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; Final Rule

Docket No. FDA-2011-N-0921

Final Regulatory Impact Analysis
Final Regulatory Flexibility Analysis
Unfunded Mandates Reform Act Analysis

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Economics Staff
Office of Planning
Office of Policy, Planning, Legislation and Analysis
Office of the Commissioner

Executive Summary

The Food and Drug Administration (FDA) is, for non-sprout covered produce, extending 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 will 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, will not change, however, because FDA is extending the compliance dates for certain provisions, the discounted value of both total costs and total benefits will decrease. There will be a reduction in present value 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 will be incurred by state, local, and tribal governments or the private sector as a result of this rule. There will be a reduction in the annualized benefits associated with extending the compliance dates, as consumers eating non-sprout covered produce will 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 final rule, using a 3 (7) percent discount rate over 10 years, will be from approximately $291 ($265) million to $280 ($254) million, resulting in a savings of approximately $12 ($10) million. The total annualized benefits to consumers, discounted at 3 (7) percent over 10 years, will decrease by approximately $104 ($96) million from approximately $800 ($740) billion to $696 ($644) million. All estimates are in 2017 dollars. Using a 3 (7) percent discount rate, the final rule will have negative annualized net benefits of approximately $92 ($86) million.

Table of Contents

I. Introduction and Summary

A. Introduction

We have examined the impacts of the final 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 any new incremental costs associated with significant new regulations "shall, to the extent permitted by law, be offset by the elimination of existing costs associated with at least two prior regulations." We expect that this final rule will qualify as a deregulatory action for the purposes of section 2 of Executive Order 13771. We believe that this final rule is an economically significant regulatory action as defined by Executive Order 12866.

The Regulatory Flexibility Act requires Agencies to analyze regulatory options that will minimize any significant impact of a rule on small entities. Because this final 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 certify that this final rule will 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 $150 million, using the most current (2017) Implicit Price Deflator for the Gross Domestic Product. This final rule will not result in an expenditure in any year that meets or exceeds this amount.

B. Summary of Costs and Benefits

This rule extends, 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, will not change. However, because FDA is extending the compliance dates for certain provisions, the discounted values of both the total costs and total benefits will 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 will be a reduction in costs associated with extending, for non-sprout covered produce, the compliance date for all 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 will 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 will 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, decrease from approximately $291 ($265) million to approximately $280 ($254) million, resulting in a savings of approximately $12 ($10) million. The present value of total costs, discounted at 3 (7) percent over 10 years, decreases by approximately $2.5 ($1.9) billion to approximately $2.4 ($1.8) billion, resulting in a savings of approximately $99 ($74) million. No additional costs would be incurred by state, local, and tribal governments or the private sector as a result of this rule.

There is a reduction in benefits associated with extending the compliance dates as described previously. Consumers eating non-sprout covered produce will not enjoy the potential health benefits (i.e., reduced risk of illness) provided by the provisions of subpart E until 2 to 4 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, decrease by $104 ($96) million from $800 ($740) billion to $696 ($644) million. The present value of total benefits, discounted at 3 (7) percent over 10 years, decreases from about $6.8 ($5.2) billion to about $5.9 ($4.5) billion. Estimated changes in benefits and costs as a result of this extension are summarized in the following table.

Table 1. Summary of Changes to Benefits and Costs as a Result of Final Rule

Category		Primary Estimate	Units		
			Year Dollars	Discount Rate	Period Covered
Forgone Benefits	Annualized Monetized $millions/year	$96	2017	7%	2016-2025
		$104	2017	3%	2016-2025
Forgone Costs	Annualized Monetized $millions/year	$10	2017	7%	2016-2025
		$12	2017	3%	2016-2025

In line with Executive Order 13771, estimates of present and annualized values of costs and cost savings over an infinite time horizon are presented in Table 2. Based on these cost-savings, this final rule will be considered a deregulatory action under EO 13771.

Table 2. EO 13771 Summary Table (in $ Millions 2016 Dollars, Over an Infinite Time Horizon)

Item	Primary Estimate (7%)	Primary Estimate (3%)
Present Value of Cost Savings	$72	$97
Annualized Cost Savings	$5	$3

C. Comments on the Preliminary RIA and Our Responses

All comments on the proposed rule are addressed in the final rule.

