PART 112

SUPPLEMENTAL NOTICE OF STANDARDS FOR THE GROWING, HARVESTING, PACKING, AND HOLDING OF PRODUCE FOR HUMAN CONSUMPTION

Economic Impact Analysis

Table of Contents

Analysis of Economic Impacts

FDA has examined the impacts of the proposed rule under Executive Order 12866 and Executive Order 13563. Executive Orders 12866 and 13563 direct Agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The Agency believes that this proposed rule is a significant regulatory action as defined by Executive Order 12866.

In a supplemental notice of proposed rulemaking, we are proposing to amend certain specific provisions of the proposed rule, Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption (which was published on January 16, 2013 (78 FR 3504)). We are taking this action because the extensive input we have received from public comments has led to significant changes in our thinking on key provisions of the proposed rule, and we are seeking public input on the amended proposed provisions. The amended proposed provisions relate to the definition of a farm; farm sizes for determining both farms that would not be covered by the rule as well as small and very small farms that would be eligible for extended compliance periods; the microbial quality standard for agricultural water used in a direct application method and additional means to achieve the specified microbial standard; testing requirements for untreated surface water and ground water; minimum application intervals for use of untreated and treated biological soil amendments of animal origin; the prevention of contamination from animals; and the process for withdrawal of a qualified exemption. In the remainder of this document, we refer to the proposed rule that we published on

January 16, 2013 (78 FR 3504) as "the original proposed rule" and the supplemental notice of proposed rulemaking as "the supplemental notice."

In the original proposed rule and the supplemental notice, we use a science-based framework to assess any potential public health risks associated with the consumption of produce, and define specific mitigation approaches that would address the risks of microbial contamination from agricultural inputs (workers, water, biological soil amendments, and tools and equipment), unsanitary conditions in buildings, and contact with wild and domesticated animals, as well as in the production of sprouts intended for human consumption. In those documents, we provide a framework to evaluate the efficacy of the proposed rule for addressing the public health risks in general, and emphasize the importance of some salient provisions as well.

In the supplemental notice, we are proposing to amend the thresholds for different farm sizes. In this economic impact analysis, we estimate the costs of each amended proposed provision by farm size.

In this economic impact analysis, we also present the total costs and benefits of the proposed regulation, as amended, and its component provisions. However, for a detailed analysis of proposed provisions that are not addressed in the supplemental notice, please see the preliminary regulatory impact analysis (PRIA) that we prepared in original proposed rule (Ref. 1).

I. Proposed changes to Standards for the Growing, Harvesting, Packing and Holding of Produce for Human Consumption

The proposed rule would establish science-based minimum standards for the safe growing, harvesting, packing, and holding of produce on farms. The proposed rule addresses microbiological risks during growing, harvesting, packing, and holding activities of covered produce, from all agricultural inputs (workers, agricultural water, biological soil amendments, and tools and equipment), from unsanitary conditions in buildings, and from contact with wild and domesticated animals, as well as in the production of sprouts intended for human consumption.

The current amendments deal primarily with changes to the definition of a farm and farm size, microbial quality standard and testing requirements and alternatives for agricultural water, minimum application intervals for untreated and treated biological soil amendments of animal origin, the prevention of contamination from animals, and FDA's process for withdrawal of qualified exemptions. Table 1 illustrates the total costs and benefits of both the original proposed rule and the supplemental notice.

Table 1. Summary of Original and Supplemental Notice (in millions)

	Benefits	**Total Costs (Domestic + Foreign)**	**Net Benefits**
Original	$1,037.78	$630.22	$407.56
Supplemental	$930.00	$529.62	$400.37
Difference	-$107.79	-$100.60	-$7.19

Notes: Costs and benefits presented are annualized over 7 years at 7%.

In the following sections we discuss how each proposed change will impact the estimated costs and benefits of the proposed rule.

II. Need for Regulation

Section 105(a) of the FDA Food Safety and Modernization Act requires that " not later than 1 year after enactment, the Secretary … shall publish a notice of proposed rulemaking to establish science-based minimum standards for the safe production and harvesting of those types of fruits and vegetables, including specific mixes or categories of fruits and vegetables, that are raw agricultural commodities for which the Secretary has determined that such standards minimize the risk of serious adverse health consequences or death."

