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IMPLEMENTING THE FOOD SAFETY MODERNIZATION ACT: AN EXAMINATION OF THE INEQUITABLE IMPACT OF THE PROPOSED PREVENTIVE CONTROLS AND PRODUCE SAFETY RULES

*Ben Metzger**

I. INTRODUCTION

Small-scale organic farmers have reaped the benefits of booming business over the past several years as a direct consequence of increased American consumer demand for organic foods.¹ The rapid increase in demand for organic food is quite remarkable. Over the past five years, the domestic industry has grown by a staggering 35%—about three times the rate of the general food industry—and now accounts for \$29 billion annually.² Many small-scale farmers worry, however, that the growth of their flourishing businesses will soon be stunted or wiped out entirely by regulations imposed as part of the Food Safety Modernization Act (“FSMA”).³

Northridge Organic Farm, for example, is a family-owned and operated certified organic farm northeast of Columbus, Ohio.⁴ The small farm, which grows an impressive array of crops ranging from asparagus to zucchini, distributes its fresh produce via a farmers’ market, local restaurants, and grocers in Central Ohio.⁵ Faced with the proposed rules of the FSMA, the farm’s owner, Mark Laughlin, predicts that Northridge will eventually incur regulatory expenses that it simply cannot afford, and he foresees high compliance costs ultimately driving some small-scale organic

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¹ Mark Peters, *A Gap in the Organic Food Chain*, THE WALL STREET JOURNAL (July 15, 2013, 12:26 AM), <http://online.wsj.com/news/articles/SB20001424127887324867904578594171667940126>.

² *Id.*

³ Mary Kuhlman, *New Food Safety Rules: Too Much for Ohio's Small Farms?*, PUBLIC NEWS SERVICE (Sept. 16, 2013), <http://www.publicnewsservice.org/2013-09-16/sustainable-agriculture/new-food-safety-rules-too-much-for-ohios-small-farms/a34454-1>.

⁴ *Northridge Organic Farm*, LOCAL HARVEST, <http://www.localharvest.org/northridge-organic-farm-M11998> (last visited Jan. 17, 2014).

⁵ *Id.*

farmers out of business.⁶ The looming costs are indeed substantial, as the Food and Drug Administration (“FDA”) forecasts an average initial cost of \$27,000 per small farm and then an average annual compliance cost of approximately \$13,000 per farm.⁷ Laughlin expresses concern that these steep costs will severely undercut his bottom line and hurt his business.⁸ He is not alone. The FDA has publicly proposed key rules for administering the FSMA, and hundreds of concerned individuals and entities have participated in the comment process by voicing their opinions.

Section I of this Note will briefly review the history of the Food Safety Modernization Act; Section II will provide a summary of two proposed rules integral to the FSMA; Section III will survey the concerns about fairness expressed by individuals, entities and Congress; and Section IV will evaluate the fairness of the rules from an economic standpoint.

II. BRIEF HISTORY OF THE FSMA AND RULE PROMULGATION

Although the United States and the global community have made significant strides in medicine over the past century, foodborne diseases—those spread via both food and beverages—remain extremely common. Within the United States each year, the Center for Disease Control (“CDC”) estimates a staggering forty-eight million people—about one in six Americans—contract an illness caused by foodborne disease, and approximately 128,000 of those individuals are hospitalized.⁹ Unfortunately, the issue of foodborne diseases is lethal for far too many innocent consumers—three thousand Americans die annually as a result of foodborne diseases.¹⁰

In light of the significant threat foodborne diseases pose to public health, President Barack Obama signed into law the Food Safety Modernization Act in early 2011. This was not a mere tweaking of existing food safety laws. It was the most sweeping overhaul of food safety

⁶ Kuhlman, *supra* note 3.

⁷ *Id.*

⁸ *Id.*

⁹ *Foodborne Diseases*, NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES, <http://www.niaid.nih.gov/TOPICS/FOODBORNE/Pages/Default.aspx> (last visited Jan. 17, 2014).

¹⁰ *Id.*

legislation in seventy years.¹¹ The FSMA armed the FDA with prevention-focused tools and a regulatory framework for ensuring the safety of food consumed in the United States, regardless of whether the food is produced domestically or overseas.¹² Historically, the FDA operated in a less-aggressive, reactionary manner, but the FSMA empowered the FDA to play a more pro-active and preventative role in combating foodborne diseases.¹³

From the beginning, the FDA understood that such a massive food safety overhaul would require a substantial amount of work and time. Only a few months after the President signed the FSMA into law, the FDA's Deputy Commissioner for Foods conceded publicly that it was "physically impossible" to meet all of the FSMA's deadlines.¹⁴ Similarly, the FDA cautioned, "[b]uilding a new food safety system based on prevention will take time, and [the] FDA is creating a process for getting this work done."¹⁵ Some critics, however, suggested the delayed implementation was a thinly-veiled political decision by the Obama Administration, which sought to avoid the perception of increasing job-killing government regulations before the 2012 elections.¹⁶ Observers noted that the delays were especially unusual considering that the proposed rules had the backing of many industry and consumer groups.¹⁷

Regardless of the reasons for the FSMA implementation delays, the FDA received judicial prodding from the United States District Court for

¹¹ Helena Bottemiller, *The Food Safety Modernization Act One Year Later*, FOOD SAFETY NEWS (Jan. 20, 2012), <http://www.foodsafetynews.com/2012/01/the-food-safety-modernization-act---one-year-later/#.UsG6b5Eu4mZ>.

¹² *Food Safety Modernization Act Frequently Asked Questions*, U.S. FOOD & DRUG ADMINISTRATION, <http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm247559.htm#general> (last visited Jan. 17, 2014).

¹³ *Background on the Food Safety Modernization Act*, U.S. FOOD & DRUG ADMINISTRATION, 1, <http://www.fda.gov/downloads/Food/GuidanceRegulation/UCM263773.pdf> (last updated July 12, 2011).

¹⁴ *Id.*

¹⁵ *Id.*

¹⁶ Sabrina Tavernise, *Groups Urge Actions on Food Safety Laws*, THE NEW YORK TIMES (July 17, 2012), http://www.nytimes.com/2012/07/17/science/consumer-groups-criticize-delay-on-food-safety-law.html?_r=4&csmid=tw-share&.

