



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 112

[Docket No. FDA-2011-N-0921]

RIN 0910-ZA50

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is proposing to extend, for covered produce other than sprouts, the dates for compliance with the agricultural water provisions in the Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption rule. We are proposing to extend the compliance dates to address questions about the practical implementation of compliance with certain provisions and to consider how we might further reduce the regulatory burden or increase flexibility while continuing to achieve our regulatory objectives, in keeping with the Administration's policies.

DATES: Submit either electronic or written comments on this proposed rule by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: You may submit comments on the extension of the compliance period as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. The <https://www.regulations.gov> electronic

filing system will accept comments until midnight Eastern Time at the end of [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in “Instructions.”

Instructions: All submissions received must include the Docket No. FDA-2011-N-0921 for “Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption; Extension of Compliance Dates for Subpart E.” Received comments, those filed in a timely manner (see ADDRESSES), will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states “THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.” The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the

body of your comments and you must identify this information as “confidential.”

Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA’s posting of comments to public docket, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Samir Assar, Center for Food Safety and Applied Nutrition (HFS-317), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240-402-1636.

SUPPLEMENTARY INFORMATION:

I. Background

This proposed extension of compliance dates concerns one of the seven foundational rules that we have established in Title 21 of the Code of Federal Regulations (21 CFR) as part of our implementation of the FDA Food Safety Modernization Act (FSMA; Pub. L. 111-353): “Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption” (the produce safety regulation, published in the *Federal Register* of November 27, 2015, 80 FR 74354) (<https://www.fda.gov/fsma>).

In the preamble of the final rule establishing the produce safety regulation, we stated that the produce safety regulation would be effective on January 26, 2016, and provided for compliance dates of 1 to 6 years from the effective date depending on farm size, commodity, and provision(s) (see table entitled “compliance dates” in the preamble of the final rule establishing the produce safety regulation, 80 FR 74354 at 74357, as corrected in a technical amendment at 81 FR 26466, May 3, 2016). (Some of the compliance dates identified in the technical amendment fall on weekends (i.e., January 26, 2019, is a Saturday and January 26, 2020, is a Sunday) and should therefore be read as referring to the next business day (i.e., January 28, 2019, and January 27, 2020, respectively). We use the latter dates throughout this document.)

For the majority of agricultural water provisions at subpart E (and for most of the other provisions in the rule), with respect to covered produce other than sprouts, we provided compliance periods of 4 years from the effective date of the rule for very small businesses, 3 years for small businesses, and 2 years for all other businesses. We provided an additional 2 years beyond those compliance periods for certain water quality requirements in § 112.44 and related provisions in §§ 112.45 and 112.46. See table 1.

In a final rule, “The Food and Drug Administration Food Safety Modernization Act: Extension and Clarification of Compliance Dates for Certain Provisions of Four Implementing Rules” (81 FR 57784, August 24, 2016) we also extended the compliance date for certain “customer provisions” in the produce safety regulation (§ 112.2(b)(3)) and clarified the compliance dates for certain agricultural water testing provisions as originally established in the produce safety regulation.

Table 1.--As Stated in Produce Safety Regulation, Compliance Dates for Requirements in Subpart E (Agricultural Water) for Covered Activities Involving Covered Produce (Except Sprouts Subject to Subpart M)

Compliance Dates of 2-4 Years Applicable to the Farm Based on its Size	Extended Compliance Date of Additional 2 ears Beyond the Compliance Date Based on Size of Farm
§ 112.41	§ 112.44
§ 112.42	§ 112.45(a) with respect to § 112.44(a) criterion
§ 112.43	§ 112.45(b)
§ 112.45(a) with respect to safe and adequate standard	§ 112.46(b)(1) with respect to untreated ground water
§ 112.46(a)	§ 112.46(b)(2) and (b)(3)
§ 112.46(b)(1) with respect to untreated surface water	§ 112.46(c)
§ 112.47	
§ 112.48	
§ 112.49	
§ 112.50	

II. Proposed Extension of Subpart E Compliance Dates for Produce Other Than Sprouts

FDA has received feedback from numerous stakeholders raising issues regarding the practicality of some of the agricultural water requirements in the produce safety regulation as applied to covered produce other than sprouts. Many of these concerns relate to the testing requirements for pre-harvest agricultural water, which are different for sprouts than they are for other types of covered produce. We are proposing this extension in light of the feedback we have received and under Executive Orders 13777, 13771, and 13563. 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 final rule.

As part of this proposed extension, we also propose to simplify the subpart E compliance period structure such that all the compliance dates for subpart E provisions as applied to non-sprout produce would occur at the same time, retaining date staggering based on farm size. Accordingly, covered farms would have 2 years beyond the previously published compliance dates for the water quality requirements in § 112.44 and related provisions in §§ 112.45 and 112.46, to comply with all of subpart E. Put another way, we propose to extend the compliance dates for provisions in the first column of table 1 by 4 years, and propose to extend the

compliance dates for provisions in the second column of table 1 by 2 years, so that the compliance dates for non-sprout covered produce for all provisions of subpart E would be those in table 2.