D. Summary of Changes

Aside from updating the inflation multiplier to 2017 dollars, the economic analysis of the final rule does not differ from the economic analysis of the proposed rule.

II. Final Regulatory Impact Analysis

A. Background

Given the feedback FDA has received on the final produce safety regulation from numerous stakeholders raising issues regarding the practical implementation of some of the agricultural water requirements, we are extending the compliance dates for subpart E, Agricultural Water, for covered produce other than sprouts. The additional time will allow us to consider how to approach these issues.

Thus, the FDA is extending 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 extending 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 will 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. Market Failure Requiring Federal Regulatory Action

This final rule is being issued after consideration of feedback from stakeholders who raised concerns regarding the practicality of some of the agricultural water requirements. Because the FSMA produce safety regulation established certain requirements related to agricultural water that covered entities must follow, the market cannot correct itself without FDA extending the compliance dates to address questions about the practical implementation of compliance with certain provisions and to considering how we might further reduce the regulatory burden or increase flexibility while continuing to protect public health.

C. Purpose of the Rule

The purpose of this rule is to extend compliance dates during which time FDA will consider how to approach the concerns raised regarding the practical implementation of some of the agricultural water requirements.

D. 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 will 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 will not change the estimated effectiveness of the produce safety regulation. The analysis herein estimates how extending the compliance dates as described above will change the total cost to covered establishments and the total benefits to consumers. While extending the compliance dates will decrease net benefits, they will still be positive.

The estimated baseline costs and benefits are summarized in Table 3. 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 2017 (as opposed to 2013) dollars, and we changed our calculations to better reflect the timing of the original compliance dates for certain provisions.

Table 3: Revised Baseline, in millions of 2017 dollars

	Discount Rate	Primary Estimate	Low Estimate	High Estimate
Annualized Benefits over 10 years	3%	$800	$612	$987
	7%	$740	$566	$912
NPV of Benefits over 10 years	3%	$6,822	$5,220	$8,418
	7%	$5,194	$3,979	$6,403
Annualized Costs over 10 years	3%	$291	$240	$310
	7%	$265	$219	$282
NPV of Costs over 10 years	3%	$2,486	$2,049	$3,739
	7%	$1,860	$1,532	$1,980

E. Benefits of the Rule

Extending these compliance dates will mean that, while consumers will enjoy the same expected safety benefits (i.e., reduced risk of illness) provided by the agricultural water provisions in the produce safety regulation, they will have to wait for them for an additional two to four years. In the first four years after the final Produce Rule is effective, no facilities will be affected by the agricultural water provisions. We therefore estimate that consumers will not forgo benefits due to the proposed rule over these years. In the fifth year after the final Produce Rule is effective, large facilities will be affected by the agricultural water provisions, and we estimate that consumers will forgo benefits due to the compliance extension in the proposed rule. In the sixth and seventh year after the final Produce Rule is effective, small and very small facilities will be affected by the agricultural water provisions, and we estimate that consumers will forgo increased benefits due to the compliance extension in the proposed rule.

Table 4 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 will be provided by this final rule. There will be a difference in annual benefits from 2020 to 2025. From 2025 onward, the annual benefits of the produce safety regulation with the compliance date extension that will be provided by this final rule will be approximately $1.4 billion.

Table 4. Average 10-year stream of benefits and annualized benefits, in millions of 2017 dollars

Year	Benefits ($ millions) of produce safety regulation with originally-published compliance dates	Benefits ($ millions) of produce safety regulation with the compliance date extension	Benefits Forgone with Compliance Extension for Subpart E
2016	$0	$0	$0
2017	$201	$201	$0
2018	$217	$217	$0
2019	$247	$247	$0
2020	$980	$868	$112
2021	$1,070	$950	$120
2022	$1,408	$1,044	$363
2023	$1,426	$1,044	$381
2024	$1,459	$1,383	$75
2025	$1,459	$1,410	$49
Total	$8,466	$7,364	$1,102
NPV 3%	$6,822	$5,934	$888
NPV 7%	$5,194	$4,520	$674
Annualized 3%	$800	$696	$104
Annualized 7%	$740	$644	$96

Consumers will see a reduction in total annualized benefits between the produce safety regulation with the originally-published compliance dates (Table 4, column 2) and the produce safety regulation with the compliance date extension that will be provided by this final rule (Table 4, column 3). Table 5 summarizes low, mean, and high annualized benefits estimates of the produce safety regulation with the compliance date extension provided by this final rule. The confidence interval is determined using the low and high estimates from the FRIA for the produce safety regulation.