¹⁷ Helena Bottemiller, *Obama Administration Sued for Delay on FSMA Implementation*, FOOD SAFETY NEWS (Aug. 31, 2012), <http://www.foodsafetynews.com/2012/08/obama-administration-sued-for-delay-on-fsma-implementation/#.UsWidpEu4ma>.

the Northern District of California in 2013.¹⁸ The suit was brought by the Center for Food Safety and the Center for Environmental Health.¹⁹ Frustrated by the FDA's "unreasonable and dangerous political foot-dragging,"²⁰ the plaintiffs sought declaratory and injunctive relief regarding the "failure of the FDA to promulgate final regulations by mandatory deadlines contained in the [FSMA]."²¹ In other words, the plaintiffs wanted to legally pressure the FDA into implementing the FSMA.

The FDA essentially argued that the FSMA was too "novel and complex" for timely implementation.²² The FDA explained that it had already established an implementation committee that created six implementation teams, and those six teams established working groups "specifically directed at the expedited implementation of the FSMA."²³ The FDA contended that since it knew it would fail to meet the deadlines, the court should resort to evaluating the reasonableness of FDA's prioritization.²⁴ The FDA cited *Telecommunications Research & Action Center v. F.C.C.* ("TRAC"),²⁵ arguing that the TRAC balancing test should be applied to determine whether the implementation had been unreasonably delayed.²⁶

The district court, however, rejected the FDA's arguments, explaining that the FSMA provided specific deadlines, so a reasonableness test should not be applied.²⁷ The court therefore ruled for the plaintiffs on the issue of declaratory relief.²⁸ Whether to grant injunctive relief, however, was a more difficult determination for the court. It was a difficult decision because of the tension between the need to compel prompt regulatory action—

¹⁸ *Center for Food Safety v. Hamburg*, 954 F. Supp. 2d 965 (N.D. Cal. Apr. 22, 2013) (No. 12-4529 PJH), (Order Regarding Cross Motions for Summary Judgment), available at http://www.centerforfoodsafety.org/files/57-sj-decision_78315.pdf.

¹⁹ *Id.* at 1.

²⁰ *Center for Food Safety Lawsuit Targets FDA, OMB on Stalled Food Safety Act*, CTR. FOR FOOD SAFETY (Aug. 30, 2012), <http://www.centerforfoodsafety.org/issues/308/food-safety/press-releases/723/center-for-food-safety-lawsuit-targets-fda-omb-on-stalled-food-safety-act#>.

²¹ Order Regarding Cross Motions for Summary Judgment, *supra* note 18, at 1.

²² *Id.* at 5.

²³ *Id.*

²⁴ *Id.* at 7.

²⁵ *Telecomm'n's Research & Action Ctr. v. F.C.C.*, 750 F.2d 78 (D.C. Cir. 1984).

²⁶ Order Regarding Cross Motions for Summary Judgment, *supra* note 18, at 7.

²⁷ *Id.* at 8.

²⁸ Order Regarding Cross Motions for Summary Judgment, *supra* note 18, at 8.

intended by Congress—and the need to provide sufficient time for effective regulation—also an intention of Congress.²⁹ The court addressed this tension by ordering the parties to meet outside the court to develop new deadlines for implementation.³⁰ The court reasoned that “Congress signaled its intention that the process be closed-ended rather than open-ended” and therefore the imposition of an injunction imposing deadlines was aligned with the purpose of the FSMA—namely to promote food safety in a timely manner.³¹

Unsurprisingly, the parties failed to agree on deadlines, so the court ordered the parties to independently propose new timelines.³² The court found both proposals unsatisfactory—instead of firm dates, the FDA advocated for soft “target timeframes” and the plaintiffs’ deadlines were too restrictive³³—so the court finally resorted to issuing its own timeline.³⁴ By the court’s schedule, the FDA had to propose all rules by November 30, 2013, and publish the final rules by June 30, 2015.³⁵

As a consequence of this legal action, the FDA has been and is currently under significant pressure to propose rules for all remaining portions of the FSMA. Many individuals and entities have expressed concern with the fairness of the proposed rules. Two provisions in particular have garnered a considerable amount of attention and comments.

III. SUMMARY OF THE PROPOSED RULES

While the FSMA is deeply involved in numerous areas of food safety, two proposed rules are particularly relevant to small-scale and organic farmers. In light of the dramatic increase in consumer demand for locally produced foods, these two regulations have the potential to impact many Americans. The first proposed rule addresses good manufacturing practices

²⁹ *Id.* at 10.

³⁰ *Id.*

³¹ *Id.*

³² *Ctr. for Food Safety v. Hamburg*, 954 F. Supp. 2d 965 (N.D. Cal. June 21, 2013) (No. C 12-4529 PJH), (Order Granting Injunctive Relief), *available at* http://www.centerforfoodsafety.org/files/fsma-remedy-order_52466.pdf.

³³ *Id.*

³⁴ *Id.*

³⁵ *Id.* at 3.

and hazard analysis and risk-based preventive controls. The second rule proposes new standards for growing, harvesting, packing, and holding produce for human consumption.

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

The first rule arises from Section 103 of the FSMA.³⁶ It applies to both domestic and foreign entities that manufacture, process, pack, or hold human food; nearly every food producer is affected.³⁷ Although there are some important exemptions, the FDA retains the ability to withdraw those exemptions if it deems such action necessary to protect public health and prevent or control a foodborne illness outbreak.³⁸ The rule can be divided into two primary features: first, its requirement for hazard analysis and risk-based preventive controls and, secondly, its revision of existing Current Good Manufacturing Practice (“CGMP”).³⁹

The FSMA defines preventative controls as “risk-based, reasonably appropriate procedures, practices, and processes that a person knowledgeable about the safe manufacturing, processing, packing, or holding of food would employ to significantly minimize or prevent the hazards . . . and that are consistent with the current scientific understanding of safe food manufacturing, processing, packing, or holding at the time of the analysis.”⁴⁰ The preventive controls feature is significant because it directly aligns with the FSMA’s goal of transitioning the FDA into a more-aggressive, preventive role.

The requirement of a written food safety plan provides the functional teeth of the preventive controls feature. Per the proposed rule, the written plan would include a hazard analysis, preventive controls, monitoring,

³⁶ Food Safety Modernization Act, Pub. L. No. 111-353, § 103, 124 Stat. 3885, 3889 (2013).

³⁷ Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food, 78 Fed. Reg. 3646, 3648 (proposed Jan. 16, 2013), (to be codified at 40 C.F.R. pts. 1, 16, 106, 110, 114, 117, 120, 123, 129, 179, 211), *available at* <http://www.gpo.gov/fdsys/pkg/FR-2013-01-16/pdf/2013-00125.pdf>.