The proposed rule is also needed to provide socially optimal private incentives for individual produce farms to ensure food safety. Food-borne illness, as a result of contaminated produce, can have a very large impact on public health. At this point in time, however, public health surveillance systems and investigation networks are frequently unable to identify specific farms associated with outbreaks linked to produce. As a result, individual produce farms do not bear the full cost of distributing unsafe food. This may cause them to invest insufficient resources toward improving food safety. The proposed rule responds to this need by requiring proper food safety standards at produce farms.

III. Regulatory Options

The regulatory options have not changed in this supplemental notice. For a detailed discussion of the regulatory options of the proposed rule, please see the PRIA (Ref.1).

Option (1) No New Regulatory Action

This option is not legally viable because Section 105(a) of FSMA requires us to conduct this rulemaking establishing produce safety standards. There were no costs or benefits calculated for this regulatory option and this has not changed due to the supplemental requirements.

Option (2) Exclude Commodities Not Associated with Outbreaks

Following the same example from the original PRIA (Ref.1), we estimate roughly 14,100 fewer farms will implement the standards outlined in the proposed rule. We would have roughly 9,000 fewer very small farms, 1,600 fewer small farms, and 3,500 fewer large farms included in the rule. Using an average cost per farm, this would represent an annual cost reduction of about $163.51 million (9,000 x $4,477 + 1,600 x $12,384 + 3,500 x $29,545) compared to the amount estimated in this supplemental proposal. While we cannot quantify the effect of this option on the benefits of the rule, we can say the benefits would likely decrease, potentially significantly, unless commodities could be chosen that we are relatively certain have little probability of a being tied to a future outbreak.

Option (3) Less-Extensive Standards

Under this Option, the proposed rule could require less extensive provisions than the proposed rule outlined in Option 6. Several provisions could be combined to provide a less extensive set of controls than in the rule. The numerical example provided in the original PRIA (Ref.1) has not changed substantially for this supplemental proposal. However, this supplemental analysis already eliminates the costs and benefits associated with biological soil amendments of animal origin. Therefore, we estimate that further eliminating provisions related to domesticated and wild animals would reduce the cost of

the proposed rule by nearly $38 million; however, potential benefits would be reduced by about $76 million.

Option (4) More-Extensive Standards

The proposed rule could be broader in scope and have more extensive provisions including: (1) covering all farms with an average annual monetary value of food sold during the previous three-year period of $25,000 or less (on a rolling basis), and (2) requiring a food safety plan and operational assessment.

Covering all farms with an average annual monetary value of produce sold during the previous three-year period of $25,000 or less (on a rolling basis) would increase costs by $173.46 million per year (39,521 x $4,389), and would only cover an additional 2 percent of covered produce acres. Requiring these farms to comply with all of the standards in the proposed rule would have a small effect on the volume of production that could become contaminated. In addition, covering these farms likely would result in the cessation of produce production at a large number of low-volume farms.

Requiring additional on-farm provisions such as a food safety plan and a yearly operational assessment would result in increased costs of $27 million. This is based on the per farm cost of conducting an assessment of all agricultural water sources on the farm of $723 per very small farm, and $470 per small and large farm, as well as accounting for the number of farms that are currently implementing a food safety program.

Option (5) A Lower Threshold for the Definition of a Covered Farm

Because FDA is currently proposing an increase in the threshold for the definition of a covered farm (by only including produce, rather than all foods, in the proposed

value), we no longer believe this to be a viable policy alternative. Additionally, this option was not originally estimated to be cost beneficial and any changes proposed would not affect that outcome.

Option (6) The Proposed Rule

The costs and benefits of the proposed rule are summarized at the beginning of this section, and are discussed at length in the following sections of this analysis and the originally proposed rule.

