DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption; Extension of Compliance Dates for Subpart E; Proposed Rule

Docket No. FDA–2011–N–0921

Preliminary Regulatory Impact Analysis
Preliminary Regulatory Flexibility Analysis
Preliminary Small Entity Analysis
Unfunded Mandates Reform Act Analysis

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Executive Summary

The Food and Drug Administration (FDA) is, for non-sprout covered produce, proposing to extend the compliance date for all of the provisions of Subpart E to four years after the relevant farm's compliance date for all other provisions of the produce safety regulation (which varies based on establishment size). This means that covered farms producing non-sprout covered produce would have an additional two years to comply with certain agricultural water provisions (see Table 1, column 1 in the proposed rule for a list), compared to the originally-published compliance dates in the produce safety regulation; and an additional four years to comply with the remaining agricultural water provisions (see Table 1, column 2 in the proposed rule for a list), compared to the originally-published compliance dates in the produce safety regulation. The estimated costs and benefits accrued in any given year of compliance with the produce safety regulation, relative to the first year of compliance, would not change; however, because FDA is proposing to extend the compliance dates for certain provisions, the discounted value of both total costs and total benefits would decrease. There would be a reduction in costs (i.e., cost savings) associated with extending, for non-sprout covered produce, the compliance date for all of the provisions of Subpart E to four years after the relevant farm's compliance date for the rest of the produce safety regulation. No additional costs would be incurred by state, local, and tribal governments or the private sector as a result of this rule. There would be a reduction in the annualized benefits associated with extending the compliance dates, as consumers eating non-sprout covered produce would not enjoy the potential health benefits (i.e., reduced risk of illness) provided by the provisions of Subpart E until two to four years (depending on the specific provision) later than originally established in the produce safety regulation. The total annualized cost decrease of this proposed rule, using a 3 (7) percent discount rate over 10 years, would be from $404 ($382) million to $392 ($370) million, resulting in a savings of $12 million. The total annualized benefits to consumers, discounted at 3 (7) percent over 10 years, would decrease by $108 ($109) million from $1.033 billion ($983 million) to $925 ($874) million. All estimates are in 2016 dollars. This comes out to approximately a 3% decrease in costs, and approximately an 11% decrease in benefits as compared to the produce safety regulation. Using a 3 (7) percent discount rate, the proposed rule would have negative annualized net benefits of $96 ($97) million.

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I. Introduction and Summary

A. Introduction

We have examined the impacts of the proposed rule under Executive Order 12866, Executive Order 13563, Executive Order 13771, the Regulatory Flexibility Act (5 U.S.C. 601-612), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4). Executive Orders 12866 and 13563 direct us 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). Executive Order 13771 requires that the costs associated with new regulations shall "be offset by the elimination of existing costs associated with at least two prior regulations." We have developed a comprehensive Economic Analysis of Impacts that assesses the impacts of the proposed rule. We believe that this proposed rule is an economically significant regulatory action as defined by Executive Order 12866. We expect that this proposed rule, if finalized, would qualify as a deregulatory action for the purposes of section 2 of Executive Order 13771.

The Regulatory Flexibility Act requires Agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities when "the agency publishes a general notice of proposed rule making." 5 U.S.C. § 601(2). FDA has analyzed this proposed rule under the Regulatory Flexibility Act. Because this proposed rule only extends the compliance dates for certain provisions of the Standards for the Growing, Harvesting, Packing and Holding of Produce for Human Consumption rule (Ref. 1) (produce safety regulation), we propose to certify that this proposed rule would not have a significant economic impact on a substantial number of small entities.

The Unfunded Mandates Reform Act of 1995 (section 202(a)) requires us to prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing "any rule that includes any Federal mandate that may result in the expenditure by state, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year." The current threshold after adjustment for inflation is $148 million, using the most current (2016) Implicit Price Deflator for the Gross Domestic Product. FDA does not expect this proposed rule to result in an expenditure in any year that meets or exceeds this amount.

B. Summary of Costs and Benefits

This rule proposes to extend, for non-sprout covered produce, the compliance date for all of the provisions of Subpart E to four years after the relevant farm's compliance date for all other provisions of the produce safety regulation (which varies based on establishment size). The estimated costs and benefits accrued in any given year of compliance with the produce safety regulation, relative to the first year of compliance, would not change. However, because FDA is proposing to extend the compliance dates for certain provisions, the discounted values of both the total costs and total benefits would decrease.