Table 5. Estimated benefits to consumers of the produce safety regulation with the compliance date extension that will be provided by this final rule, in millions of 2017 dollars

	Low	Mean	High
Annualized benefits, 3%	$534	$696	$855
Annualized benefits, 7%	$495	$644	$791
Net present value of benefits, 3%	$4,557	$5,934	$7,293
Net present value of benefits, 7%	$3,473	$4,520	$5,549

The total annualized benefits to consumers of the produce safety regulation with the compliance date extension that will be provided by this final rule, using a 3 percent discount rate over 10 years, will be from $534 to $855 million (a decrease from the range $805 to $1,299 million for the produce safety regulation with the originally-published compliance dates); with a 7 percent discount rate, the annualized benefits will be $495 to $791 million (a decrease from the range $767 to $1,235 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 will 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 will be provided by this final rule may be underestimated.

It is possible that this analysis may overstate the anticipated loss of benefit. The original benefit calculation was based on an assumption that the requirements would be fully understood and properly implemented, which is something we expect with every rule. However, FDA is aware of widespread concerns about complexity and serious questions about how the requirements can be implemented in practical ways on farms. To the extent that farms would not have been able to fully understand and implement the requirements in time to meet the original compliance dates, it is possible that the estimated public health benefits that were reflected in the original benefit calculation would not have been fully realized. Our hope is that the compliance date extension will result in a successful, albeit delayed, implementation of the agricultural water provisions.

F. Costs of the Rule

Extending the compliance dates as described above will 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 will create no additional costs to state, local, and tribal governments or the private sector. In the first four years after the final Produce Rule is effective, no facilities will be affected by the agricultural water provisions. We therefore estimate that will be no costs savings due to the proposed rule over these years. In the fifth year after the final Produce Rule is effective, large facilities will be affected by the agricultural water provisions, and we estimate that covered facilities will experience cost savings due to the compliance extension in the proposed rule. In the sixth and seventh year after the final Produce Rule is effective, small and very small facilities will be affected by the agricultural water provisions, and we estimate that covered facilities will experience cost savings due to the compliance extension in the proposed rule. 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 final rule), we assume covered establishments will have the same fixed costs, but will not incur them until four years later, relieving them of four years of compliance costs.

Table 6 summarizes the costs for the entire produce safety regulation with the originally-published compliance dates and with the compliance date extension that will be provided by this final rule.

Table 6. Average 10-year stream of costs and annualized costs, in millions of 2017 dollars

Year	Costs ($ millions) produce safety regulation with originally-published compliance dates	Costs ($ millions) produce safety regulation with the compliance date extension	Cost Savings with Compliance Extension for Subpart E
2016	$0	$0	$0
2017	$5	$5	$0
2018	$6	$6	$0
2019	$8	$8	$0
2020	$330	$324	$6
2021	$431	$422	$9
2022	$582	$549	$33
2023	$584	$549	$34
2024	$588	$564	$24
2025	$588	$569	$19
Total	$3,123	$2,997	$125
NPV 3%	$2,486	$2,387	$99
NPV 7%	$1,860	$1,786	$74
Annualized 3%	$291	$280	$12
Annualized 7%	$265	$254	$10

The reduction in total annualized 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 will be provided by this final rule (Table 6, column 3) are approximately $11.6 million (= $291.45 - $279.82), discounted at 3 percent. Table 7 summarizes low, mean, and high annualized costs estimates of the produce safety regulation with the compliance date extension that will be provided by this final rule. The confidence interval is calculated using the low and high estimates from the FRIA of the produce safety regulation.

Table 7. Costs to industry of the produce safety regulation, with the compliance date extension that will be provided by this final rule, in millions of 2017 dollars

	Low	Mean	High
Annualized costs, 3%	$229	$280	$302

Annualized costs, 7%	$208	$254	$275
Net present value of costs, 3%	$1,981	$2,387	$2,577
Net present value of costs, 7%	$1,464	$1,786	$1,930

The total annualized costs to industry of the produce safety regulation with the compliance date extension that will be provided by this final rule, using a 3 percent discount rate over 10 years, will be from $229 to $302 million (a decrease from the range, $340 to $439 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 will be provided by this final rule will be $208 to $275 million (a decrease from the range, $321 to $414 million under the produce safety regulation with the originally- published compliance dates).