IV. Definition of a farm and farm size

The supplemental notice includes proposed changes to the definition of "farm" and related terms (such as "harvesting," "packing," "holding," and "manufacturing/ processing"). These changes would result in, among other things, bringing packing and holding of covered produce grown on another farm under different ownership within the definition of "farm" and therefore within the coverage of the proposed produce safety rule (while such activities would have been outside the farm definition and thus potentially subject to the Preventive Controls Proposed Rule for Human Food under our original proposal). However, we do not estimate a change in the number of covered farms, total costs, or total benefits of this proposed rule due to these changes. The number of farms remains unchanged because any farms involved in the growing of covered produce, regardless of other activities, were already included in our original estimates. Similarly, costs do not change because although the total volume of produce subject to the proposed produce rule on farms may increase due to the revised farm definition, our cost estimates are not calculated based on output but rather a function of average farm characteristics, such as acreage, workers, and number of machines. Finally,

we do not estimate a change in benefits due to the changes to the farm definition because all illnesses attributable to produce, whether raw agricultural commodities or fresh-cut, were already included in our original benefit estimates for this proposed rule.

We are also proposing to amend the definition of covered, small, and very small farms from being based on the value of "total food sales" to the value of "produce". This change will affect the number of farms counted in each category: very small, small, and large, and the number of farms that are not covered by the requirements of this rule based on the value of their "produce" sold.

Costs

Because size categories are now based on produce revenue rather than total food revenue, every farm's revenue for purposes of size categorization is now smaller or unchanged, shifting some farms toward smaller size categories. This reduces estimated total costs as farms move from very small to not covered, from small to very small, or from large to small because of the extended compliance dates.[1]

We estimate that the number of very small covered farms will fall by 11 percent; small farms will fall by 12 percent, and large farms will fall by 15 percent. Table 2 shows the estimated change to farm numbers due to this change and the associated costs of the change based on data from the National Agricultural Statistical Service's (NASS) Census of Agriculture (Ref.2).

[1] We estimate average costs here as presented in the PRIA; however, because many costs are based on things like average number of produce acres harvested, or average acres of manure/irrigated acres this change may also increase the cost to an average farm through changes in the make-up of each size category. Using currently available data we are not able to identify individual farms that may now be excluded, and therefore our average farm characteristics by farm size have not changed.

Table 2. New Estimated Total Costs Based on Value of Produce

	Qualified Exemption Farms/Farms Not Covered	Very Small	Small	Large	Total
Original Total Number of Farms	113,870	53,429	9,147	13,191	**189,637**
Original Total Covered Farms	--	26,947	4,693	8,571	**40,211**
Supplemental Total Farms	130,204	40,936	7,151	11,346	**189,637**
Supplemental Total Covered Farms	--	24,062	4,139	7,302	**35,503**
Original Average Cost per farm[1]	$88	$4,697	$12,972	$30,566	
Supplemental Average Cost per farm[2]	$88	$4,477	$12,384	$29,545	
Original Total Cost (in millions)	$10.06	$126.58	$60.88	$261.98	**$459.56**
Supplemental Total Cost (in millions)	$11.50	$107.73	$51.26	$215.73	**$386.23**
Difference (in millions)	-$1.44	$18.84	$9.62	$46.25	**$73.33**

Notes: Costs presented are annualized over 7 years at 7%.

1. We estimate positive costs to farms eligible for a qualified exemption and farms not covered for both the original and supplemental estimates. These costs occur from things like learning about the rule for all farms and things like labeling or point of purchase disclosures for farms with a qualified exemption. The cost per individual farm in this size category has not changed; the increase in total costs for this size category of farms in the supplemental notice comes from the fact that we now estimate more farms to fall within this category.

2. Average costs in this table differ from the PRIA because of other changes put forward in this supplemental notice; the resulting changes in cost estimates will be discussed in more detail in subsequent portions of this regulatory impact analysis.

In total we estimate that this change will reduce the number of covered farms by 4,708 (40,211 – 35,503) with an associated cost savings of approximately $73.33 million.

