hard evidence that physical or chemical contaminants in food have caused significant injuries, but they have triggered high-profile recalls of processed foods with some frequency. For example, Lean Cuisine (a Nestlé brand) recalled more than 500,000 frozen dishes earlier this year after customers found glass in them, which followed an earlier Nestlé recall due to red plastic fragments and an even earlier Lean Cuisine recall due to blue plastic fragments.¹²⁵ Meanwhile, the Kellogg Company recalled 2.8 million packages of Mini-Wheats cereals due to metal fragments in 2012, costing the company about \$30 million; two years earlier, it had recalled 28 million boxes of cereal because of elevated levels of a chemical in the packaging.¹²⁶

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 processing facilities begin monitoring for additional contamination risks and detecting problems they might have missed before. And as the FDA explained in its original draft, “human error will still occur.” But “[o]ver time, once better supplier controls have been adopted for a sufficient period, there should be a lower initial risk of adulteration, along with a greater chance of catching any adulterated products earlier, which should cause fewer and smaller food recalls,” in the agency’s own words (which were eliminated by OIRA).¹²⁷ The proposed rule also requires that each facility establish a written recall plan, to ensure rapid and effective recalls in case contamination is discovered.¹²⁸ These written procedures should help to minimize the disruptive economic impacts of those recalls that will still occur under the rule.

This benefit of the rule should make it particularly attractive to members of the processed-food industry, many of which have witnessed or experienced the ruinous impacts of recalls caused by inadequate safety measures. According to an FDA report, dairy products, bakery items, candies, nut and seed products, snack foods, seasonings, prepared foods, soups, sauces, meal replacement foods, cereals, frozen foods, pasta, and food additives were responsible for a total of 116 recall events from September 2011 to September 2012.¹²⁹

¹²⁵ Kim Painter, *Lean Cuisine Recall: Glass Found in Mushroom Ravioli*, USA TODAY, Feb. 12, 2013, <http://www.usatoday.com/story/news/nation/2013/02/12/lean-cuisine-recall-glass/1912307>.

¹²⁶ Schuyler Velasco, *Kellogg Company Recalls Mini-Wheats. Metal Fragments in Cereal.*, THE CHRISTIAN SCIENCE MONITOR, Oct. 11, 2012, <http://www.csmonitor.com/Business/2012/1011/Kellogg-Company-recalls-Mini-Wheats.-Metal-fragments-in-cereal>; Dan Shapley, *Kellogg's Cereal Recall Highlights a New Concern: Chemicals Leaching from Food Packaging*, THE DAILY GREEN, July 12, 2010, <http://www.thedailygreen.com/healthy-eating/eat-safe/kellogg-cereal-recall-0628>.

¹²⁷ OMB Redlined PRIA, *supra* note 7, at 48.

¹²⁸ Proposed Rule on CGMP and HARPC for Human Food, 78 Fed. Reg. at 3745-46.

¹²⁹ FDA, THE REPORTABLE FOOD REGISTRY: TARGETING INSPECTION RESOURCES AND IDENTIFYING PATTERNS OF ADULTERATION THIRD ANNUAL REPORT: SEPTEMBER 8, 2011 – SEPTEMBER 7, 2012, at 12 (2013), <http://www.fda.gov/downloads/Food/ComplianceEnforcement/RFR/UCM349856.pdf>.

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.¹³⁰

When a food 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—Nestlé recalled 300,000 cases of cookie dough after consumers became infected with *E. coli*.¹³¹ The financial cost of a recall is greatly compounded if the recalled product was used as an ingredient in other foods, which is very common with processed foods. In 2010, 177 different products were recalled because they contained hydrolyzed vegetable protein potentially contaminated with *Salmonella*.¹³² Just the year before, *Salmonella*-tainted peanut paste led to the recall of nearly 4,000 different products.¹³³ Many of these products were made by small businesses; one family-run company had to recall 170 tons of its ice cream and spent 2,100 hours on the recall.¹³⁴

Companies pay to administer the recall, including transporting and destroying the recalled batches, conducting public relations, and internally investigating the cause. They may have to stop operating for a period of time, to allow government investigation or to modify their processes, causing further business interruptions.¹³⁵ ConAgra spent \$78 million to recall Peter Pan peanut butter in 2007, including the cost of tracking down and destroying the products, notifying customers, and implementing a toll-free hotline for consumers. The company also lost additional sales worth \$55 million during that period and paid another \$15 to \$20 million to renovate the broken sprinklers and leaking roof that likely caused the contamination.¹³⁶

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.¹³⁷ Stigma associated with a recalled product can persist long after the recall is over. Peanut sales declined by nearly 25 percent in the months following the 2009 outbreak as shoppers shunned peanut products. It took about four months for sales to return to previous levels—and this was likely only because peanut

¹³⁰ 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](http://www.ey.com/Publication/vwLUAssets/Capturing_Recall_Costs/$FILE/Capturing_recall_costs.pdf) [hereinafter CAPTURING RECALL COSTS].

¹³¹ Nestle Recalls Cookie Dough over Illnesses, CBS NEWS, Apr. 10, 2010, http://www.cbsnews.com/2100-204_162-5097306.html.

¹³² FDA, Recall: Products Containing Hydrolyzed Vegetable Protein, Apr. 1, 2010, <http://www.accessdata.fda.gov/scripts/hvpcp>.

¹³³ FDA, Peanut Butter and other Peanut Containing Products Recall List, Oct. 28, 2009, <http://www.accessdata.fda.gov/scripts/peanutbutterrecall>.

¹³⁴ Christopher Duering, *Peanut Recall Having Big Impact on Small Firms*, REUTERS, Mar. 11, 2009, <http://www.reuters.com/article/2009/03/11/us-salmonella-peanuts-idUSTRE52A4AT20090311>.

¹³⁵ See CAPTURING RECALL COSTS, *supra* note 130, at 5-6.

¹³⁶ Jane McGrath, *10 Costly Food Recalls: Peter Pan Peanut Butter*, HOW STUFF WORKS, <http://www.howstuffworks.com/10-food-recalls.htm#page=6> (last visited Oct. 27, 2013).

¹³⁷ See CAPTURING RECALL COSTS, *supra* note 130, at 6.

butter is such a staple of the American diet (markets for less essential foods would probably have taken even longer to recover).¹³⁸

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.¹³⁹ Indeed, the market impacts of recalls are detrimental to consumers as well. Large recalls reduce the availability of products that consumers enjoy and rely on.