³⁸ *Id.* at 3649.

³⁹ *Id.* at 3648.

⁴⁰ Food Safety Modernization Act, *supra* note 36, at 3896.

corrective actions, verification, and recordkeeping.⁴¹ Depending on likely hazards present at a particular location, the preventive controls may include process controls, food allergen controls, sanitation controls, and a recall plan.⁴² The written plan would include these preventive controls, along with documentation of periodic monitoring, corrective actions, and verification of the efficacy of the controls.⁴³ The FSMA requires such documentation be “promptly available” to an authorized FDA representative upon written or oral request.⁴⁴ Further adding to this new burden, the written plan must be devised or overseen by a “qualified individual.”⁴⁵ To be a qualified individual, one must successfully complete food safety training according to standardized curriculum or be otherwise qualified by job experience.⁴⁶ Many small-scale food producers do not currently use written plans, so these written requirements would add an entirely new aspect to food production.

The other significant feature of the proposed rule is its revision to the Current Good Manufacturing Practices. The existing practices would be updated to include protection against cross-contact of food by allergens, and may also require documented training for all employees of food producers.⁴⁷ This requirement lacks the exemptions available for the first major feature, so the rule’s application would immediately be more sweeping.⁴⁸

The proposed rule provides staggered compliance dates based on revenues. Very small businesses—most small-scale and organic farms—would have three years to comply with the final rule.⁴⁹ The FDA proposed three thresholds for defining a very small business; the final rule is likely to have a threshold between \$250,000 and \$1,000,000 in annual sales of food,

⁴¹Current Good manufacturing Practice and Hazard Analysis, *supra* note 37, at 3660.

⁴²*Id.* at 3678.

⁴³*Id.*

⁴⁴Food Safety Modernization Act, *supra* note 37, at 3891.

⁴⁵*FSMA Proposed Rule for Preventive Controls for Human Food*, U.S. FOOD & DRUG ADMINISTRATION, 1, 3, <http://www.fda.gov/downloads/Food/GuidanceRegulation/FSMA/UCM360735.pdf> [hereinafter *FSMA Proposed Rule*](last visited Jan. 17, 2014).

⁴⁶*Id.*

⁴⁷*Id.*

⁴⁸*Id.*

⁴⁹*Id.*

adjusted for inflation.⁵⁰ For small businesses of less than 500 employees, compliance would be required within two years after the final rule is published.⁵¹ All other businesses must comply within a year of the final rule.⁵²

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

Produce accounts for nearly half of all foodborne illnesses, making it the leading culprit in the American food supply.⁵³ In fact the FDA traced the largest foodborne illness outbreak of 2013 to salad and cilantro, leading to 631 cases of Cyclosporiasis across twenty-five states.⁵⁴ In light of the particularly persistent threat posed by produce, the proposed rule for produce is lengthy—nearly 550 pages of dense text.⁵⁵ It is, however, a rule required by Section 105 of FSMA.⁵⁶

The rule applies to farms that “grow, harvest, pack or hold most fruits and vegetables when those fruits and vegetables are in their raw or natural (unprocessed) state.”⁵⁷ Foods rarely consumed raw—potatoes, for example—would be exempt, at least initially.⁵⁸ Covered products would include common produce such as lettuce, spinach, cantaloupe, tomatoes, sprouts, mushrooms, onions, peppers, cabbage, citrus, strawberries, and walnuts.⁵⁹ Other exemptions would apply for any foods grown for personal

⁵⁰ *Id.*

⁵¹ *FSMA Proposed Rule*, *supra* note 45, at 3.

⁵² *Id.*

⁵³ Cole Petrochko, *CDC: Produce Biggest Player in Foodborne Illness*, MEDPAGE TODAY (Jan. 30, 2014), <http://www.medpagetoday.com/InfectiousDisease/Surveillance/37104>.

⁵⁴ *Cyclosporiasis Outbreak Investigations—United States, 2013*, CENTER FOR DISEASE CONTROL AND PREVENTION, <http://www.cdc.gov/parasites/cyclosporiasis/outbreaks/investigation-2013.html> (last visited Oct. 14, 2013).

⁵⁵ *See* Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption, 78 Fed. Reg. 54,17142, (proposed correction March 20, 2013) (to be codified at 21 C.F.R. pts. 16, 112) *available at* <http://www.gpo.gov/fdsys/pkg/FR-2013-03-20/pdf/2013-06372.pdf>.

⁵⁶ FDA Food Safety Modernization Act, *supra* note 37, at 3899-3900.

⁵⁷ *Produce Safety: Does This Rule Apply to You?*, U.S. FOOD & DRUG ADMINISTRATION, 1 (Aug. 9, 2013), <http://www.fda.gov/downloads/Food/GuidanceRegulation/FSMA/UCM360251.pdf>.

⁵⁸ *Id.*

⁵⁹ *FSMA Proposed Rule for Produce Safety*, U.S. FOOD & DRUG ADMIN., 1, 6, <http://www.fda.gov/downloads/Food/GuidanceRegulation/FSMA/UCM359258.pdf> (last visited Sep. 30, 2014).

consumption or commercial processing (such as canning) with a kill-step.⁶⁰

The produce rule establishes science-based minimum standards for each aspect of growing produce.⁶¹ The rule proposes standards for agricultural water, biological soil amendments of animal origin, employee hygiene, farm animals, equipment and buildings, sprouts, and training.⁶² The rule also requires that food producers maintain proper documentation showing that standards have been met.⁶³ The agricultural water-testing component has drawn much criticism, and the FDA has published additional materials to explain its requirements. Farmers would be required to test their water sources and water distribution systems at the beginning of each growing season and continue monitoring and testing the waters used in production; all tests must meet certain scientific standards.⁶⁴

In 2010, this burdensome produce provision of the FSMA was met with a firestorm of criticism from the sustainable farming community. John Tester, the junior United States Senator from Montana and the only farmer serving in the Senate at the time, co-sponsored an amendment with Kay Hagan, the junior Senator from North Carolina, to provide some limited exemptions for small farmers.⁶⁵

The Tester-Hagan amendment provides partial exemptions from the produce rule if two requirements are met. First, the farm must have food sales averaging less than \$500,000 annually over the past three years.⁶⁶ Second, the farm must sell more than half of its produce directly to individuals or to a restaurant or retail food establishment within the state or not more than 275 miles away from the farm.⁶⁷ Senator Tester argued:

[Small farmers] have more control over the food they

⁶⁰ *Id.* at 1.