Benefits

Removing these additional farms from coverage will also reduce the estimated benefits of this rule. In the PRIA (Ref.1), we estimated that qualified farms[2] accounted

[2] Qualified farms are those that sell less than $500,000 in annual food sales and sell more than half of their product to a qualified end user, as provided in proposed § 112.5.

for 13.4 percent of domestic produce acreage that may be associated with foodborne illness and farms exempt due to low monetary value of food accounted for 0.7 percent of domestic produce acreage. In total, we estimated that 14.1 percent of all domestic acreage that may be associated with foodborne illness was not covered by the rule, and therefore a maximum of 14.1 percent of all foodborne illnesses associated with produce would not be captured by the proposed rule. Because we have not changed the estimation methodology for qualified farms, that percentage (13.4) remains unchanged, however, because there are now more farms that would not be covered by the rule based on their monetary value of produce, some additional potential illnesses will not be prevented by the proposed rule. With an additional 4,708 farms not covered by the rule, we estimate that the portion of produce acreage which may be associated with foodborne illness not covered due to low monetary value of produce by the rule will increase from 0.7 percent to approximately 2 percent. This means that 15.4 (13.4 + 2.0) percent of total acres which may be associated with foodborne illness must be removed from our benefits estimate. Table 3 shows the impact of this exemption on estimated benefits.

Table 3. New Estimated Total Benefits Based on Value of Produce (in millions)

	Cost of Illnesses Attributable to Produce	**% Acreage Excluded**	**Total Cost of Illnesses Avoided Due to this Rule**	**% Reduction in Risk**	**Total Benefits**
Original Estimate of Benefits	$1,865.26	0.141	$1,602	64.77%	**$1,037.78**
Supplemental Estimate of Benefits	$1,865.26	0.154	$1,435[1]	64.77%[2]	**$930.00**

Notes: Benefits presented are annual values.

1. The cost of illnesses avoided due to this supplemental proposed rule is lower than the original estimate because of the higher percentage of acres excluded and the illnesses dropped due to the removal of an application interval for untreated biological soil amendments of animal origin (discussed in detail in Section VI of this analysis). In the original PRIA, we estimated that 241,314 illness or $142.85 million ($1,865.26*[1-0.154]-$142.85=$1,435) were attributable to this requirement.

2. The calculation of this percentage reduction in risk is laid out in detail in the PRIA (Ref. 2) Section F.2.c, beginning on page 71. We do not alter this percentage for the supplemental proposal because removing the estimated efficacy of untreated biological soil amendments of animal origin (65.62% in Table 24 of the

original PRIA) would not significantly change the presented estimate of 64.77%. However, this estimate may change for the final cost benefit analysis.

In total we estimate that this change will result in a reduction of total benefits by about $107.79 million ($1,037.78 million - $930.00 million).

V. Testing requirements for agricultural water

We previously proposed a microbial quality standard for agricultural water of no more than 126 colony forming units (CFU) per 100 mL (a rolling geometric mean of 5 samples) and 235 CFU of generic E. coli per 100 mL for any single sample. As previously proposed, water not meeting either one of these criteria would result in the discontinuation of water for the purpose of direct application until certain specified corrective actions are taken. We are proposing certain amendments to this provision: (1) revised microbial quality standard in § 112.44(c) to a geometric mean of no more than126 CFU per 100 mL and (when applicable) a statistical threshold value (STV) of no more than 410 CFU per 100 mL; (2) provisions to incorporate additional flexibility and provide means to achieve the proposed microbial quality standard for agricultural water used for direct application for growing produce other than sprouts, i.e., by applying either a time interval between last application of water and harvest using 0.5 log per day microbial die-off rate, and/or a time interval between harvest and end of storage (see proposed §§ 112.44(c)(1) and (c)(2)), such that the recommended microbial quality levels are met. We are retaining the previously proposed provision that would allow for the discontinuation of water usage until certain specified corrective actions are taken. Additionally, we are proposing to amend the testing frequency requirements for untreated surface water used for direct application during growing of produce other than sprouts (as

proposed in 112.45(b)) to include a baseline survey of the water quality, consisting a minimum of 20 samples over 2 years, followed by annual surveys of your water source, using a minimum of five samples per year. We are also proposing to amend the testing frequency requirements for ground water to include annual surveys using four samples during the growing season or calendar year, initially, which may be reduced to a single sample per year if test values do not exceed the recommended levels. For untreated surface water used for purposes listed in § 112.44(a), we are not proposing specific testing frequency requirements; rather, we are proposing that each source of the water be tested with an adequate frequency to provide reasonable assurances that the water meets the required microbial standard.