The negative impacts of outbreaks and recalls often spread to other companies making similar products that had nothing to do with the contamination. In the aftermath of the 2009 outbreak linked to peanut paste from the Peanut Corporation of America (PCA), sales of Skippy peanut butter fell 54 percent and sales of Peter Pan fell 45 percent, even though PCA processed only 2 percent of U.S. peanuts and jarred peanut butter was largely not implicated.¹⁴⁰ 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.¹⁴¹

Finally, as the FDA originally stated in its draft PRIA, major recalls can result in the bankruptcy of companies that played any part in the production or distribution of the contaminated product, with potentially far-reaching economic implications.¹⁴² Sunland Inc. never recovered from its large nut-butter recall following an outbreak in 2012. Owing about \$100 million to thousands of creditors, Sunland finally filed for bankruptcy last month. The roughly 100 people employed by the company in Portales, New Mexico lost their jobs (and the company was expected to hire 40 more workers this year). Meanwhile, the mayor claimed the city would suffer from the loss of Sunland's tax payments, and peanut growers in the Southwest said they will have nowhere to go to sell their current peanut crop.¹⁴³

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 extensive costs that would then be avoided.

¹³⁸ See Andrew Martin & Liz Robbins, *Fallout Widens as Buyers Shun Peanut Butter*, THE NEW YORK TIMES, Feb. 6, 2009, <http://www.nytimes.com/2009/02/07/business/07peanut.html>; Zach Mallove, *USDA Releases Study on Peanut Industry*, FOOD SAFETY NEWS, Feb. 4, 2010, <http://www.foodsafetynews.com/2010/02/usda-releases-study-on-peanut-industry>; 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>.

¹³⁹ 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>.

¹⁴⁰ Mallove, *supra* note 138.

¹⁴¹ 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>.

¹⁴² OMB Redlined PRIA, *supra* note 7, at 49-50.

¹⁴³ Dan Flynn, *Nation's Biggest Organic Peanut Processor Shuts Down*, FOOD SAFETY NEWS, Oct. 11, 2013, <http://www.foodsafetynews.com/2013/10/nations-biggest-organic-peanut-processor-shuts-down>.

Avoided Dread and Panic from Exposure to Potentially Contaminated Foods

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,¹⁴⁴ 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.¹⁴⁵ 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.¹⁴⁶ These psychological costs of exposure are very real, but often overlooked.

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.¹⁴⁷ While contamination at local retail establishments and restaurants will continue to require their swift investigation, the FDA's proposed rule will presumably avoid a number of outbreaks due to processing-level contamination that have proven burdensome and time-consuming for state and local agencies.

There is no data on how much agencies actually spend on these investigations. But 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

¹⁴⁴ See, e.g., Christopher Beam, *Total Recall: I Just Ate Salmonella-Tainted Peanut Butter. What Do I Do Now?*, SLATE (Jan. 30, 2009), http://www.slate.com/articles/news_and_politics/explainer/2009/01/total_recall.html; Posting of Saggyrl to <http://answers.yahoo.com/question/index?qid=20090216172056AAAd4IUA> (2008) ("I just had some Reeses peanut butter cups without thinking about it and am worried about the salmonella scare! I am almost 40 weeks pregnant.").

¹⁴⁵ 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.

¹⁴⁶ 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>.

¹⁴⁷ 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.

health services. Nine percent of local health departments cut food safety programs specifically.¹⁴⁸ Any meaningful reduction in food 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.¹⁴⁹ 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.¹⁵⁰

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).¹⁵¹ By reducing contamination of processed foods, 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 rule (mainly price effects),¹⁵² but it does not consider that the rule will also protect U.S. export markets. U.S. exports of processed foods including ingredients, dairy products, frozen foods, and beverages totaled \$50 billion in 2011.¹⁵³ 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.”¹⁵⁴ The proposed rule will provide foreign countries with greater security in the safety of U.S. processed foods and help to prevent trade disruptions caused by contamination events. Indeed, several studies demonstrate that adoption of a HACCP program improves export performance.¹⁵⁵

¹⁴⁸ *Id.* at 7.

¹⁴⁹ *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>.

¹⁵⁰ 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>.

¹⁵¹ 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>.

¹⁵² Final Draft PRIA, *supra* note 2, at 121-22.

¹⁵³ Kerstin Braun, *How to Feast on the U.S. Food Export Boom without Fear of Credit Risk*, FOOD LOGISTICS, Mar. 16, 2012, <http://www.foodlogistics.com/article/10657446/how-to-feast-on-the-us-food-export-boom-without-fear-of-credit-risk>.

¹⁵⁴ GARCIA-FUENTES ET AL., *supra* note 141, at 5.

¹⁵⁵ Kay Cao et al., *The Economics of HACCP (Hazard Analysis & Critical Control Point): A Literature Review*, Agribusiness Perspectives Papers (2004), available at <http://www.agrifood.info/perspectives/2004/Cao.html>

Greater Efficiency and Profitability, Less Waste

In response to the rule, many companies are likely to modernize their facilities and operations in ways that make them not only safer but more efficient and profitable as well, offsetting their compliance costs to some extent. Food companies often report that production defects cost them between 3 to 7 percent of their total sales. Effective HACCP plans typically reduce the frequency of safety and quality defects, which leads to improvements in yields, line efficiencies, and overall plant capacity.¹⁵⁶ The FDA itself describes how the introduction of HACCP sharply reduced the number of “rejected lots” in ready-to-eat lobsters and shrimp.¹⁵⁷

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.”¹⁵⁸ 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.¹⁵⁹

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 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.¹⁶⁰

As the FDA explained in its original draft, these studies imply that the value of safer processed foods would be between \$19.6 and \$130.8 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.¹⁶¹ 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.”

(summarizing two studies showing that HACCP adoption had a positive impact on exports for the Oman fish processing industry and Turkish food processing firms).

¹⁵⁶ Larry Keener, *HACCP: A View to the Bottom Line*, FOOD TESTING & ANALYSIS (2001), available at <http://www.zipcon.net/~foodsafe/bottomline.pdf>.

¹⁵⁷ Final Draft PRIA, *supra* note 2, at 33-34.

¹⁵⁸ OMB Redlined PRIA, *supra* note 7, at 50.

¹⁵⁹ *Id.* at 51.

¹⁶⁰ 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).

¹⁶¹ OMB Redlined PRIA, *supra* note 7, at 50-51.