In the final regulatory impact analysis of Subpart E of the produce safety regulation, we only considered §§ 112.42, 112.44, 112.45(a)(2), 112.45(b)(3), 112.46(b), and 112.46(c) to result in a cost. Therefore, while Subpart E has other provisions, only the aforementioned provisions are relevant to and addressed in this cost and benefit analysis.

There would be a reduction in costs associated with extending, for non-sprout covered produce, the compliance date for all of the provisions of Subpart E to four years after the relevant farm's compliance date for the rest of the produce safety regulation. With respect to their non-sprout covered produce, covered farms would have four years from the compliance date for the other provisions of produce safety regulation to comply with the provisions in Subpart E. Thus, while all initial start-up costs and recurring costs would remain the same as estimated in the final regulatory impact analysis for the produce safety regulation (Ref. 2), the annualized total costs, discounted at 3 (7) percent over 10 years, would decrease by about 3 percent from $404 (382) million to $392 (370) million. Put another way, this proposed rule would change the produce safety regulation compliance dates in a way that would reduce annualized costs to industry by about $12 million. We welcome comment on our cost analysis, including on additional ways that this proposed delay would impact the cost of complying with subpart E. No additional costs would be incurred by state, local, and tribal governments or the private sector as a result of this proposed rule. There would be a reduction in the annualized benefits associated with extending the compliance dates as described above. Consumers eating non-sprout covered produce would not enjoy the potential health benefits (i.e., reduced risk of illness) provided by the provisions of Subpart E until two to four years (depending on the specific provision) later than originally established in the produce safety regulation. Thus, the annualized total benefits to consumers, discounted at 3 (7) percent over 10 years, would decrease by about 10 (11) percent from $1.033 (983) billion to $925 (874) million. Estimated changes in benefits and costs as a result of this proposed extension are summarized in Table 1. Using a 3 (7) percent discount rate, the effect of these changes would be a reduction in annualized net benefits of $96 ($97) million.

Table 1: Summary of the changes in benefits and costs as a result of this proposed rule, annualized over 10 years, in millions of 2016 dollars

	Costs to industry under 2015 final rule	Costs to industry with the proposed compliance extension	Benefits of reduced risk of illness under 2015 final rule	Benefits of reduced risk of illness with the proposed compliance extension

annualized 3%	$404	$392	$1,033	$925
annualized 7%	$382	$370	$983	$874
Net present value of 10 years of costs or benefits 3%	$3,443	$3,340	$8,811	$7,886
Net present value of 10 years of costs or benefits 7%	$2,681	$2,598	$6,901	$6,143

II. Preliminary Regulatory Impact Analysis

A. *Background and Need for Regulation*

Given the feedback FDA has received on the final produce safety regulation from numerous stakeholders raising issues regarding the practicality of some of the agricultural water requirements, and given the principles and policies set forth in Executive Orders 13777, 13771, and 13563, we are proposing to extend the compliance dates for subpart E, Agricultural Water, for covered produce other than sprouts. The additional time would allow us to consider approaches to address these issues, as well as opportunities there may be to reduce the cost and enhance the flexibility of these requirements beyond those reflected in the produce safety regulation.

Thus, the FDA is proposing to extend the compliance dates, for non-sprout covered produce, for all of the provisions in Subpart E to four years after the relevant farm's compliance date for the other provisions of the produce safety regulation. The produce safety regulation appeared in the Federal Register of November 27, 2015 and provided, for covered activities involving non-sprout covered produce, a two-year extension (compared to the primary compliance date) for certain agricultural water provisions, §§ 112.44, 112.45(a) (with respect to the § 112.44(a) criterion), 112.45(b), 112.46(b)(1) (with respect to untreated ground water), 112.46(b)(2) and (b)(3), and 112.46(c). The produce safety regulation did not provide an extension for §112.42 and §112.46(b)(1) with respect to untreated surface water, or for other subpart E provisions not relevant to this analysis. FDA is now proposing to extend the compliance dates, for non-sprout covered produce, for all of the provisions in Subpart E to four years after the relevant farm's compliance date for the other provisions of the produce safety regulation. This means that covered farms producing non-sprout covered produce would have an additional two years to comply with §§ 112.44, 112.45(a) (with respect to the § 112.44(a) criterion), 112.45(b), 112.46(b)(1) (with respect to untreated ground water), 112.46(b)(2) and (b)(3), and 112.46(c) compared to the originally- published compliance dates in the produce safety regulation; and an additional four years to comply with §§ 112.42 and 112.46(b)(1) (with respect to untreated surface water) compared to the originally-published compliance dates in the produce safety regulation.