Costs

We estimate one primary change to the costs of agricultural water provisions based on the changes discussed above, which are presented in Table 4. Because the minimum number of samples allowable for baseline and annual survey for ground water has been changed to collecting 4 samples for establishing a baseline in the first year and 1 sample per year for an annual survey thereafter, we estimate that farms using untreated ground water for purposes that trigger a testing requirement will now test their water supply a maximum of 5 times in the first year (4 per year/growing season plus one test per year) rather than testing on a quarterly basis as originally proposed. For untreated surface water used for growing produce other than sprouts using a direct water application method, the required testing would involve the collection of 20 samples over the first 2 years followed by an annual minimum sampling of 5 per year, rather than monthly or weekly as previously estimated. These changes in testing frequency, applied

to our original estimates, serve to reduce the cost of "Water sampling and testing surface water used for direct application irrigation water other than for sprouts" by about 65 percent (newly estimated cost of 2.72 million minus originally estimated cost of 7.83 million divided by originally estimated cost of 7.83 million).[3]

Table 4. New Estimated Costs of the Agricultural Water Provisions, Excluding Records

Description	**Very small**	**Small**	**Large**
Inspection and maintenance of agricultural water sources	$10,350,937	$1,384,028	$2,860,020
Water sampling and testing surface water used for direct application irrigation water other than for sprouts	$1,841,867	$320,131	$562,812
Water sampling and testing for farms that use water or ice in direct contact with covered produce or food contact surfaces, for harvest, packing and holding operations, water for hand-washing during and after harvest, water for treated agricultural teas, and also for sprouting operations	$1,330,014	$308,425	$542,285
Water treatment to meet quality criteria of 410 MPN / 100ml	$865,170	$444,266	$409,224
Water treatment to meet quality criteria of no detectable E. coli	$4,091,012	$1,529,594	$5,288,496
Establish and implement water management practices for harvest, packing, and holding operations	$2,230,473	$953,154	$1,662,818
Total cost by size category	$20,709,473	$4,939,599	$11,325,654
Total cost of the agricultural water provisions	**$36,974,726**		

Note: These costs take into account the lower number of farms covered by the rule, due to language from the supplemental notice. Costs presented are annualized over 7 years at 7%.

We estimate that changing these provisions will reduce the total cost of Agricultural Water provisions, excluding record-keeping, to $36.97 million, annually; or an approximately 24 percent reduction (where approximately 13 percent is due solely to the changes to water testing requirements and 11 percent is due to the change in the size threshold for application of the proposed rule). Additionally, assuming a similar

[3] We do not add additional costs for the baseline survey comprised of 10 samples (20 samples/ 2 years) in each of the first two years for surface water, because some of the costs will be absorbed by the annual testing requirements that we explicitly re-estimate, and the remaining testing costs are accounted for in the original estimates of the "Inspection and maintenance of agricultural water sources".

reduction in the costs of Agricultural water records yields a costs savings of approximately $1.72 million ($7.17 million x 0.24), annually.[4]

Because the microbial quality standard based on generic E. coli has approximately doubled (i.e., no more than 235 CFU for any single sample (in the original proposed rule) to no greater than 410 CFU of the sample estimate of the statistical threshold value (in the supplemental notice), farms may experience some cost savings though a reduction in water sources that do not meet the requirements of this supplemental proposal. We previously estimated (in table 48 of the PRIA) (Ref.1) that 2.4 percent of all water sources would not meet the recommended levels, however, because we do not have further information to base how much, if at all, the number of water sources that be above this new threshold, we do not adjust this original estimate further. We request comment on this estimate.

There could also be additional costs savings, which are not explicitly captured by these estimates. It is likely that farms will experience fewer corrective actions due to agricultural water because the water quality threshold that may trigger a corrective action has been raised. In Table 119 of the PRIA (Ref.1), we estimate that farms may incur $882,385 in costs due to corrective action from failed standards directed to Agricultural Water. However, with the proposed higher standard, the percentage of tests that fail may fall. We request comment on this estimate.