Table 2.--Proposed Compliance Dates for Requirements in Subpart E for Covered Activities Involving Covered Produce (Except Sprouts Subject to Subpart M)

Size Of Covered Farm	Proposed Time Periods Starting from The Effective date of the November 27, 2015, Produce Safety Final Rule (January 26, 2016)	
	Compliance Period	Compliance Date
Very Small Business	8 years	January 26, 2024
Small Business	7 years	January 26, 2023
All Other Businesses	6 years	January 26, 2022

We believe the simpler compliance date structure would alleviate confusion, and because we are proposing it as part of a proposal to provide additional time for compliance with all of the provisions, we expect it to alleviate burden. We do not anticipate that the change would result in any practical or logistical compliance challenges. We request comment on whether this change to the compliance date structure would be helpful.

This proposed rule is limited in scope to extending the compliance dates for covered produce other than sprouts. The proposed rule does not address the underlying requirements in subpart E, but only the compliance dates for those requirements (for covered produce other than sprouts). We will continue to work with stakeholders on the issues raised regarding the agricultural water requirements.

Our goal is to complete this rulemaking as quickly as possible. However, we are aware that many farms have been working well in advance of their compliance dates to come into compliance. As we continue to work with stakeholders on issues raised regarding the agricultural water requirements, we intend to exercise enforcement discretion for covered produce other than sprouts relative to the agricultural water provisions in subpart E of the produce safety regulation. This means that while we are considering these issues, we do not

intend to enforce the requirements in subpart E of the regulation for covered produce other than sprouts. Thus, by announcing we intend to exercise enforcement discretion for covered produce other than sprouts relative to the agricultural water provisions in subpart E, farms may choose to continue with their current water testing programs or allocate their resources differently to avoid incurring additional costs based on our proposal to extend the agricultural water compliance dates. And, as explained above, when we finalize compliance dates, we intend to continue to work with stakeholders to address agricultural water questions and with farms to prepare for compliance.

This proposed rule also would not change the compliance dates for sprouts. In the final produce safety regulation, we provided staggered compliance periods based on farm size for covered activities involving sprouts. The compliance date for activities involving sprouts for very small businesses is January 28, 2019. The compliance date for activities involving sprouts for small businesses is January 26, 2018. The compliance date for activities involving sprouts for all other businesses is January 26, 2017. Because sprouts present a unique safety risk, the final produce safety regulation established sprout-specific requirements on multiple topics, including agricultural water. The agricultural water requirements for sprouts are different from the agricultural water requirements for other produce commodities (compare §§ 112.44(a)(1) and 112.44(b)). Moreover, based on the information available to us, many sprout farms use municipal water for growing activities; and under the produce safety regulation, covered farms are not required to test water from a public supply when certain conditions are met (see 21 CFR 112.46(a)(1) and (2)). We also established earlier compliance dates for sprouts than for other covered produce, and the first compliance date for covered sprout farms (January 26, 2017) has already passed. We have not received any significant feedback from sprout farms that subpart E

has posed particular challenges. Accordingly, we are proposing to take no action with regard to compliance dates for activities involving sprouts and thus the compliance dates for covered farms with respect to sprouts are the original compliance dates, including for the agricultural water provisions in Subpart E.

Table 3 summarizes the compliance dates for the produce safety regulation as they would be if this proposed rule is finalized. Time periods start from effective date of the produce safety rule (January 26, 2016) except as otherwise specified.

Table 3.--Compliance Dates for the Produce Safety Regulation, if this Extension is Finalized (21 CFR Part 112)

Size of farm	Compliance dates relating to covered activities on covered farms			Compliance dates relating to certain exemptions							
	Covered activities involving sprouts covered under subpart M (i.e., subject to all requirements of Part 112)	Covered activities involving all other covered produce (i.e., subject to part 112, except subpart M)		Farms eligible for a qualified exemption (if applicable)				Farms relying on the exemption in § 112.2(b) for produce that receives commercial processing that adequately reduces microorganisms of public health concern			
		Agricultural water requirements in subpart E	All other requirements	Retention of records supporting eligibility in § 112.7(b)	Modified requirement in § 112.6(b)(1)	All other requirements in §§ 112.6 and 112.7 for farms producing sprouts	All other requirements in §§ 112.6 and 112.7 for farms not producing sprouts	Requirement to obtain customer written assurances in § 112.2(b)(3) for sprouts that would otherwise be subject to subpart M	All other requirements in § 112.2(b) for sprouts that would otherwise be subject to subpart M	Requirement to obtain customer written assurances in § 112.2(b)(3) for all other produce that would otherwise be covered	All other requirements in § 112.2(b) for all other produce that would otherwise be covered
Very small businesses	3 years (Jan. 28, 2019)	8 years (Jan. 26, 2024)	4 years (Jan. 27, 2020)	Effective date of rule (Jan. 26, 2016)	Jan. 1, 2020	3 years (Jan. 28, 2019)	4 years (Jan. 27, 2020)	5 years (Jan. 26, 2021)	3 years (Jan. 28, 2019)	6 years (Jan. 26, 2022)	4 years (Jan. 27, 2020)