REGULATORY OPTIONS

The FDA Should Select the \$250,000 Cutoff for Very Small Businesses

The FDA originally proposed that only businesses with less than \$250,000 in sales should be exempted from the rule's HARPC requirements as "very small businesses" (VSBs).¹⁶² But OIRA introduced two other "co-proposed" options for the cutoff—\$500,000 and \$1 million—that would leave large holes in the rule's coverage.¹⁶³

The FDA is already required by the FSMA (under the Tester amendment) to exempt facilities with annual sales less than \$500,000 where more than half is from direct sales to consumers or to restaurants and retailers in the same state or within 275 miles.¹⁶⁴ This exemption at least includes constraints that are intended, however naïvely, to limit the geographic scope of outbreaks caused by exempt foods and further a policy of promoting locally grown food.¹⁶⁵ On the other hand, raising the threshold for the blanket exemption to \$500,000—or higher—would render the Tester constraints meaningless, since all facilities below that cutoff would be exempt by virtue of their size alone, without having to satisfy any direct-marketing requirements. This is surely not what Congress intended when it crafted those requirements in the first place.

Each of the new options would lower the rule's costs, but only at the public's expense. The middle cutoff would reduce the costs by about \$80 million (a 17-percent reduction) while exempting another 11,000 facilities from the HARPC requirements (a 22-percent reduction in covered facilities). The highest cutoff would reduce the costs by \$156 million (a 33-percent reduction from the \$250,000 cutoff), but it would reduce the rule's coverage to a far greater extent by exempting an additional 29,000 facilities (a 56-percent reduction in covered facilities).¹⁶⁶

Because virtually all large facilities already have a HACCP system in place, the most substantial benefits of this rule will derive from small- and medium-sized plants adopting preventive controls.¹⁶⁷ Exempting too many of these plants would remove from the rule's coverage precisely those companies whose practices would be most improved by the proposed rule.

¹⁶² *Id.* at 68.

¹⁶³ Final Draft PRIA, *supra* note 2, at 56.

¹⁶⁴ Proposed Rule on CGMP and HARPC for Human Food, 78 Fed. Reg. at 3649; Food Safety Modernization Act, sec. 103(a), § 418(1)(1)(C), 124 Stat. at 3892-93.

¹⁶⁵ *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.”).

¹⁶⁶ See Final Draft PRIA, *supra* note 2, at 7-12 (showing total costs of the rule under each option), 58-61 (showing total number of “qualified” (exempt) facilities under each option).

¹⁶⁷ See *id.* at 27 (82 percent of facilities with 20-99 employees, and 42 percent of facilities with fewer than 20 employees, have already adopted HACCP systems).

Also, HACCP is now an industry standard, frequently required by retailers and other buyers as a condition of doing business with the processing facility. By maximizing the adoption of preventive controls by businesses of various sizes, the FDA will fill in some of the remaining gaps in the industry and bring lagging businesses up to date—which will help them in the long run with their market access, competitiveness, and brand protection.

For the \$250,000 cutoff to break even, the FDA estimates the rule would have to reduce annual illnesses by roughly one-quarter (about 230,000 illnesses).¹⁶⁸ Under our alternative estimation of the cost of illnesses caused by processed foods, it would be even easier to justify this option: it would only have to reduce illnesses by 16 percent to break even.¹⁶⁹ And neither of these figures takes into account the fact that the PRIA overestimated the costs of the rule by assuming companies would incur the costs of manual recordkeeping; the rule would be easier still to justify if more realistic cost estimates were used.

It is important to remember that 99 percent of the facilities that will incur costs in establishing a HARPC system are considered “small businesses” (those with fewer than 500 employees).¹⁷⁰ Small businesses would have two years after the rule’s publication date to begin complying with it.¹⁷¹ This will ease some of their cost burden and give them more time to prepare. Also, the FDA plans to educate small facilities on the rule’s requirements through the Food Safety Preventive Controls Alliance it is developing with the Illinois Institute of Technology. The Alliance will develop a standardized training curriculum for the food processing industry and help small firms adjust to the new requirements.¹⁷²

The FDA Should Restore the Crucial Provisions Eliminated by OIRA

During its review, OIRA deleted seven essential provisions from the FDA’s proposed rule, with no explanation as to why they should not be included. In the final draft, the FDA merely requests comment on these provisions while clarifying that they are not being proposed at this time.¹⁷³ Originally, the FDA also included extensive material explaining and justifying the need for these provisions, but OIRA relegated this material to an appendix at the back of the proposed rule.¹⁷⁴

According to expert elicitations and the FDA’s study of recent recalls, the chief contributing factors to food safety problems in processed foods include (1) deficient employee training, (2)

¹⁶⁸ *Id.* at 6.

¹⁶⁹ We estimated that illnesses caused by processed foods cost \$3.00 billion per year. If the rule were to prevent 15.9 percent of these illnesses, the resulting benefits would be about \$475 million, which breaks even with the FDA’s estimated cost for the rule (\$475 million).

¹⁷⁰ See Final Draft PRIA, *supra* note 2, at 7 (add up the number of facilities subject to HARPC requirements that have fewer than 500 employees and divide them by the total number of facilities subject to HARPC).

¹⁷¹ Proposed Rule on CGMP and HARPC for Human Food, 78 Fed. Reg. at 3674.

¹⁷² See FDA, Food Safety Preventive Controls Alliance,

<http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm284406.htm> (last visited Nov. 1, 2013).

¹⁷³ See Proposed Rule on CGMP and HARPC for Human Food, 78 Fed. Reg. at 3762; Final Draft PRIA, *supra* note 2, at 136-37.

¹⁷⁴ See Proposed Rule on CGMP and HARPC for Human Food, 78 Fed. Reg. at 3648 (listing contents of Appendix), 3812-21 (Appendix).

poor sanitation, (3) a lack of supplier controls, and (4) a lack of environmental monitoring.¹⁷⁵ And yet the agency’s proposed requirements that would have specifically addressed these four areas were among those eliminated by OIRA.

The FDA estimates that 66 percent of all facilities already have in place some kind of HACCP system, including virtually all facilities with more than 100 employees.¹⁷⁶ And yet these HACCP plants have been the source of recent outbreaks, from Farm Rich frozen products to ConAgra pot pies. While the rule as proposed would improve those systems to some degree, these more extensive standards are necessary to achieve substantial gains in safety for both HACCP and non-HACCP plants alike.

We urge the FDA to restore all these provisions, described below, in the final rule.