⁶¹ *Id.*

⁶² *Id.* at 3-4.

⁶³ *Id.* at 4.

⁶⁴ See *More on the Proposed Agricultural Water Standards – FDA’s Proposed Rule for Produce Safety*, U.S. FOOD & DRUG ADMINISTRATION, 1, 2, <http://www.fda.gov/downloads/Food/GuidanceRegulation/FSMA/UCM360242.pdf> (last visited Oct. 15, 2014).

⁶⁵ Helena Bottemiller, *Tester: Small Farms Won with Food Safety Exemption*, FOOD SAFETY NEWS (May 5, 2011), <http://www.foodsafetynews.com/2011/05/tester-tours-fsma-victory-at-sustainable-food-conference/#.UsgyNpEu4mY>.

⁶⁶ *FSMA Proposed Rule for Produce Safety*, *supra* note 59, at 6.

⁶⁷ *Id.* at 6-7.

produce. And if there is a problem, it's not like some food factory that can send bags of lettuce to 40 different states in a matter of hours. The real problem was never with the folks who take their goods to the farmer's market in a wheelbarrow. The real problem was with our centralized food system—the factories that churn out hundreds of jars of peanut butter every day—and ship them to every corner of the country.⁶⁸

Well-funded food industry groups fiercely fought the Tester-Hagan amendment, but in Senator Tester's words, "common sense prevailed" and the amendment made its way into the FSMA.⁶⁹

There is, however, some concern that the amendment is too weak to give small farmers any peace of mind. If the FDA eventually targets a small farm or group of small farms, it has the authority to withdraw the partial exemption.⁷⁰ The withdrawal of the partial exemption could be fatal to a small farm. Under the proposed rules, the farmer would have only ten days to submit a written appeal, the FDA would not be required to grant a hearing, and the farmer would have sixty days to comply with all FSMA provisions, including the onerous produce rule.⁷¹ Perhaps most disconcerting is the lack of a specific standard of evidence that must be shown to justify revocation of the exemption.⁷²

Outside of the Tester-Hagan Amendment, the proposed rule provides a blanket exemption for all farms with an average annual food value of \$25,000 or less over the preceding three years.⁷³ This exemption does not include any geographical restrictions.

The rule provides varying timeframes for compliance contingent on venues. Very small businesses, defined as those averaging less than \$250,000 annually, would have four years to comply with the final rule and six years

⁶⁸ Bottemiller, *supra* note 65.

⁶⁹ *Id.*

⁷⁰ *Id.*

⁷¹ *Tell FDA to Treat Small Farmers Fairly*, FARM-TO-CONSUMER LEGAL DEFENSE FUND (Aug. 5, 2013), http://www.farmtoconsumer.org/news_wp/?p=11306.

⁷² *Id.*

⁷³ *FSMA Proposed Rule for Produce Safety*, *supra* note 59, at 5.

to comply with the water provision.⁷⁴ Small business, those averaging less than \$500,000 annually, would have three years to comply and four years to comply with the water provision.⁷⁵ All other food producers would have two years to comply and four years to comply with the water provision.⁷⁶

III. PUBLIC COMMENTS EXPRESSING CONCERN

For most of 2013, both the preventive controls rule and the produce rule were open for public comment.⁷⁷ The proposed rules received national media attention and garnered thousands of comments from individuals, organizations, and political leaders. Many of the respondents voiced their concern about the fairness of the proposed rules, particularly as applied to small scale and organic farmers.⁷⁸ This section provides an analysis of selected public comments.

A. Comments on Preventive Controls Rule

According to Regulations.gov, the FDA received approximately 7500 comments on the preventive controls rule.⁷⁹ The comments came from a wide array of sources, ranging from individuals to various size farms to multi-million dollar food enterprises.

The FDA received numerous comments from concerned individuals. For example, Joe Ferrari, a walnut grower in California, submitted a six-page comment expressing his concern about the written plan requirement, among other items.⁸⁰ Ferrari argued that an exemption is necessary in order to keep small-scale growers in business. He explained that the added

⁷⁴ *Produce Safety: Does This Rule Apply to You?*, *supra* note 57, at 1.

⁷⁵ *Id.*

⁷⁶ *Id.*

⁷⁷ *FSMA Proposed Rule for Produce Safety*, *supra* note 59, at 5.

⁷⁸ Kelsey Gee, *FDA Plans to Revamp Proposals on Food Safety Rules After Backlash*, WALL STREET JOURNAL (Dec. 19, 2013, 6:01 PM), <http://online.wsj.com/news/articles/SB10001424052702303773704579268460299767736>.

⁷⁹ *Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls For Human Food*, Docket No. FDA-2011-N-0920-1553 Docket Folder Summary REGULATIONS.GOV, <http://www.regulations.gov/#!docketDetail;D=FDA-2011-N-0920> (last visited Sept. 30, 2014).

⁸⁰ Letter from Joe Ferrari to Div. of Dockets Mgmt., FDA (Sept. 12, 2013) (Docket No. FDA-2011-N-0920-0196), available at <http://www.regulations.gov/#!documentDetail;D=FDA-2011-N-0920-0196>.

burden of extra recordkeeping and documentation would cause financially constrained farmers to reconsider whether they even want to maintain processing facilities on their premises.⁸¹ And, significantly, he ultimately questioned the fairness of the proposed rule as it relates to small food producers such as his own operation:

They are, in a sense, taxed financially, morally, and physically in a way that a larger on-farm facility is not: this alone puts a smaller on-farm facility on an *unequal playing field* with a larger on-farm facility. It is *simply not fair* to the smaller farm to require such a disproportional increase in recordkeeping—and in many cases it can be considered a *legitimate hardship*, since often it is the owner/operator of this “farm mixed type facility” that must *alone* perform the overlapping tasks of farming, irrigating, bookkeeping, performing repairs on the on-farm facility, managing employee activities, performing payroll functions, reporting quarterly payroll reports to the state and federal taxing authorities, repairing their farm equipment, replanting trees, fertilizing, pruning trees, treating insect and spider mite infestations, harvesting their crops, and managing the on-farm facilities within their control.⁸²

This sentiment is echoed by many of the individual comments. Small farmers view the larger operations as well positioned to absorb the burden imposed by regulations requiring written preventive control plans.⁸³ On the other hand, they view themselves as lacking the financial strength, time, and skills to comply with the proposed rule.⁸⁴ Moreover, many of the comments ultimately assert or insinuate the proposed rule could never fairly be applied

⁸¹ *Id.*

⁸² *Id.* (emphasis added).