Small businesses	2 years (Jan. 26, 2018)	7 years (Jan. 26, 2023)	3 years (Jan. 28, 2019)			2 years (Jan. 26, 2018)	3 years (Jan. 28, 2019)	4 years (Jan. 27, 2020)	2 years (Jan. 26, 2018)	5 years (Jan. 26, 2021)	3 years (Jan. 28, 2019)
All other businesses	1 year (Jan. 26, 2017)	6 years (Jan. 26, 2022)	2 years (Jan. 26, 2018)	N/A			3 years (Jan.28, 2019)	1 year (Jan. 26, 2017)	4 years (Jan. 27, 2020)	2 years (Jan. 26, 2018)	

III. Economic Analysis of Impacts

We have examined the impacts of this proposed rule under Executive Order 12866, Executive Order 13563, the Regulatory Flexibility Act (5 U.S.C. 601-612), the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4), and Executive Order 13771 on Reducing Regulation and Controlling Regulatory Costs (January 30, 2017). 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 13563 states the importance of quantifying costs and benefits, reducing costs and burdens, and harmonizing rules. We conclude that this proposed rule would not increase compliance costs and would instead reduce compliance costs by delaying certain compliance dates. Moreover, it would serve an important purpose of providing us an opportunity to consider how to reduce burdens on the public. We conclude that this proposed rule is an economically significant regulatory action as defined by Executive Order 12866.

This rule would extend, for non-sprout covered produce, the compliance date for all of the provisions of subpart E to 4 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 the compliance dates for certain provisions would be extended, 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 4 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 4 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. 1), the annualized total costs, discounted at 3 percent over 10 years, would decrease by about 3 percent from \$404 million to \$392 million, resulting in a savings of \$12 million. 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 benefits associated with extending the compliance dates as described previously. 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 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 percent over 10 years, would decrease by \$108 million from \$1.033 billion to \$925 million. Estimated changes in benefits and costs as a result of this proposed extension are summarized in the following table.

Table 4.--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 3%	\$3,443	\$3,340	\$8,811	\$7,886
Net Present Value 7%	\$2,681	\$2,598	\$6,901	\$6,143

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 rulemaking.” (5 U.S.C. 601(2)). We have analyzed this proposed rule under the Regulatory Flexibility Act and determined that, because it would only extend certain compliance dates for agricultural water provisions in the produce safety regulation, it 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 issuing “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. We have determined that this proposed rule would not result in an expenditure in any year that meets or exceeds this amount.

Executive Order 13771, entitled Reducing Regulation and Controlling Regulatory Costs, was issued on January 30, 2017. Section 2(a) of Executive Order 13771 requires an agency, unless prohibited by law, to identify at least two existing regulations to be repealed when the

agency publicly proposes for notice and comment or otherwise promulgates a new regulation. In furtherance of this requirement, section 2(c) of Executive Order 13771 requires that the new incremental costs associated with new regulations shall, to the extent permitted by law, be offset by the elimination of existing costs associated with at least two prior regulations. This proposed rule is expected to be an Executive Order 13771 deregulatory action. Details on the estimated cost savings of this proposed rule can be found in the rule's economic analysis.

For interested persons, the detailed preliminary regulatory impact analysis is available in the docket for this rule (Ref. 2) at <https://www.regulations.gov>, and at <https://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/default.htm>.

IV. Analysis of Environmental Impact

We have determined under 21 CFR 25.30(j) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

V. Paperwork Reduction Act of 1995

This proposed rule contains no collection of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

VI. Federalism

We have analyzed this proposed rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the proposed rule does not contain policies that have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, we conclude that the proposed rule does not contain

policies that have federalism implications as defined in the Executive order and, consequently, a federalism summary impact statement is not required.

VII. Executive Order 13175

We have analyzed this proposed rule in accordance with the principles set forth in Executive Order 13175. We have determined that the proposed rule does not contain policies that have substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes. Accordingly, we conclude that the proposed rule does not contain policies that have tribal implications as defined in the Executive order and, consequently, a tribal summary impact statement is not required.

VIII. References

The following references are on display in the Dockets Management Staff (see ADDRESSES) and is available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they are also available electronically at <https://www.regulations.gov>. FDA has verified the website address, as of the date this document publishes in the Federal Register, but websites are subject to change over time.

1. FDA, “Final Regulatory Impact Analysis, Standards for the Growing, Harvesting, Packing and Holding of Produce for Human Consumption.” November 2015. Available at: <https://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/ucm472310.htm>.
2. FDA, “Preliminary Regulatory Impact Analysis, Preliminary Regulatory Flexibility Analysis, and Unfunded Mandates Reform Act Analysis for the Standards for

the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption; Extension of Compliance Dates for Subpart E; Proposed Rule,” 2017. Available at: <https://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/>.

Dated: September 8, 2017.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2017-19434 Filed: 9/12/2017 8:45 am; Publication Date: 9/13/2017]