Establish Sanitation Requirements in Place of Non-Binding Guidance in the CGMP

The FDA originally proposed revising certain sections of the “current good manufacturing practices” (CGMP) for food facilities so that they would require, rather than just recommend, a number of specific sanitation steps, including:

- Proper storage of utensils and portable equipment to prevent contamination of foods
- Cleaning of non-food-contact surfaces to protect against possible contamination of food-contact surfaces and food
- Inspection of containers of raw materials upon their receipt to ensure they have not contributed to contamination of the food
- Installation and maintenance of equipment in a manner that facilitates cleaning
- Protection of food from contaminants that may drip, drain, or be drawn into it during various manufacturing steps
- Proper heating and cooling of food during blanching
- Adequate operating temperatures and periodic cleaning of blanchers

OIRA deleted all these changes from the proposed rule itself, changing them from “proposed changes” to “potential changes.”¹⁷⁷

The FDA acknowledges that poor sanitation “continues to be an ongoing factor for foodborne illness,” despite the current provisions on sanitation in the CGMP.¹⁷⁸ The FDA found that a lack of sanitation controls played a role in 62 percent of recalls triggered by *Listeria* or *Salmonella*

¹⁷⁵ See Final Draft PRIA, *supra* note 2, at 25-26.

¹⁷⁶ *Id.* at 27.

¹⁷⁷ See OMB Review of FDA Proposed Rule Preamble on CGMP and Hazard Analysis and Risk Based Preventive Controls, Part 1 of 3, at 366-69, 373, 377, 390-93, Apr. 15, 2013, available at <http://www.regulations.gov/contentStreamer?objectId=0900006481294301&disposition=attachment&contentType=pdf> [hereinafter OMB Redlined Preamble]. See also Proposed Rule on CGMP and HARPC for Human Food, 78 Fed. Reg. at 3728-29 tbl.11 (a list of CGMP changes that were downgraded from “proposed” to “potential,” including these sanitation measures).

¹⁷⁸ Final Draft PRIA, *supra* note 2, at 133.

contamination.¹⁷⁹ Indeed, poor sanitation was a key factor in the 2008-2009 peanut-paste outbreak. Among many other issues that the FDA found in its investigation of the plant, the agency took note of a felt material at the end of the peanut roaster that was not capable of being cleaned and a portable conveyor belt that was stored in a moldy, dirty wash room.¹⁸⁰ The FDA's proposed requirements would directly address these kinds of dangerous practices.

These requirements would also fill in some of the proposed rule's coverage gaps, since it would apply to qualified facilities (those that are otherwise exempt from the rule's HARPC requirements), and to covered facilities whose self-designed preventive controls do not fully address these sanitation issues.¹⁸¹

The cost of converting these recommendations into requirements is expected to be minimal. Since all facilities already conduct cleaning and sanitation operations, the FDA believes it is not the absence of cleaning but poor cleaning practices that lead to contamination. The agency reasonably concludes that the only cost of these changes would be the cost of training employees in better sanitation practices: \$15.6 million per year.¹⁸² These requirements would only have to reduce illnesses by less than 1 percent to break even with their costs.

Establish Training Requirements in Place of Non-Binding Guidance in the CGMP

The FDA originally proposed revising other sections of the CGMP so that they would require, rather than just recommend, certain education and training measures. The proposal went beyond merely replacing "should" with "must"—the FDA intended to add a number of specific training requirements that are not currently in the CGMP at all:

- (1) Each person engaged in manufacturing, processing, packing, or holding food (including temporary and seasonal personnel) or in the supervision thereof, must receive training, as appropriate to the person's duties upon hiring and periodically thereafter. The training must include the principles of food hygiene and food safety, including the importance of employee health and personal hygiene, as applied at the facility.
- (2) Each person engaged in manufacturing, processing, packing or holding food (including temporary and seasonal personnel), or in the supervision thereof, must have the training, in combination with education or experience, to perform the person's assigned duties.

¹⁷⁹ Analysis of Food Recalls Initiated in 2008-2009 by an FDA CGMP Working Group, Feb. 13, 2012, at 9, available at <http://www.regulations.gov/contentStreamer?objectId=09000064811b3d7b&disposition=attachment&contentType=pdf> [hereinafter FDA Recall Analysis].

¹⁸⁰ FDA, Inspection Report of Peanut Corp. of America Facility in Blakely, GA, Jan. 2009, at 5-6, available at <http://www.marlerblog.com/uploads/file/Blakely%20GA%20Form%20483.pdf>.

¹⁸¹ Final Draft PRIA, *supra* note 2, at 133-34.

¹⁸² *Id.* at 134-36.

(3) Plant management must establish and maintain records that document required training of personnel, including the date of the training, the type of training, and the person(s) trained.¹⁸³

OIRA deleted this material from the actual proposal and instead had the FDA request comment on whether and how to revise the provision on education and training (whether the revisions should be general or detailed, whether or not they should apply to qualified facilities, etc.).¹⁸⁴

The FDA found that deficient employee training was a contributing factor in 24 percent of recalls in 2008 and 2009.¹⁸⁵ The agency's own surveys show that a sizable portion of food facilities do not provide adequate training, despite the existing guidance. For example, 61 percent of facilities with between 20 to 499 employees either do not cover the principles of food safety, foodborne hazards, and prevention in their training, or spend less than one hour doing so. While all facilities with 500 or more employees provide some training, still 60 percent spend less than an hour on these subjects. Among facilities with more than 20 employees, 53 percent spend less than one hour on personal-hygiene training. And overall, 15 percent of facilities do not provide refresher training at all.¹⁸⁶

In a separate survey of 649 worldwide food and drink manufacturers (most of them in North America), more than 70 percent reported “scheduling time for training” as the biggest obstacle to training employees, which suggests they may not be adequately prioritizing it.¹⁸⁷ The establishment of specific training requirements in the CGMP—with recordkeeping requirements, too—may provide the emphasis necessary to get the industry to take this responsibility more seriously. A number of studies illustrate the effectiveness of training in promoting safe practices, finding that workers are more likely to practice good hygiene where there are formal training programs, and that increased levels of training resulted in lower bacterial counts on retail foods.¹⁸⁸

It is important that the FDA place these standards in subpart B of the regulations instead of subpart C, so that they would apply across the board, improving food safety even at qualified facilities that are exempt from the rule's HARPC requirements.