[4] Using the 24 percent reduction in record keeping costs assumes that record keeping and water testing costs are comprised of the same mix of fixed and variable costs. This may not be correct, as the fixed costs of record keeping could be greater or less than the fixed costs of water testing; however, without further evidence we are unable to quantify how much this percentage may vary. We request comment on this estimate.

Finally, some farms may see a reduction in costs through implementing application intervals that take into account pathogen die-off and/or removal on the commodity. These are new options that farms could use if a test is higher than the microbial standard, in addition to the previously proposed options of discontinuing water usage and conducting corrective steps, or switching water sources. To the extent that these methods are cheaper than switching water sources, our estimates may be higher than actual costs on some farms.

Benefits

The amendments to the original water standards have been made to address the comments that we received requesting that FDA incorporate flexibility to the standards more explicitly without impacting the level of safety beyond what was initially proposed. Therefore, we do not estimate any further reduction in the estimated benefits of this rule due to these changes.

VI. Minimum application intervals to biological soil amendments of animal origin

The minimum application interval for biological soil amendments of animal origin that have been treated by composting has been lowered from 45 days to 0 days. No costs were attributed to an application interval of 45 days as stated in footnote 32, page 181-182, of the PRIA (Ref.1). We realize that this may have been an oversimplification of the cost incurred by farms and therefore acknowledge that the removal of this restriction on the application of treated biological soil amendments eases the burden of costs to some farms. We do not adjust the benefits of the rule based on this change because we would not expect the lowering of this interval to make a difference in food safety.

In addition, we are proposing to amend 112.56(a)(1)(i) to remove the 9-month application interval and defer our decision on an appropriate time interval until we take certain specified actions, which are described in the supplemental NPRM. We estimate that removing this provision will lower the costs by the entirety of the originally estimated amount, $9.2 million dollars. Similarly, all of the originally estimated potential benefits times the estimated efficacy of this rule, approximately 156,299 (241,314 x .6477) illnesses or $92.52 ($142.85 x .6477) million, are removed from this analysis. These changes are reflected in all tables, in terms of a lower average cost to all covered farms (Table 5) and a lower number of illnesses avoided directly attributable to this rulemaking (Tables 3 and 6).

VII. Prevention of contamination from animals

In the supplemental notice, we propose to add a new provision to state that the produce safety rule does not authorize or require covered farms to take actions that would constitute the "taking" of threatened or endangered species in violation of the Endangered Species Act, and that the rule does not require covered farms to take measures to exclude animals from outdoor growing areas, destroy animal habitat, or otherwise clear farm borders around outdoor growing areas or drainages. This provision codifies our previous intention expressed in the original proposed rule. No costs or benefits were originally calculated for either harming or removing endangered animals or destroying habitat and, therefore, we do not estimate a change in either costs or benefits of this rule due to these proposed changes.

VIII. FDA's process of withdrawal of qualified exemptions

In the supplemental notice, we are proposing certain amendments to the circumstances and process for FDA withdrawing a qualified exemption and we are proposing a provision for reinstating a qualified exemption. We do not attribute costs or benefits to having an exemption withdrawn or reinstated since we do not have sufficient information about the frequency with which this may occur; therefore, these amendments do not change the estimated costs or benefits associated with this rule.

IX. Summary

This document has detailed the analysis of the actual changes to the proposed rule. For detailed analysis of the pieces of the proposed rule that have not changed, see the PRIA (Ref.1). The supplemental notice includes new language on the definition of a farm and farm size, testing requirements for agricultural water, minimum application intervals to treated biological soil amendments of animal origin, the prevention of contamination from animals, and FDA's process of withdrawal of qualified exemptions. We explicitly estimate a change in costs and benefits of the proposed "Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption" due to the changes related to the definition of a farm and farm size and the testing requirements for agricultural water. In addition, we discuss why cost and benefits are not altered due to the new language related to biological soil amendments of animal origin, the prevention of contamination from animals, and the withdrawal of qualified exemptions.