B. Baseline Conditions

The final regulatory impact analysis (FRIA) for the produce safety regulation serves as a baseline for this analysis (Ref 2). Extending the compliance dates as described above would change the expected timeline for costs incurred to comply with the produce safety regulation, and for the expected benefits consumers enjoy as a result of the regulation, but it would not change the estimated effectiveness of the produce safety regulation. The analysis herein estimates how extending the compliance dates as described above would change the total cost to covered establishments and the total benefits to consumers. While extending the compliance dates would decrease net benefits, they would still be positive.

The estimated baseline costs and benefits are summarized in Table 2. These differ slightly from the costs and benefits published in the FRIA for the produce safety regulation because we used a GDP deflator to update them to reflect 2016 (as opposed to 2013) dollars, and we changed our calculations to better reflect the timing of the original compliance dates for certain provisions. In the FRIA, all of the Agricultural Water provisions that imposed costs were treated as subject to the two year extension compared to the primary compliance date, when, in actuality, two of the provisions (§ 112.42, and § 112.46(b)(1) with respect to untreated surface water) were actually subject to the primary compliance date. This resulted in an underestimation of costs and benefits in the FRIA. To update the baseline costs, we simply change the timing of the compliance dates for these two provisions to reflect the actual timing of their original compliance dates. Because the benefits of all of the Agricultural Water provisions in Subpart E of the produce safety regulation were calculated as a whole, and not by specific provision, we assume that the benefit of each provision is proportional to its coverage (e.g., § 112.42, and § 112.46(b)(1) with respect to untreated surface water account for 33 percent of the costs of the Agricultural Water provisions;[1] therefore we assume they account for 33 percent of the benefits from the Agricultural Water provisions). These small changes can lead to large overall differences, particularly in estimated benefits, due to the magnitude of the estimates. The analysis has not changed from the FRIA for the produce safety regulation.

Table 2: Revised Baseline, in millions of 2016 dollars

	Discount Rate	Primary Estimate	Low Estimate	High Estimate
Annualized Benefits over 10 years	3%	$1,033	$790	$1,274
	7%	$983	$752	$1,211

[1] This proportion holds for very small, small, large and total farms. More specifically, §112.42 accounts for about 18 percent of Agricultural Water costs, and §112.46(b)(1) with respect to untreated surface water accounts for about 15 percent of Agricultural Water costs.

NPV of Benefits over 10 Years	3%	$8,811	$6,741	$10,871
	7%	$6,901	$5,285	$8,506
Annualized Costs over 10 Years	3%	$404	$333	$430
	7%	$382	$315	$406
NPV of Costs over 10 Years	3%	$3,443	$2,838	$3,666
	7%	$2,681	$2,209	$2,855

C. Benefits of this Proposed Rule

Extending these compliance dates would mean that, while consumers would enjoy the same expected safety benefits (i.e., reduced risk of illness) provided by the agricultural water provisions in the produce safety regulation, they would have to wait for them for an additional two to four years. If the compliance date for the agricultural water provisions, §§ 112.44, 112.45(a) (with respect to the § 112.44(a) criterion), 112.45(b), 112.46(b)(1) (with respect to untreated ground water), 112.46(b)(2) and (b)(3), and 112.46(c) (as originally published) is January, 2020, for large farms (January, 2021, for small farms, and January, 2022 for very small farms), we estimate that consumers would receive approximately $273 million per year in benefits from covered large establishments in 2020 and 2021 (2021 and 2022 for small establishments, and 2022 and 2023 for very small establishments) complying with these specific provisions. If the compliance date is extended two additional years for these provisions (as provided by this proposed rule), we assume that consumers would ultimately enjoy the same benefits, but would not begin benefitting for an additional two years. Similarly, if the compliance date for the agricultural water provisions §112.42, and §112.46(b) with respect to untreated surface water is (as originally published) is January, 2018, for large farms (January, 2019, for small farms, and January, 2020, for very small farms), we estimate that consumers would receive approximately $134 million per year in benefits from covered large establishments in 2018-2021 (2019 - 2022 for small establishments, and 2020- 2023 for very small establishments) complying with these specific provisions. If the compliance date is extended four additional years for these provisions, we assume that consumers would ultimately enjoy the same benefits, but would not begin benefitting for an additional four years. It is possible that some covered establishments may comply with these agricultural water provisions prior to the relevant compliance date. Table 3 compares the annual benefits of the produce safety regulation with the originally-published compliance dates to the benefits of the produce safety regulation with the compliance date extension that would be provided by this proposed rule. There would only be a difference in annual benefits in 2018 through 2023. From 2024 onward, the annual benefits for both the produce safety regulation with the originally-published compliance dates, and the produce safety regulation with the compliance date extension that would be provided by this proposed rule would be at approximately $1.43 billion.