⁸³ Letter from Rebecca Goodman to Div. of Dockets Mgmt., FDA (Dec. 19, 2013) (Docket No. FDA-2011-N-0920-0370), available at <http://www.regulations.gov/#!documentDetail;D=FDA-2011-N-0920-0370>.

⁸⁴ *See id.*

to small operations without resulting in their demise.⁸⁵

Some individuals concede the compelling need to enhance food safety, but they consider the proposed rule to be generally inapplicable to the majority of farms. This leads them to conclude that the rule is “unfair and burdensome.”⁸⁶

Larger-scale farmers are also concerned about the fairness of the rule. Don Andrews Farms LLC is a third-generation grower, packer, and shipper of fresh fruit and vegetables.⁸⁷ The California farm expressed concern about the fairness of exposing producers to greater liability:

It seems *unfair that growers are liable from "womb to tomb"* or from field, to hauling, to [a] warehouse, then back on another truck to direct store drops. Much handling occurs in this process[,] which brings into play more chances of bacteria that are not caused by the grower. However the grower is the one who has to accept responsibility and defend himself in lawsuits.⁸⁸

Many other food producers are similarly concerned about the disproportionate regulatory burden falling on them instead of being equally distributed among all handlers along the food chain.

B. Comments on Produce Safety Rule

The proposed rule for produce safety received an overwhelming number of comments—approximately 18,500.⁸⁹ Just a few hundred

⁸⁵ See *id.*

Letter from Howard to Div. of Dockets Mgmt., FDA (Nov. 20, 2013) (Docket No. FDA-2011-N-0920-0292), available at <http://www.regulations.gov/#!documentDetail;D=FDA-2011-N-0920-0292>.

⁸⁷ DAN ANDREWS FARMS LLC, <http://www.danandrewsfarms.com> (last updated Mar. 19, 2014).

⁸⁸ Letter from Daniel A. Andrews, Dan Andrews Farm LLC to Div. of Dockets Mgmt., FDA (Jan. 16, 2013) (Docket No. FDA-2011-N-0920-0002) (emphasis added), available at <http://www.regulations.gov/#!documentDetail;D=FDA-2011-N-0920-0002>.

⁸⁹ *Standards for the Growing, Harvesting, Packing and Holding of Produce for Human Consumption*, Docket No. FDA-2011-N-0921-0973 Docket Folder Summary, REGULATIONS.GOV., <http://www.regulations.gov/#!docketDetail;D=FDA-2011-N-0921> (last visited Sep. 30, 2014).

comments, however, were published on Regulations.gov; presumably because most of the comments received were repetitive, pre-written submissions prompted by the campaigns of third-party groups.⁹⁰

Several associations apparently encouraged their members and other individuals to submit comments in opposition to the proposed rules. Analysis reveals that form letters served as the basis of many comments. Dr. Jeffrey McCombs wrote that he found the proposed rule to be “harsh and unfair,”⁹¹ and then proceeded to copy and paste a form letter,⁹² which can be traced to the Weston A. Price Foundation, a nonprofit organization supporting organic and biodynamic farming.⁹³ The comment takes aim at the ease with which the FDA may revoke the Tester-Hagan exemptions. Dr. McCombs—using the Price Foundation’s language verbatim—pleads for a ninety-day appeals period, the provision of a hearing upon request, clear evidentiary standards for the revocation of the exemption, two years for full compliance if the exemption is revoked, and a process for reinstatement of the exemption.⁹⁴ All five suggestions represent a significant loosening of the proposed rules.

Gary Henneke, a farmer in southeastern Texas, submitted a comment expressing his concerns with the proposed rule.⁹⁵ He argued that regulations do not necessarily make food safer, especially when the regulations take a one-size-fits-all approach.⁹⁶ Henneke lamented that he simply cannot comply with the proposed rules, but he suggested that a group other than the FDA already regulates his operation effectively.⁹⁷ Henneke noted, “I am regulated very well by my customers. If I produce a bad product I will be out of business long before there is any major outbreak from a

⁹⁰ See *id.*

⁹¹ Letter from Jeffrey S. McCombs to Div. of Dockets Mgmt., FDA (July 23, 2013) (Docket No. FDA-2011-N-0921-0183), *available at* <http://www.regulations.gov/#!documentDetail;D=FDA-2011-N-0921-0183>.

⁹² *Tell FDA to Treat Small Farmers Fairly*, WESTON A. PRICE FOUND. (July 23, 2013), <http://www.westonaprice.org/2013-action-alerts/tell-fda-to-treat-small-farmers-fairly>.

⁹³ Jill C. Nienhiser, *About the Foundation*, WESTON A. PRICE FOUND. (Jan. 1, 2000), <http://www.westonaprice.org/about-the-%20foundation/about-the-foundation>.

⁹⁴ Letter from Jeffrey S. McCombs to Div. of Dockets Mgmt., *supra* note 91.

⁹⁵ Letter from Gary V. Henneke, Henneke Farms to Div. of Dockets Mgmt., FDA (Nov. 21, 2013) (Docket No. FDA-2011-N-0921-0323), *available at* <http://www.regulations.gov/#!documentDetail;D=FDA-2011-N-0921-0323>.

⁹⁶ *Id.*

⁹⁷ *Id.*

contaminated product.”⁹⁸

Several industry associations have issued comments representing their members. The National Onion Association (“NOA”), for example, submitted a ten-page comment on the proposed rule. The NOA vented frustration that its producers would be held to the new rule, even though onions pose little threat to food safety. The association wrote:

We understand that the FDA’s rationale is that predicting which commodity might cause illness in the future is not possible, so all raw agricultural commodities must be regulated. *This approach is not scientific, not fair, and not balanced in term of cost and benefit.* There is a long history of foodborne illness outbreaks in the United States, and the differences in risk among commodities are well known. This approach unfairly burdens commodities that have never had a foodborne illness outbreak with an undue and heavy economic burden.⁹⁹

Even the National Water Resources Association (“NWRA”)—a prominent water conservation group¹⁰⁰—expressed concern about the proposed rule. The NWRA concluded, “[r]egrettably the Rule goes too far and will violate the stated purposes of the FSMA if the Rule is adopted with no major changes.”¹⁰¹

The comments could not paint a clearer picture—both individuals and groups are concerned about the apparent inequities of the proposed produce safety rule.