G. Distributional Effects

We do not expect any significant distributional effects as a result of this rule. Reduction in burden and therefore cost savings will be proportional to covered entities' production.

H. International Effects

We do not expect any significant effects on international trade, as the extension would apply to both foreign and domestic covered entities.

I. Uncertainty and Sensitivity Analysis

The sources of uncertainty in this rule are the same as those in the produce safety final rule. The low and high estimates can be found in Table 5 and Table 7 in this analysis. In addition, because some farms may have already taken steps to comply with the agricultural water provisions in the produce safety regulation, the cost savings, as well as the forgone benefits, due to the compliance date extension that will be provided by this final rule may be overestimated.

J. Analysis of Regulatory Alternatives to the 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 approximately $39.6 ($37.8) 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 approximately $58.1 ($55.9) million at the 3 (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 approximately $56.6 ($54.4) million at the 3 (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. Option 4 would have negative annualized net benefits of approximately $48.1 ($48.3) million at the 3 (7) percent discount rate.

The costs and benefits of the four options are presented in Tables 8-11. The estimation methods are identical to those described in sections above.

Table 8: Option 1, in millions of 2017 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%	$291	$289	$800	$758
Annualized, 7%	$265	$263	$740	$700
Net present value, 3%	$2,486	$2,468	$6,822	$6,466
Net present value, 7%	$1,860	$1,846	$5,194	$4,971

Table 9: Option 2, in millions of 2017 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%	$291	$285	$800	$736
Annualized, 7%	$265	$259	$740	$678
Net present value, 3%	$2,486	$2,439	$6,822	$6,281
Net present value, 7%	$1,860	$1,823	$5,194	$4,759

Table 10: Option 3, in millions of 2017 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%	$291	$285	$800	$738
Annualized, 7%	$265	$259	$740	$680
Net present value, 3%	$2,486	$2,436	$6,822	$6,292
Net present value, 7%	$1,860	$1,822	$5,194	$4,774

Table 11: Option 4, in millions of 2017 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%	$291	$287	$800	$748
Annualized, 7%	$265	$261	$740	$688
Net present value, 3%	$2,486	$2,452	$6,822	$6,377
Net present value, 7%	$1,860	$1,833	$5,194	$4,841

III. Final Small Entity Analysis

The Regulatory Flexibility Act requires Agencies to analyze regulatory options that will minimize any significant impact of a rule on small entities. Because FDA has examined the economic implications of this final rule under the Regulatory Flexibility Act, and in this final rule, the burden will lie solely on the consumers in the way of lost benefits, we certify that the final rule will not have a significant economic impact on a substantial number of small entities. This analysis, as well as other sections in this document, serves as the Final Regulatory Flexibility Analysis, as required under the Regulatory Flexibility Act.

A. Description and Number of Affected Small Entities

The Small Business Administration defines farms involved in crop production as "small" if their total revenue is less than $750,000 (Ref 3). In the final Standards for the Growing, Harvesting, Packing and Holding of Produce for Human Consumption rule, NASS data on farm revenue was used to estimate that approximately 95 percent of all farms that grow covered produce are considered small by the SBA definition.

B. Description of the Potential Impacts of the Rule on Small Entities

In this final rule, we estimate that there will be no burden on state, local, and tribal governments or the private sector, and therefore, we estimate that there will be no burden on small entities. Like all covered farms affected by the rule, small farms will benefit from having additional time to comply with the agricultural water provisions in the final Produce Rule. In addition, farms that meet the definition of a "small business" under 21 CFR § 112.3 will have more time to comply with agricultural water provisions than larger farms, and farms that meet the definition of a “very small business” under 21 CFR § 112.3 will have even more time to comply.

C. Alternatives to Minimize the Burden on Small Entities

Because we estimate that this rule does not burden small entities, we estimate that this rule does not disproportionately affect small entities. The regulatory alternatives and associated estimated costs and forgone benefits discussed in section J of this analysis apply to all covered farms. We estimate that approximately 95 percent of these farms are considered small by the SBA definition.

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-growingharvesting-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

3) U.S. Small Business Administration. “Table of Size Standards 2017.” November 13, 2018. Available at: https://www.sba.gov/document/support--table-size-standards