According to the FDA, the training requirements it originally proposed would cost \$93 million per year.¹⁸⁹ They would only have to reduce illnesses by 5 percent (assuming the FDA's estimate for the annual burden of illnesses) or 3 percent (assuming our alternative estimate) in order to

¹⁸³ See OMB Review of FDA Proposed Rule on CGMP and Hazard Analysis and Risk Based Preventive Controls, Part 3 of 3, at 778, Apr. 15, 2013, available at <http://www.regulations.gov/contentStreamer?objectId=0900006481294303&disposition=attachment&contentType=pdf> [hereinafter OMB Redlined Proposed Rule].

¹⁸⁴ See OMB Redlined Preamble, *supra* note 177, at 356-58; Proposed Rule on CGMP and HARPC for Human Food, 78 Fed. Reg. at 3729.

¹⁸⁵ FDA Recall Analysis, *supra* note 179, at 7.

¹⁸⁶ Final Draft PRIA, *supra* note 2, at 127-28.

¹⁸⁷ Lack of Time Biggest Obstacle to Food Safety Training, Survey Shows, Food Safety News, Apr. 5, 2013, <http://www.foodsafetynews.com/2013/04/lack-of-time-is-biggest-barrier-to-food-safety-training-survey-shows>.

¹⁸⁸ See Final Draft PRIA, *supra* note 2, at 124-27.

¹⁸⁹ *Id.* at 131-32.

break even.

Require Review of Consumer Complaints

The FDA's original proposal would have required each facility to review consumer complaints and evaluate how they relate to the effectiveness of the facility's food safety plan, but OIRA deleted the provision.¹⁹⁰

Consumer complaints are an essential feedback mechanism that can shed light on food safety flaws before problems get significantly worse. The FDA's group of experts found that while large facilities seem to take complaints very seriously and modify their food safety plans in response, small and medium-sized companies may deal with them initially but then move on without formally reviewing them, analyzing trends, or reevaluating their practices.¹⁹¹

The FDA estimated that facilities would spend between 4 and 24 hours per month reviewing complaints (depending on the size of the facility), at a total cost of \$11.5 million.¹⁹² The provision would only have to reduce illnesses by less than 1 percent to break even.

Require Environmental Monitoring for Pathogens Reasonably Likely to Occur

Originally, the FDA would have required facilities to monitor the processing environment for any pathogens that are reasonably likely to contaminate the food (or indicator organisms that suggest the possible presence of those pathogens). They would have to collect samples at least once a month from various locations within the facility and then test them to determine whether the preventive controls in place are succeeding in minimizing or preventing contamination.¹⁹³

Experts from industry, government, and consumer groups have all promoted environmental monitoring as an essential tool for verifying the effectiveness of sanitation procedures, which makes OIRA's deletion of this requirement that much more outrageous.¹⁹⁴ In its outbreak investigations, the FDA often finds the relevant pathogen on a variety of surfaces throughout the facility, including those that directly contact the food (counters, conveyor belts) and those that do not (floors, walls, ventilation systems, drains).

Many outbreaks and recalls might have been prevented if the plants had detected contamination in the processing environment and then made improvements to their sanitation procedures, or modified their buildings or equipment to avoid creating harborage sites for bacteria. Pathogens from the plant environment likely played a key role in *Salmonella* contamination of cereal,

¹⁹⁰ OMB Redlined Proposed Rule, *supra* note 183, at 801. Proposed Rule on CGMP and HARPC for Human Food, 78 Fed. Reg. at 3767 (requesting comment on the provision instead of proposing it).

¹⁹¹ Final Draft PRIA, *supra* note 2, at 137-38.

¹⁹² *Id.* at 138.

¹⁹³ OMB Redlined Proposed Rule, *supra* note 183, at 801-02.

¹⁹⁴ See, e.g., ALMOND BOARD OF CALIFORNIA, PATHOGEN ENVIRONMENTAL MONITORING PROGRAM (PEM) 48 (2010) (claiming that environmental monitoring should not even be considered a cost, but rather a crucial investment in the company); Douglas Marshall, *The Fourth Pillar of Food Safety - Environmental Monitoring*, FOOD TESTING NEWSLETTER (Eurofins, Luxembourg), Mar. 2012, at 1, available at <http://www.eurofins.de/food-analysis/information/food-testing-newsletter/food-newsletter-38/environmental-monitoring.aspx>.

peanut butter, whey protein, and white pepper, and *Listeria* contamination of queso fresco, chopped celery, and cantaloupes.¹⁹⁵ The FDA also found that a lack of environmental controls contributed to 48 percent of recalls due to these two pathogens in 2008 and 2009.¹⁹⁶ A HACCP plan alone is often not enough to prevent contamination when, for example, the food is re-exposed to the processing environment after a kill step.¹⁹⁷

Environmental monitoring can be enormously beneficial to the food company itself. Former FDA Associate Commissioner of Foods David Acheson writes that once you find the optimal frequency and intensity of environmental testing, “program management becomes more economical, as you are more effective at cleaning and more efficient at finding and eliminating niches which can equal better brand protection.” Typically, underwriters even lower the facility’s insurance premiums to reward effective safety measures. He concludes that while OIRA may have deleted the provision due to concerns over how much it would cost, companies should adopt environmental monitoring precisely because of how much it would save them.¹⁹⁸

Monthly testing for *Salmonella* and *Listeria* is estimated to cost only about \$9.6 million. (For comparison purposes, the FDA estimated that weekly testing, which may be more appropriate for some plants and processes, would cost \$36 million).¹⁹⁹ Monthly testing would break even if it reduced illnesses by less than 1 percent.

Require Finished Product Testing When Appropriate Based on Risk

The FDA originally intended to require testing of finished products as well, when appropriate based on risk, to assess whether the preventive controls in place are working well enough to control contamination.²⁰⁰ Finished product testing is often the last line of defense, since it can uncover contamination that may have been missed at an earlier stage, or that may have been undetectable before the product was in its final form. When ConAgra could not determine exactly how its 25-ingredient frozen pot pies became contaminated with *Salmonella*, even after testing each of its incoming ingredients, the company instituted additional finished product testing to ensure that its facility was not continuing to produce tainted food.²⁰¹

Finished product testing also benefits food companies in a number of ways. If the company tests for an indicator organism, it may detect that its preventive controls are in the process of failing, and it can remedy the problems before there is a need to dispose of the product. Collecting test information on finished products over time allows companies to better pinpoint which batches may have been affected in the event of a recall, to minimize its disruptive effects. And it allows

¹⁹⁵ See Proposed Rule on CGMP and HARPC for Human Food, 78 Fed. Reg. at 3813-15.