⁹⁸ *Id.*

⁹⁹ Letter from Nat’l Onion Assoc. to Div. of Dockets Mgmt., FDA (May 23, 2013) (Docket No. FDA-2011-N-0921) (emphasis added), available at <http://www.regulations.gov/#!documentDetail;D=FDA-2011-N-0921-0148>.

¹⁰⁰ *Mission Statement*, NAT’L WATER RESOURCES ASS’N, <http://www.nwra.org/about.html> (last visited Sep. 30, 2014).

¹⁰¹ Letter from Nat’l Water Res. Assoc. to Div. of Docket Mgmt., FDA (Oct. 29, 2013) (Doc. No. FDA-2011-N-0921-0259), available at <http://www.regulations.gov/#!documentDetail;D=FDA-2011-N-0921-0259>.

C. Congressional Comments

The comment period for the proposed rules elicited such a high volume of responses that it drew the attention of Congress. Senators and members of Congress responded with comments of their own. Their comment letters effectively served as well-written summaries of the concerns voiced by their constituents.

One week after the proposed rules closed for comments, about seventy-five members of Congress submitted a letter to Margaret Hamburg, the Commissioner of the FDA. In a sign of solidarity, the letter included the signatures of both Democrats and Republicans from the House and Senate.¹⁰² It addressed concerns with the produce safety rule and preventive controls rule.¹⁰³ The letter acknowledged the FDA's attempt to engage with stakeholders, but expressed concern about "the ambiguity surrounding many aspects of the proposed rules."¹⁰⁴

The letter echoed some of the public comments by suggesting that the high costs of complying with the proposed rules will ultimately force some food producers and processors out of business.¹⁰⁵ With a dramatic flair, the letter forecasted that the proposed rules would ultimately lead to a "multitude of unintended consequences," which would be "severely detrimental" to all levels of agricultural.¹⁰⁶

Congress outlined six concerns that it received from constituents. Those general concerns included:

- [1] The testing frequency required for certain agricultural waters;
- [2] restrictions placed on the usage of biological soil amendments;
- [3] compliance issues at mixed-use facilities;
- [4] new requirements that conflict with existing conservation and environmental standards and practices of

¹⁰² See Letter from Sen. Jeanne Shaheen et al., U.S. Senate, to Margaret Hamburg, Comm'r U.S. Food and Drug Admin., (Nov. 22, 2013), available at <http://sustainableagriculture.net/wp-content/uploads/2013/11/11-22-13-Shaheen-Blunt-Courtney-Gibson-Kuster-FSMA-Letter-to-FDA-Second-Draft-of-Rules.pdf>.

¹⁰³ See *id.*

¹⁰⁴ *Id.*

¹⁰⁵ *Id.*

¹⁰⁶ *Id.*

the U.S. Department of Agriculture; [5] the limiting definitions used in the rule for “farm,” “small business” and “very small business”; and [6] the lack of consideration of the complexity of various farm ownership entities.¹⁰⁷

While these concerns were frequently cited in public comments, their inclusion in a Congressional letter gave credence and some degree of legitimacy to each one.

In light of the legal pressure coming from the United States District Court for the Northern District of California, Congress made a rather ironic request of the FDA with its letter. It was written to not only express concern with the proposed rules, but also to request an entirely new comment period for a *second* set of the *same* proposed rules.¹⁰⁸ The letter concludes, “[b]y seeking additional input through second proposed rules for public comment before final rules, we believe that producers’ concerns can be addressed and unintended consequences can be greatly mitigated.”¹⁰⁹ The letter avoided any discussion—or even a mere mention—of the FDA’s legal pressure from the Northern District of California, and it is unclear whether Congress believes the FDA actually has the ability to initiate a new comment period for the two already-proposed rules.

On the same day—only a week after the close of the comment period for the proposed rules—other members of House submitted a separate letter to the FDA Commissioner. All members of the House Organic Caucus signed the letter, giving it particular relevance to the proposed food safety legislation. The letter was considerably more specific than other letters from Congress, and it addressed only the proposed rule for produce safety.¹¹⁰

The letter from the House Organic Caucus explained that the produce safety rule—as drafted—conflicted with portions of the Organic Food

¹⁰⁷ *Id.*

¹⁰⁸ Letter from Sen. Shaheen et al. to Comm’r Hamburg, *supra* note 102.

¹⁰⁹ *Id.*

¹¹⁰ See Letter from Rep. Peter DeFazio et al., U.S. House of Representatives, to Margaret Hamburg, Comm’r, U.S. Food and Drug Admin. (Nov. 22, 2013), available at <http://sustainableagriculture.net/wp-content/uploads/2013/11/FSMA-Organic-Letter-Signed-FINAL.pdf>.

Production Act of 1990 (“OFPA”), and the FSMA specifically prohibited such a conflict.¹¹¹ The letter warned that to be compliant with the proposed produce rule, organic farmers would run the risk of being non-compliant with the National Organic Program (“NOP”), which was established under OFPA. According to the letter, the FSMA would restrict the ability of farmers to rotate crops, causing the farmers to fall out of compliance with NOP regulations aimed at—ironically—food safety.¹¹² As a consequence, this would “effectively eliminate” the use of manure and compost, which are vital to the operation of organic farms.

In addition, the letter blasted the FDA’s proposed rule as lacking a scientific grounding, alleging the FDA “relies on selective science from worst-case scenarios to assess pathogen risk from manure and compost.”¹¹³ It firmly concluded that, “[w]ithout an adequate scientific basis, FDA’s proposed standards on biological soil amendments of animal origin seem arbitrary at best and at worst a blatant effort to ignore the framework established by FSMA for flexible, science-based minimum standards for produce safety.”¹¹⁴ The letter stopped short of calling for a new round of public comments, but it insisted the FDA ensure the final rule avoid conflict with the current NOP organic regulations.¹¹⁵

Senators Tester and Hagan, the sponsors of the successful Tester-Hagan Amendment, also submitted an important letter in an attempt to clarify—or perhaps emphasize—their intent behind the Tester-Hagan Amendment. Simply stated, the amendment was “to prevent excessive regulations from constraining small farm and food processing operations and instead ensure that FDA focused its limited resources on areas of greater risk to food safety.”¹¹⁶ The senators observed that small producers pose less risk than the large food operations, so the same regulations need