Table 3. Comparison of Total Rule Benefits; Produce Safety Regulation and Produce Safety Regulation with Proposed Compliance Extension- Average 10-year stream of benefits and annualized benefits, in millions

year	benefits ($ millions) of produce safety regulation with originally-published compliance dates	benefits ($ millions) of produce safety regulation with the proposed compliance date extension	Benefits Foregone with Compliance Extension for Subpart E
Year 1	$0	$0	$0
Year 2	$197	$197	$0
Year 3	$961	$851	-$110
Year 4	$1,049	$931	-$118
Year 5	$1,380	$1,024	-$356
Year 6	$1,398	$1,024	-$374
Year 7	$1,430	$1,356	-$74
Year 8	$1,430	$1,382	-$48
Year 9	$1,430	$1,430	$0
Year 10	$1,430	$1,430	$0

Total	$10,706	$9,625	
NPV 3%	$8,811	$7,886	
NPV 7%	$6,901	$6,143	
Annualized 3%	$1,033	$925	
Annualized 7%	$983	$875	

Consumers would see a reduction in total annualized benefits between the produce safety regulation with the originally-published compliance dates (Table 3, column 2) and the produce safety regulation with the compliance date extension that would be provided by this proposed rule (Table 3, column 3). Table 4 summarizes low, mean, and high annualized benefits estimates of the produce safety regulation with the compliance date extension provided by this proposed rule. The confidence interval is determined using the low and high estimates from the FRIA for the produce safety regulation.

Table 4. Estimated benefits to consumers of the produce safety regulation with the compliance date extension that would be provided by this proposed rule, in millions of 2016 dollars

	low	mean	high
annualized 3%	$710	$925	$1,136
annualized 7%	$672	$874	$1,074
npv 3%	$6,057	$7,886	$9,692
npv 7%	$4,722	$6,143	$7,542

The total annualized benefits to consumers of the produce safety regulation with the compliance date extension that would be provided by this proposed rule, using a 3 percent discount rate over 10 years, would be from $710 to $1,136 million (a decrease from the range, $790 to $1,274 million for the produce safety regulation with the originally-published compliance dates); with a 7 percent discount rate, the annualized cost would be $672 to $1,074 million (a decrease from the range, $752 to $1,211 million for the produce safety regulation with the originally-published compliance dates). In our analyses, we make the assumption that all costs and benefits of the agricultural water provisions would be incurred by farms at the farm's applicable compliance date. Because some farms may have already taken steps to comply with the agricultural water provisions in the produce safety regulation, the benefits of the produce safety regulation with the compliance date extension that would be provided by this proposed rule may be underestimated.

D. Costs of this Proposed Rule

Extending the compliance dates as described above would delay the cost to covered farms of complying with some provisions of the produce safety regulation for an additional two to four years. Extending these compliance dates would create no additional costs to state, local, and tribal governments or the private sector. If the compliance date for the agricultural water provisions, §§ 112.44, 112.45(a) (with respect to the § 112.44(a) criterion), 112.45(b), 112.46(b)(1) (with respect to untreated ground water), 112.46(b)(2) and (b)(3), and 112.46(c) is (as originally published) January, 2020, for large farms (January, 2021, for small farms, and January, 2022, for very small farms), we estimate that covered large establishments would spend an average estimated $9 million per year in 2020 and 2021 (2021 and 2022 for small establishments, and 2022 and 2023 for very small establishments) on these specific provisions in order to be in compliance. If the compliance date is extended two additional years (to four years after the compliance date for the rest of the produce safety regulation) for these provisions (as provided by this proposed rule), we assume covered establishments would have the same fixed costs, but would not incur them until two years later, relieving them of two years of compliance costs.