¹⁹⁶ FDA Recall Analysis, *supra* note 179, at 9.

¹⁹⁷ See MICROORGANISMS IN FOOD 7: MICROBIOLOGICAL TESTING IN FOOD SAFETY MANAGEMENT 199-210 (2002).

¹⁹⁸ David Acheson, *What Is Your Environmental Monitoring “Sweet Spot”?*, The Acheson Group (June 13, 2013), <http://achesongroup.com/2013/06/what-is-your-environmental-monitoring-sweet-spot>.

¹⁹⁹ Final Draft PRIA, *supra* note 2, at 144-49 (adding together the total cost of monthly testing for *Salmonella* and the total cost of monthly testing for *Listeria*, plus the cost of writing procedures for environmental monitoring).

²⁰⁰ OMB Redlined Proposed Rule, *supra* note 183, at 801-02.

²⁰¹ See Moss, *supra* note 30; Press Release, ConAgra, ConAgra Foods Resumes Production of Banquet and Private Label Pot Pies (Nov. 14, 2007), <http://www.conagrafoods.com/news-room/news-ConAgra-Foods-Resumes-Production-of-Banquet-and-Private-Label-Pot-Pies-1078267>.

companies to analyze trends in the levels of pathogens in their finished products and how they correlate with changes in their processes, their suppliers, and their food safety plan.²⁰²

The FDA estimated this proposed requirement would cost \$23.6 million,²⁰³ which would break even if it reduced illnesses by just 1 percent.

Require Supplier Approval and Verification Programs Where Appropriate

The FDA originally included a well-designed, robust proposal to require each facility to establish a supplier approval and verification program for all raw materials and ingredients with hazards that are reasonably likely to occur. Generally, facilities would have to maintain a written list of their suppliers and perform supplier verification activities to assure that these hazards are significantly minimized or prevented. In most cases, the facility would have to conduct or obtain documentation of an “onsite audit” of the supplier. In other scenarios, it would be able to choose among a list of verification activities (onsite audits, periodic sampling and testing of ingredients, periodic review of the supplier’s food safety records, or other appropriate measures).²⁰⁴

OIRA removed this entire set of requirements from the proposed rule. Instead, the FDA is requesting comment on whether a supplier verification system should be adopted at all, and if so, how detailed and extensive it should be.²⁰⁵

Thousands of products have become entangled in outbreaks and recalls because they failed to anticipate or detect contamination in their raw ingredients, including peanut paste, nonfat dried milk, whey protein, fruit stabilizers, and hydrolyzed vegetable protein.²⁰⁶ The FDA found that a lack of supplier controls contributed to 37 percent of all recalls in 2008 and 2009.²⁰⁷ Supplier approval and verification programs are widely promoted by industry groups and international

²⁰² Proposed Rule on CGMP and HARPC for Human Food, 78 Fed. Reg. at 3820.

²⁰³ Final Draft PRIA, *supra* note 2, at 152-55 (adding total annualized cost of testing, holding the product, and writing procedures).

²⁰⁴ See OMB Redlined Proposed Rule, *supra* note 183, at 803-07. Originally, the FDA would have required an onsite audit in all cases where the supplier is subject to a “designated food safety regulation” with respect to that ingredient. This would include (eventually) not only the FSMA rules on produce and processed foods, but also the set of current good manufacturing practices (CGMP) and several other commodity-specific rules. *Id.* at 762. The seriousness of the hazard would only determine the frequency of follow-up audits: For hazards posing a reasonable probability of “serious adverse health consequences or death to humans or animals” (SAHCODHA), follow-up audits would have to be done at least once a year; for less serious hazards, follow-up audits would have to be done at least every two years. These requirements were identical to those in the “foreign supplier verification program” (FSVP) rule, *as it was originally drafted by the FDA*. Now, however, the FDA seems to suggest that *if* it were to require supplier approval and verification programs as part of this rulemaking, it would instead only require onsite audits for the most serious (SAHCODHA) hazards, while hazards thought to be less serious could be addressed through any of the other verification activities. See Proposed Rule on CGMP and HARPC for Human Food, 78 Fed. Reg. at 3766; Final Draft PRIA, *supra* note 2, at 168. This design matches the FSVP proposal *after it had been revised by OIRA*. It would likely require much fewer onsite audits, which would weaken the program’s effectiveness. For a discussion of the implications of OIRA’s changes to the FSVP rule, see Michael Patoka, *White House Changes to Food Import Rule Weaken Consumer Protections*, CPRBlog (Oct. 25, 2013), <http://progressivereform.org/CPRBlog.cfm?idBlog=F04A33D7-FB5F-A47D-AFC16B73FBB7F80D>.

²⁰⁵ Proposed Rule on CGMP and HARPC for Human Food, 78 Fed. Reg. at 3765-67.

²⁰⁶ *Id.* at 3820.

²⁰⁷ FDA Recall Analysis, *supra* note 179, at 7.

organizations.²⁰⁸ But still, many companies discover the value of such a program too late: only after its frozen pies sickened 401 people did ConAgra began requiring its vegetable suppliers to test for pathogens.²⁰⁹ Like all the other provisions eliminated by OIRA, an across-the-board requirement for supplier controls would not only protect the public from potentially widespread contamination, but also protect food-processing companies from being dragged down by their tainted ingredients.

Relationship between this rule and the rules on imported foods

Clearly it is not only imported ingredients that pose safety risks. And yet if a supplier approval and verification program is not included in this final rule, only importers of foreign foods would have to verify the safety of their suppliers under the FDA's rule on foreign supplier verification programs (FSVP).²¹⁰

There are some other differences between the two rules. The FSVP rule imposes the supplier-approval-and-verification requirements on all "importers" (including processing facilities, restaurants and retailers, and even commodity brokers) that receive foods and ingredients from foreign suppliers. The supplier provisions in the Preventive Controls rule would apply only to registered "facilities" that manufacture, process, pack, or hold food, and only to the raw materials and ingredients they receive (not finished food products), but it would require each facility to verify the food safety compliance of *both* its domestic and foreign suppliers.²¹¹

There would be significant overlap between the two rules in application, which is why the FDA originally made clear that facilities already in compliance with the supplier provisions of the Preventive Controls rule would essentially be in compliance with the FSVP rule as well.²¹² The FDA has also stated that *if* it adopts supplier controls in this rule, it will align them as much as possible with those in the FSVP rule to avoid duplicative or unnecessary requirements.²¹³

As the Center for Science in the Public Interest has pointed out, omitting the supplier provisions from this rule but including them in the FSVP rule might trigger challenges to the regulations under international trade agreements.²¹⁴ Foreign food suppliers and their governments could

²⁰⁸ See Proposed Rule on CGMP and HARPC for Human Food, 78 Fed. Reg. at 3821.