¹¹¹ *Id.*

¹¹² *Id.*

¹¹³ *Id.*

¹¹⁴ *Id.*

¹¹⁵ *Id.*

¹¹⁶ See Letter from Sen. John Tester & Sen. Kay Hagan, U.S. Senate, to Margaret Hamburg, Comm’r, U.S. Food and Drug Admin. (Nov. 13, 2013), available at <http://www.scribd.com/doc/184454294/Tester-Letter-to-FDA-Hamburg-FSMA-Produce-Protective-Controls-Rules-Comments>.

not apply across the board.¹¹⁷ The letter stated that the country needs *more* small farms and facilities, and the proposed rules “must not stymie this local economic growth.”¹¹⁸

The Tester-Hagan letter identified some serious problems leading to inequity in the application of the produce and preventive controls rules. First, it noted an unacceptable level of ambiguity surrounding the key words used in determining whether a food producer qualifies for an exemption.¹¹⁹ For example, the proposed rules do not specify that only food subject to the new regulations should count toward the threshold amounts used in determining whether an exemption applies. In other words, if a farm primarily raises beef cattle but also grows a small amount of produce, the dollars generated by the livestock could trigger the full arsenal of FSMA regulations, thus effectively killing the farm’s small-scale production of produce. In addition, as expressed in some of the public comments, the proposed rules lack a definition of the material conditions necessary for the FDA to withdraw the exemption for small food producers.¹²⁰ Without a clear description of what constitutes grounds for revoking the exemption, small-scale food producers fear that the FDA could arbitrarily shut down operations by unleashing the full array of FSMA regulations. The letter emphasized that food producers deserve a clear description for the sake of transparency and in the interest of smart decision-making; without it, they will be operating in the dark.¹²¹

In addition to expressing concern over what *triggers* a revocation of the exemption, the letter also addresses the *process* utilized by the FDA in revoking the exemption for a small-scale producer. The letter blasts the FDA’s proposed process—in the preventive controls and produce rules—as “overly severe, *unfair*, and does not all recourse for the farmer or owner.”¹²² It goes on to suggest that the FDA should send warning letters to operators if it detects food safety issues with a qualified exempt entity.¹²³ The entity

¹¹⁷ *Id.*

¹¹⁸ *Id.*

¹¹⁹ *Id.*

¹²⁰ *See id.*

¹²¹ *Id.*

¹²² Letter from Sens. Tester & Hagan to Comm’r Hamburg, *supra* note 116 (emphasis added).

¹²³ *Id.*

should lose its exempt status only if the FDA finds “repeated, egregious, or intentional actions” threatening food safety.¹²⁴ If this does happen, the Tester-Hagan letter recommended the FDA provide a “reasonable path and timeline” for the violator to regain its exempt status.¹²⁵

The letter also echoed the concerns raised by the House Organic Caucus—that is, the proposed produce rule should avoid conflict with the NOP. It stated, “[s]etting even more restrictive standards than organic for produce farmers is unnecessary and would make organic produce farming nearly impossible.”¹²⁶ Finally, the letter concluded by criticizing the water testing component of the produce safety rule and calling for its omission entirely.¹²⁷ It characterized the water-testing component as “unworkable and unaffordable for small farms.”¹²⁸ The letter pointed out that there is little evidence of irrigation water causing food safety issues, so the component is not even needed.¹²⁹ It suggested the FDA should only implement such a rule if it is warranted and can be supported with scientific data.¹³⁰

The three letters from Congress illustrate the concerns of organic and small-scale food producers. Although the proposed rules have been in the making for several years, numerous individuals and businesses are clearly concerned that the rules have not been drafted fairly and may force them to shutter operations. Analysis suggests that inequity is the common thread throughout most of the comments received from individuals, small-scale food producers, and members of Congress. The general fear is that large industrial food producers will reap benefits from the regulations because of the crushing burdens potentially imposed on the smaller players.

¹²⁴ *Id.*

¹²⁵ *Id.*

¹²⁶ *Id.*

¹²⁷ *See id.*

¹²⁸ Letter from Sens. Tester & Hagan to Comm'r Hamburg, *supra* note 116.

¹²⁹ *See id.*

¹³⁰ *Id.*

IV. COST-BENEFIT ANALYSIS

In assessing the fairness of the rules, it is helpful to turn to a cost-benefit analysis. The rules have an enormous impact on existing food safety measures—recall that the FSMA represents the most sweeping overhaul to food safety in seventy years. The FDA published financial statistics, which are helpful in understanding the economic impact of the two proposed rules addressed in this Note.

The preventive controls rule is poised to have a significant financial impact in the United States. About one million annual illnesses are caused by foods falling under the proposed rule, and the economic impact of those illnesses is somewhere around \$2 billion.¹³¹ But what cost must the economy expend in order to assuage the steep medical bill for these illnesses? These costs are admittedly difficult to calculate, but the FDA has suggested that the first year implementation costs would be slightly more than \$700 million, and the annual cost would be about \$472 million.¹³² The FDA estimates that the preventive controls rule would impact more than 200,000 facilities—approximately 97,600 domestic and 109,200 foreign producers.¹³³

The FDA conducted “a very rigorous cost benefit analysis with the best available public data” and presented its results at a public meeting in Washington D.C. in February 2013.¹³⁴ The FDA estimated that the preventive controls rule combined with the produce safety rule would cost \$5000 per very small farm, \$13,000 per small farm, and \$31,000 per large farm.¹³⁵ Interestingly, the largest contributor to the cost is the requirement of employee health and hygiene.¹³⁶ This part of the preventive controls rule would cost nearly \$138 million, or about 30% of the annual cost of the preventive controls rule.¹³⁷ The FDA suggested that this is not actually a

¹³¹ Food Safety Modernization Act, Pub. L. No. 111-353, § 103, 124 Stat. 3885, 3889 (2013).

¹³² *Id.*

¹³³ *Id.*

¹³⁴ Travis Minor, Presentation at the FSMA Public Meeting Concerning Proposed Rules for Preventive Controls in Human Food and Produce Safety Standards 95 (Feb. 28, 2013), *available at* <http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm336329.htm>.

¹³⁵ *Id.* at 88.

¹³⁶ *Id.* at 89.

¹³⁷ *Id.*

cost that producers will have to issue a check for; instead, it merely represents an opportunity cost.¹³⁸ The FDA noted that inadequate employee hygiene is the largest contributor to foodborne disease outbreaks, accounting for about 581,000 illnesses.¹³⁹ It makes sense that the largest allocation of cost corresponds to the largest contributor to disease outbreaks.