Similarly, if the compliance dates of agricultural water provisions § 112.42, and § 112.46(b)(1) with respect to untreated surface water is (as originally published) January, 2018, for large farms (January, 2019, for small farms, and January, 2020, for very small farms), we estimate that covered large establishments would spend an average estimated $24 million per year in 2018-2021 (2019 - 2022 for small establishments, and 2020- 2023 for very small establishments) on these specific provisions in order to be in compliance. If the compliance date is extended four additional years (to four years after the compliance date for the rest of the produce safety regulation) for these provisions (as provided by this proposed rule), we assume covered establishments would have the same fixed costs, but would not incur them until four years later, relieving them of four years of compliance costs.

Table 5 summarizes the costs for the entire produce safety regulation with the originally-published compliance dates and with the compliance date extension that would be provided by this proposed rule.

Table 5. Average 10-year stream of costs and annualized costs, in millions of 2016 dollars

year	costs ($ millions) produce safety regulation with originally-published compliance dates	costs ($ millions) produce safety regulation with the proposed compliance date extension
2016	$0	$0
2017	$5	$5
2018	$323	$317
2019	$423	$414
2020	$571	$538
2021	$572	$538
2022	$577	$553
2023	$577	$558
2024	$577	$577
2025	$577	$577
Total	$4,201	$4,078
NPV 3%	$3,443	$3,340
NPV 7%	$2,681	$2,598

Annualized 3%	$404	$392
Annualized 7%	$382	$370

The reduction in total cost between the produce safety regulation with the originally-published compliance date (Table 5, column 2) and the produce safety regulation with the compliance date extension that would be provided by this proposed rule (Table 5, column 3) are an estimated $12 million ($12=$404 - $392). Table 6 summarizes low, mean, and high annualized costs estimates of the produce safety regulation with the compliance date extension that would be provided by this proposed rule. The confidence interval is calculated using the low and high estimates from the FRIA of the produce safety regulation.

Table 6. Costs to industry of the produce safety regulation, with the compliance date extension that would be provided by this proposed rule, in millions of 2016 dollars

	low	mean	high
annualized 3%	$321	$392	$423
annualized 7%	$303	$370	$400
npv 3%	$2,738	$3,340	$3,607
npv 7%	$2,129	$2,598	$2,807

The total annualized costs to industry of the produce safety regulation with the compliance date extension that would be provided by this proposed rule, using a 3 percent discount rate over 10 years, would be from $321 to $423 million (a decrease from the range, $333 to $430 million under the produce safety regulation with the originally- published compliance dates). With a 7 percent discount rate, the annualized costs to industry of the produce safety regulation with the compliance date extension that would be provided by this proposed rule would be $303 to $400 million (a decrease from the range, $315 to $406 million under the produce safety regulation with the originally- published compliance dates). Because we make the assumption that all costs of complying with the agricultural water provisions would be incurred by farms at the farm's applicable compliance date, the costs of compliance with the produce safety regulation with the compliance date extension that would be provided by this proposed rule may be underestimated. FDA solicits comment on our analysis of the costs and benefits of this proposed extension.

III. Analysis of Regulatory Alternatives to This Proposed Rule

We present four alternative regulatory options:

1. Extending (only for non-sprout covered produce) by an additional 2 years the compliance dates for the provisions in Subpart E that originally had a two year extension (compared to the primary compliance date) in the produce safety regulation (§ 112.44, § 112.45(a) with respect to the § 112.44(a) criterion, § 112.45(b), § 112.46(b)(1) with respect to untreated ground water, § 112.46(b)(2) and (b)(3), and § 112.46(c)); option 1 would have negative annualized net benefits of $51 ($50) million at the 3 (7) percent discount rate.

2. Extending (only for non-sprout covered produce) the compliance dates for all of Subpart E by 2 years, keeping the originally- published two-year difference between the compliance dates for some provisions as compared to others intact; option 2 would have negative annualized net benefits of $74 million at the 3 and 7 percent discount rate.