²⁰⁹ Moss, *supra* note 30.

²¹⁰ Foreign Supplier Verification Programs for Importers of Food for Humans and Animals; Proposed Rule, 78 Fed. Reg. 45730 (proposed July 29, 2013), available at <http://www.regulations.gov/#!documentDetail;D=FDA-2011-N-0143-0023>.

²¹¹ See OMB Review of FDA Proposed Rule on Foreign Supplier Verification Programs 25-26, Aug. 15, 2013, available at <http://www.regulations.gov/contentStreamer?objectId=09000064814413c8&disposition=attachment&contentType=pdf>.

²¹² See OMB Review of Preliminary Regulatory Impact Analysis for FDA Proposed Rule on Foreign Supplier Verification Programs 16, Aug. 15, 2013, available at <http://www.regulations.gov/contentStreamer?objectId=09000064814413c7&disposition=attachment&contentType=pdf>.

²¹³ See Proposed Rule on CGMP and HARPC for Human Food, 78 Fed. Reg. at 3767.

²¹⁴ Comment from Ctr. for Sci. in the Pub. Interest on Supplier Approval and Verification Requirements in the Preventive Controls Rule, May 17, 2013, available at

allege discriminatory treatment because, unlike domestic suppliers, they would have to go through certain verification steps in order to sell their products in the United States—like arranging and paying for an onsite audit. The FDA could immunize its new food safety system from these kinds of challenges by including supplier provisions in the Preventive Controls rule that would parallel the obligations placed on importers and foreign suppliers in the FSVP rule.

The FDA intends to set up a trusted and reliable system for accreditation of third party auditors, expecting that these auditors will play a number of roles in ensuring the safety of imported foods, including conducting onsite audits that would satisfy the requirements of the FSVP rule. But once that system is in place, food facilities would likely be able to rely on these same accredited auditors to satisfy any domestic supplier verification requirements under the Preventive Controls rule as well. One of the agency’s goals is for each supplier to obtain just one onsite audit from an accredited auditor that would be sufficiently reliable to satisfy all its customers, in order to eliminate the costs of redundant audits. This would help lower the costs associated with supplier verification activities and presumably enhance their quality and effectiveness.

The FDA estimated that supplier controls would cost just \$17 million. This estimation does reflect the added efficiency of each supplier obtaining only one onsite audit each year, although it likely overestimates the cost of the provisions in a couple ways: (1) it does not account for the number of processing facilities that have a kill step and thus would not need to conduct supplier verification; and (2) it considers all manufacturers of potential ingredients (like butter) to be “suppliers” in need of verification, even though some may instead produce that ingredient only as a final product.²¹⁵ Nevertheless, even assuming the FDA’s estimated cost, supplier controls would still only have to reduce illnesses by less than 1 percent to break even.

Require Review of Records Created by These Activities

The benefits of environmental monitoring, finished product testing, consumer complaints, and supplier verification activities can be realized only if companies review the resulting records within a reasonable time (noticing changes, analyzing trends, and incorporating the information into their food safety plans). Because these activities were eliminated from the proposal, the requirement to review their associated records was also deleted.²¹⁶

The FDA estimated that companies would spend between 15 minutes and one hour each month reviewing these records, at a cost of \$2 million per year.²¹⁷ This provision would break even if it reduced illnesses by 0.1 percent.

Summary of Breakeven Thresholds for These Provisions

Each of these provisions would have to reduce illnesses by a relatively small amount each year in order to justify its costs. Under our more comprehensive estimate for the cost of illnesses caused

<http://www.regulations.gov/contentStreamer?objectId=09000064812eadf6&disposition=attachment&contentType=pdf>.

²¹⁵ Final Draft PRIA, *supra* note 2, at 155-67.

²¹⁶ OMB Redlined Proposed Rule, *supra* note 183, at 802.

²¹⁷ Final Draft PRIA, *supra* note 2, at 169.

by processed foods, the breakeven thresholds would be even lower (see Table 1). Considering how often outbreaks and recalls are attributed to a lack of these same measures, it is entirely plausible that they would be able to achieve reductions of this scale, if not much larger ones.

Table 1: Breakeven Thresholds for Provisions Eliminated by OIRA

Provision Originally Proposed by FDA	Cost Estimated by FDA	Percentage Reduction in Illnesses the Provision Would Have to Achieve to Break Even	
		Assuming FDA estimate for cost of illnesses: \$1.97 billion	Assuming our estimate for cost of illnesses: \$3.00 billion*
Sanitation Requirements in CGMP	\$15.6 million	0.8%	0.5%
Training Requirements in CGMP	\$93.3 million	4.7%	3.1%
Review of Consumer Complaints	\$11.5 million	0.6%	0.4%
Environmental Monitoring (monthly testing)	\$9.6 million	0.5%	0.3%
Finished Product Testing	\$23.6 million	1.2%	0.8%
Supplier Approval and Verification	\$17.4 million	0.9%	0.6%
Review of Records	\$2.0 million	0.1%	0.1%

* Even this estimate is still based on extrapolations from the FDA’s very incomplete outbreak database. The true cost of illnesses attributable to processed foods is likely much greater than this, meaning that the breakeven thresholds would be even lower.

Ultimately, however, all these provisions would act in combination with the rule’s more general CGMP and HARPC requirements to reduce illnesses. It is somewhat artificial to look at each one in isolation, when all together they would form a comprehensive suite of food safety protections, each measure potentially preventing or detecting contamination that another one might miss.

The FDA estimates that if all these eliminated provisions were incorporated into the final rule, the rule’s total cost would be \$648 million per year, as compared to \$475 million without them (assuming the cutoff for “very small business” is \$250,000).²¹⁸ This more effective version of the rule would break even if it reduced illnesses by 33 percent (assuming the FDA’s estimate for the cost of illnesses) or, more realistically, 22 percent (assuming our estimate).

A reduction of this size is certainly plausible. Indeed, the rule proposed by the FDA has a breakeven percentage of 16-24 percent (depending on which VSB threshold is selected), and by proposing it the FDA implies that illness reductions of 16-24 percent are plausible even for a

²¹⁸ *Id.* at 173.

version of the rule that omits these crucial provisions.²¹⁹ So, it is clearly reasonable to anticipate at least a 22-percent reduction in illnesses if these eliminated measures—which may ultimately be more effective than any of the standards actually proposed—are restored to the rule.