Table 5 presents the total costs by provision and the average cost per farm by farm size of the proposed rule as amended in our supplemental notice of rulemaking. In

each size category the total and average cost per farm has fallen from those initially estimated in the PRIA.

Table 5. Summary of Costs for Supplemental Produce Safety Rule (in millions)

Cost Sections	Not Covered	Very Small	Small	Large	Total	Original	Diff.
Administrative cost to learn the rule	$11.50	$14.34	$6.09	$7.17	**$39.10**	$36.79	$2.31
Health and Hygiene	$0.00	$23.24	$12.88	$82.06	**$118.17**	$138.21	-$20.04
Agricultural water	$0.00	$20.29	$4.84	$11.10	**$36.23**	$48.55	-$12.32
Biological soil amendments of animal origin	$0.00	$0.00	$0.00	$0.00	**$0.00**	$9.20	-$9.20
Domesticated and wild animals	$0.00	$8.82	$5.10	$18.38	**$32.30**	$37.78	-$5.48
Growing, harvesting, packing, and holding activities	$0.00	$0.15	$0.08	$0.14	**$0.36**	$0.42	-$0.06
Equipment, tools, buildings, and sanitation	$0.00	$9.73	$7.03	$33.58	**$50.34**	$58.87	-$8.53
Sprouting operations	$0.00	$0.64	$0.61	$5.19	**$6.44**	$7.53	-$1.09
Personnel Qualifications and training	$0.00	$16.76	$10.98	$50.43	**$78.17**	$91.42	-$13.25
Corrective steps	$0.00	$0.41	$0.19	$0.85	**$1.44**	$2.09	-$0.65
Variances	$0.00	$0.00	$0.01	$0.01	**$0.08**	$0.10	-$0.02
Recordkeeping	$0.00	$13.36	$3.47	$6.76	**$23.59**	$28.60	-$5.01
Total Costs (annual in millions)	$11.50	$107.73	$51.26	$215.73	**$386.23**	$459.56	$73.33
Average Cost per farm	$88	$4,477	$12,384	$29,545	**$10,996**	$11,430	-$433.65
Total Cost to Foreign Farms *					**$143.39**	$170.62	-$27.23

Notes: Costs presented are annualized over 7 years at 7%. The costs of almost all of these categories have fallen from those originally proposed, due to either reduced requirements or a smaller number of covered farms estimated to incur costs. The sole exception is the total costs to farms not covered by the supplemental proposal. The costs to this group have grown simply because we now estimate there are more farms that would not be covered or would qualify for an exemption; the per-farm costs to this group have not changed.

* The costs to foreign farms are calculated in the same way they were calculated in the original RIA. We start with an estimate of the total number of foreign farms, and then scale this by the percentage of domestic farms that are covered by the rule. Then we apply the average cost incurred by a domestic farm to the foreign count of covered farms.

Table 6 presents a summary of the total costs and benefits estimated to be associated with the proposed rule as amended by this supplemental notice. We estimate the total benefits of the proposed rule as amended by this supplemental notice to be $930 million, annually and the annualized costs to be $529.62 million, annually. This results in $400.37 million in estimated potential net benefits.

Table 6. Summary of Costs and Public Health Benefit (in millions)

Prevented Foodborne Illnesses	**Total Benefits**	**Total Domestic Costs**	**Total Foreign Costs**	**Total Costs**	**Net Benefits**
1.57	$930.00	$386.23	$143.39	$529.62	$400.37

Notes: Costs and benefits presented are annualized over 7 years at 7%.

In total, this represents a cost savings of $73.33 ($459.56 - $386.23) million for domestic produce farms, and a decrease in overall net benefits of $7.19 ($400.37 - $407.56) million.

Reference List

(1) FDA. Analysis of Economic Impacts - Standards for the Growing, Harvesting, Packing and Holding of Produce for Human Consumption. http://www.fda.gov/downloads/Food/GuidanceRegulation/FSMA/UCM334116.pdf . 2013.

(2) USDA, NASS. 2007 Census of Agriculture. http://www.agcensus.usda.gov/Publications/2007/Getting_Started/Guide_to_Census_Products/ . 2007.