Another 20%—or \$91 million—of the total cost of the rule is related to training and personnel qualifications.¹⁴⁰ Again, the FDA insisted that this does not represent a substantial cost to farmers but is merely an included cost because it adds a burden as an opportunity cost.¹⁴¹ Interestingly, the FDA conspicuously downplayed the burden imposed by the record-keeping requirement—which has elicited much criticism—and suggested that it only accounted for about 6% of the total cost of the rule.¹⁴² During a presentation, an FDA representative ensured his audience that the FDA is trying to keep the record-keeping requirement “as small a burden as possible.”¹⁴³ The presentation concluded that if costs hit the 95th percentile—in other words, near the highest possible projections—and the benefits are merely in the 5th percentile—far short of what is anticipated—the benefits would still outweigh the costs.¹⁴⁴

Although the preventive controls rule packs a powerful punch, the produce safety rule may have an even greater impact on the American economy. Because produce is the most frequent cause of foodborne diseases, ensuring its safety should lead to drastic savings. The FDA estimates that tainted produce is responsible for nearly 1.75 million illnesses each year.¹⁴⁵ This means that the United States could save over \$1 billion annually if the produce safety rule is effective.¹⁴⁶ However, it may be telling that the FDA has failed to provide an estimate for first-year, initial costs to the industry.

¹³⁸ *Id.* at 90.

¹³⁹ *Id.* at 93.

¹⁴⁰ Minor, *supra* note 134, at 90.

¹⁴¹ *Id.* at 90-91.

¹⁴² *Id.* at 92.

¹⁴³ *Id.*

¹⁴⁴ *Id.* at 95.

¹⁴⁵ *Costs to Farmers and Consumers, - Produce Rule*, NAT'L SUSTAINABLE AGRIC. COAL., <http://sustainableagriculture.net/fsma/learn-about-the-issues/costs-to-farmers-and-consumers-produce-rule> (last updated Nov. 2013).

¹⁴⁶ *Id.*

This omission may be indicative of costs outweighing the financial benefit. The FDA did, however, provide estimates for annual costs of compliance with the produce safety rule. These substantial savings come at a higher annual price relative to the preventive controls rule. FDA figures indicate an estimated annual cost of about \$460 million for domestic producers and \$171 million for foreign producers, for a combined annual compliance cost of around \$631 million.¹⁴⁷

At least initially, the produce safety rule would cover about 40,500 domestic farms and 15,000 foreign farms.¹⁴⁸ The FDA estimates that over 75,000 farms would be partially exempt under the Tester-Hagan Amendment, and another 34,000 farms would be exempt under the \$25,000 threshold included in the proposed rule.¹⁴⁹ Still, the produce safety rule would touch the vast majority of produce consumed in the United States.¹⁵⁰

The costs of the proposed rules may best be viewed as a percentage of annual sales per farm type. It should first be noted that in 2011, the average net farm income was around ten percent of annual gross sales.¹⁵¹ For a very small farm, the proposed rules would impose a cost equal to about 6% of annual sales.¹⁵² In other words, *more than half* of a farm's income may be potentially eliminated by regulations imposed under the proposed rules. As the size of the food producer increases, the percentage of income required for compliance decreases, which makes sense considering that larger players are better equipped to absorb regulatory costs. For example, for a small farm, the cost of compliance would be about four percent, and for a large farm, about one percent.¹⁵³ One advocate of sustainable agriculture bluntly stated, "[t]hrough they do not come right out and say so directly, the obvious implication is that FDA believes its new rules will concentrate farming into fewer and fewer hands."¹⁵⁴ Indeed, in light of the high costs of regulatory compliance, many small producers may be forced to shutter their

¹⁴⁷ *Id.*

¹⁴⁸ Food Safety Modernization Act, Pub. L. No. 111-353, § 103, 124 Stat. 3885, 3889 (2013).

¹⁴⁹ *Id.*

¹⁵⁰ *Id.*

¹⁵¹ NAT'L SUSTAINABLE AGRIC. COAL., *supra* note 145.

¹⁵² *Id.*

¹⁵³ *Id.*

¹⁵⁴ *Id.*

operations.

This leads to the most important economic inquiry. If small producers are in fact forced out of the market by a disincentive flowing from regulatory expenses, what will happen to the price of food and is that dollar change offset by the decreased risk of contracting food-borne illness? The FDA has not addressed the potential increase in food prices, but elementary economics make it clear that increased production expenses are normally passed on to consumers. There is no way to know exactly how much that increase will be, but it is very likely to increase over time. The organic market will not immediately dry up under the FSMA. Instead, the supply of foods from small and organic farms is likely to gradually decrease over time. In light of the trend for increased demand for local organic foods, prices will most certainly increase.

According to FDA economists, the average food illness costs about \$2,000 in medical expenses.¹⁵⁵ Adjusted for the odds of contracting a foodborne disease, the annual dollar-risk per person can be estimated at about \$330. This amounts to \$27.50 per month, which is important. It means that if consumers must spend an extra \$27.50 (or more) for food per month, then the costs imposed by the rules are not easily justified. It is very possible that a decreasing supply of organically-produced food coupled with increasing consumer demand will lead to average prices well-exceeding this threshold.

V. CONCLUSION

In December 2013, the FDA finally acknowledged serious inequities within the two proposed rules. In an official blog post, the Deputy Commissioner of the FDA publicly conceded that “significant changes must be made” to the proposed rules in light of the comments received.¹⁵⁶ The FDA plans to revise the language affecting farmers, and it will then re-

¹⁵⁵ Peter Vardon, Presentation at the FSMA Public Meeting Concerning Proposed Rules for Preventive Controls in Human Food and Produce Safety Standards 271 (Feb. 28, 2013), available at <http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm336329.htm>.

¹⁵⁶ Michael R. Taylor, *Your Input is Bringing Change to Food Safety Rules*, U.S. FOOD AND DRUG ADMIN. FDAVOICE BLOG (Dec. 19, 2013), <http://blogs.fda.gov/fdavoicel/index.php/2013/12/your-input-is-bringing-change-to-food-safety-rules/>.

propose the rules in early summer 2014.¹⁵⁷ Moving forward, the rules must be written fairly in order to prevent suppression of the supply of organic foods and an unbalanced increase in food costs. Equitable rules are within reach, and such rules are necessary for the safety and efficiency of America's food supply.

¹⁵⁷ *Id.*