CONCLUSION

We have confidence in the FDA's intention to issue a set of stringent standards that will substantially improve food safety practices in processing facilities and better protect the American public from the devastating effects and complications of foodborne illness. We are very concerned, however, that many of the rule's clearest and most effective requirements were deleted from the proposal by OIRA, leaving in place a general framework for facility-written food safety plans that fails to guarantee certain fundamental controls and activities be included.

Also, as we have demonstrated, the PRIA—even as it suggests that the rule's benefits would easily break even with 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 and concern about the rule, from members of Congress, smaller processing facilities, and some industry associations.

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 sets science-based minimum standards for practices that will significantly minimize or prevent food safety hazards, consistent with its statutory mandate. To achieve this, the FDA must restore in its final rule all the crucial provisions that were eliminated during the process of White House review and select the \$250,000 cutoff for very small businesses.

²¹⁹ See Proposed Rule on CGMP and HARPC for Human Food, 78 Fed. Reg. at 3649-50.

APPENDIX: ALTERNATIVE ESTIMATION OF THE COST OF ILLNESSES DUE TO PROCESSED FOODS

The following sections demonstrate how we calculated the alternative estimates for the cost of processed-food-related illnesses given in previous sections of this comment.

Calculating the Burden of Illness after Accounting for Deaths from Unidentified Pathogens

Multiplying the death rate for unidentified pathogens (0.00439%)²²⁰ by the value of a statistical life (VSL) used by the FDA (\$7.9 million)²²¹ 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 accounting for deaths due to unidentified pathogens, the cost of illnesses attributable to processed foods rise to \$2.22 to \$2.25 billion—a 14-percent increase over the PRIA’s estimate. See Table 2 below.

Table 2: Calculating Illnesses from Processed Foods, Including Deaths from Unidentified Pathogens²²²

Agent	FDA’s Dollar Loss per Case	Burden of Illnesses due to Processed Foods	
		Attributable illnesses	Dollar Burden
Listeria monocytogenes	\$1,360,067	862	\$1,172,377,754
Mycobacterium bovis	\$437,413	60	\$26,244,780
Salmonella	\$4,622	109,949	\$508,184,278
Unidentified	\$214 \$561	806,247	\$452,304,567
SUMS		917,118	\$2,159,111,379

A = Total Cost of Illnesses Due to Foods Covered Under This Rule = \$2,159,111,379

B = Total Cost After Adding Cost of Avoided Allergic Reactions = A + \$101,878,576 = \$2,260,989,955

Cost of Illnesses Due to Foods Processed in Covered Facilities (depending on the threshold for “very small business”):

Total Less 0.5% (if VSB < \$250,000) = B * 99.5% = \$2,249,685,005

Total Less 1% (if VSB < \$500,000) = B * 99.0% = \$2,238,380,055

Total Less 2% (if VSB < \$1,000,000) = B * 98.0% = \$2,215,770,156

These three totals (\$2.22 - \$2.25 billion) are 14 percent higher than the cost of illnesses estimated in the PRIA (\$1.94 - \$1.97 billion).

²²⁰ See Scallan et al., *supra* note 56, at 20 tbl. (estimating 1,686 deaths out of 38,392,704 illnesses due to unidentified pathogens).

²²¹ Final Draft PRIA, *supra* note 2, at 214.

²²² The numbers in this table are taken from Table 4 on page 21 of the PRIA, except where they have been corrected.

Calculating the Burden of Illness 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)²²³ by the ratio of the FDA’s VSL (\$7.9 million) to Scharff’s VSL (\$7.33 million).²²⁴
- **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).²²⁵

Then, for each pathogen, we added together the relevant components of Scharff’s estimated cost using these adjusted figures.²²⁶

Using these more comprehensive estimates, the cost of illnesses due to processed foods would be \$2.95 to \$3.00 billion—a 52-percent increase over the PRIA’s original estimate. See Table 3 below.

Table 3: Calculating Illnesses from Processed Foods, Using Cost-Per-Illness Figures from Scharff²²⁷

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 Processed Foods	
				Illnesses	Dollar Burden
Listeria monocytogenes	\$1,360,067	\$1,282,069	\$1,354,950	862	\$1,167,966,804
Mycobacterium bovis	\$437,413	--	--	60	\$26,244,780
Salmonella	\$4,622	\$11,086	\$8,330	109,949	\$915,923,704
Unidentified	\$214 \$561	\$1,178	\$992	806,247	\$799,798,770
SUMS				917,118	\$2,909,934,057

* Scharff did not estimate a dollar loss per case for *Mycobacterium bovis*, so we relied on the FDA’s estimated cost for this pathogen in our calculations.

²²³ This portion is listed separately in Table 2 of Scharff’s study. See Scharff, *supra* note 19, at 126 tbl.2.

²²⁴ Compare Scharff Appendix, *supra* note 94, at 6-7 (VSL of \$7.33 million) with Final Draft PRIA, *supra* note 2, at 214 (VSL of \$7.9 million).

²²⁵ Compare Scharff Appendix, *supra* note 94, at 6-7 (VSLY of \$356,500) with Final Draft PRIA, *supra* note 2, at 214 (VSLY of \$214,000).

²²⁶ To obtain the resulting QALY estimate, we added together the following components: “Medical Care,” “Caregiver productivity loss,” “Quality 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 19, at 125-26.

²²⁷ The numbers in this table are taken from Table 4 on page 21 of the PRIA, except where they have been taken from Scharff’s study and modified.

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A = Total Cost of Illnesses Due to Foods Covered Under This Rule = \$2,909,934,057

B = Total Cost After Adding Cost of Avoided Allergic Reactions = A + \$101,878,576 = \$3,011,812,633

Cost of Illnesses Due to Foods Processed in Covered Facilities (depending on the threshold for “very small business”):

Total Less 0.5% (if VSB < \$250,000) = B * 99.5% = \$2,996,753,570

Total Less 1% (if VSB < \$500,000) = B * 99.0% = \$2,981,694,507

Total Less 2% (if VSB < \$1,000,000) = B * 98.0% = \$2,951,576,381

These totals (\$2.95 to \$3.00 billion) are 52 percent higher than the cost of illnesses estimated in the PRIA (\$1.94 - \$1.97 billion).