3. Extending (only for non-sprout covered produce) the compliance dates as in the first option, but also including § 112.46(b)(1) with respect to untreated surface water in this extension; option 3 would have negative annualized net benefits of $72 million at the 3 and 7 percent discount rate.

4. Extending (only for non-sprout covered produce) the compliance dates for certain testing-related provisions of Subpart E § 112.44, § 112.45(a) with respect to the § 112.44(a) criterion, § 112.45(b), § 112.46(b) and § 112.46(c)) by 2 years beyond their originally-published dates. The costs and benefits of the four options are presented in Tables 7-10. The estimation methods are identical to those described in sections above. Option 4 would have negative annualized net benefits of $61($63) million at the 3 (7) percent discount rate.

Table 7: Option 1, in millions of 2016 dollars

	Costs to industry under 2015 produce safety regulation	Costs to industry with this compliance extension	Benefits of reduced risk of illness under 2015 produce safety regulation	Benefits of reduced risk of illness with this compliance extension
annualized 3%	$404	$401	$1,033	$979
annualized 7%	$382	$379	$983	$930
npv 3%	$3,443	$3,418	$8,811	$8,351
npv 7%	$2,681	$2,661	$6,901	$6,532

Table 8: Option 2, in millions of 2016 dollars

	Costs to industry under 2015 produce safety regulation	Costs to industry with this compliance extension	Benefits of reduced risk of illness under 2015 produce safety regulation	Benefits of reduced risk of illness with this compliance extension
annualized 3%	$404	$396	$1,033	$951
annualized 7%	$382	$374	$983	$901
npv 3%	$3,443	$3,378	$8,811	$8,112
npv 7%	$2,681	$2,627	$6,901	$6,324

Table 9: Option 3, in millions of 2016 dollars

	Costs to industry under 2015 produce safety regulation	Costs to industry with this compliance extension	Benefits of reduced risk of illness under 2015 produce safety regulation	Benefits of reduced risk of illness with this compliance extension
annualized 3%	$404	$396	$1,033	$953

annualized 7%	$382	$374	$983	$903
npv 3%	$3,443	$3,374	$8,811	$8,126
npv 7%	$2,681	$2,626	$6,901	$6,343

Table 10: Option 4, in millions of 2016 dollars

	Costs to industry under 2015 produce safety regulation	Costs to industry with this compliance extension	Benefits of reduced risk of illness under 2015 produce safety regulation	Benefits of reduced risk of illness with this compliance extension
annualized 3%	$404	$398	$1,033	$966
annualized 7%	$382	$376	$983	$914
npv 3%	$3,443	$3,396	$8,811	$8,236
npv 7%	$2,681	$2,642	$6,901	$6,431

III. Preliminary Small Entity Analysis

The Regulatory Flexibility Act requires us to analyze regulatory options that would minimize any significant impact of a rule on small entities when "the agency publishes a general notice of proposed rule making." 5 U.S.C. § 601(2). FDA has examined the economic implications of this proposed rule under the Regulatory Flexibility Act, and in this proposed rule, the burden would lie solely on the consumers in the way of lost benefits. Therefore, we propose to certify that this proposed rule would not have a significant economic impact on a substantial number of small entities.

In this proposed rule, there would be no burden on state, local, and tribal governments or the private sector. In the produce safety regulation, it was estimated that 95 percent of all farms that grow produce covered by the rule are considered small by the SBA definition. The produce safety regulation reduces the burden on small entities in part through the use of limitations and exemptions, in part through providing all farms flexibility for alternative practices to be used for certain specified requirements related to agricultural water, and in part through non-uniform compliance dates (with smaller entities having longer compliance periods than larger entities). In addition to these measures, further delaying certain compliance dates as provided by this proposed rule would allow for greater flexibility in cost-effective compliance. This analysis, together with other relevant sections of this document, serves as a Preliminary Regulatory Flexibility Analysis, for purposes of the Regulatory Flexibility Act.

IV. References

1) US Food and Drug Administration. *Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption.* November 27, 2015. Available at: https://www.federalregister.gov/articles/2015/11/27/2015-28159/standards-for-the-growing-harvesting-packing-and-holding-ofproduce-for-human-consumption

2) FDA. "Final Regulatory Impact Analysis, Standards for the Growing, Harvesting, Packing and Holding of Produce for Human Consumption." November 2015. Available at: http://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/ucm472310.htm