

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Supplemental Notice of Proposed Rulemaking:
Standards for the Growing, Harvesting, Packing,
and Holding of Produce for Human
Consumption Relating to Agricultural Water

Docket No. FDA-2021-N-0471

Preliminary Regulatory Impact Analysis
Initial Regulatory Flexibility Analysis
Unfunded Mandates Reform Act Analysis

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Table of Contents

I. Introduction and Summary 3

 A. Introduction..... 3

 B. Summary of Costs and Benefits 4

II. Preliminary Economic Analysis of Impacts..... 5

 A. Background 6

 B. Need for Federal Regulatory Action 8

 C. Purpose of the Proposed Rule 8

 D. Benefits of the Proposed Rule..... 9

 E. Costs of the Proposed Rule..... 9

III. Initial Small Entity Analysis 10

 A. Description and Number of Affected Small Entities 11

 B. Description of the Potential Impacts of the Rule on Small Entities..... 11

 C. Alternatives to Minimize the Burden on Small Entities 11

IV. References..... 12

I. Introduction and Summary

A. Introduction

We have examined the impacts of the supplemental proposed rule to the 2021 proposed rule, “Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption related to Agricultural Water” (Docket No. FDA-2021-N-4071; hereafter “2021 Agricultural Water Proposed Rule”) under Executive Order 12866, Executive Order 13563, 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). The Office of Information and Regulatory Affairs in the Office of Management and Budget determined that the 2021 Agricultural Water Proposed Rule is a significant regulatory action as defined by Executive Order 12866. This supplemental NPRM has also been designated as a significant regulatory action under E.O. 12866.

The Regulatory Flexibility Act requires us to analyze regulatory options that would minimize any significant impact of a rule on small entities. We previously concluded that the 2021 Agricultural Water Proposed Rule would not have a significant economic impact on a substantial number of small entities. Because this supplemental proposed rule proposes compliance dates without imposing additional costs to farms (except reading the rule), we anticipate this supplemental proposed rule will not change that conclusion. If the 2021 Agricultural Water Proposed Rule as amended by this

supplement is finalized, we may, if appropriate, certify that the final rule does not have a significant 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 \$165 million, using the most current (2021) Implicit Price Deflator for the Gross Domestic Product. The 2021 Agricultural Proposed Rule as amended by this supplemental proposed rule would not result in an expenditure in any year that meets or exceeds this amount.

B. Summary of Costs and Benefits

We estimate costs and benefits of the 2021 Agricultural Water Proposed Rule in the “Standards for the Growing, Harvesting, Packing and Holding of Produce for Human Consumption Relating to Agricultural Water; Preliminary Regulatory Impact Analysis” (Docket No. FDA-2021-N-4071; Ref. 1; hereafter 2021 Agricultural Water PRIA).

This supplemental proposed rule makes no substantive changes to the provisions in the 2021 Agricultural Water Proposed Rule. Rather, this supplemental proposed rule proposes compliance dates for the pre-harvest agricultural water provisions for covered produce other than sprouts, which are not specified in the 2021 Agricultural Water Proposed Rule.

Table 1: Summary of Benefits, Costs, and Distributional Effects of This Supplemental Proposed Rule (in Millions 2020\$)

Category	Primary Estimate	Low Estimate	High Estimate	Units			Notes	
				Year Dollars	Discount Rate	Period Covered		
Benefits	Annualized Monetized \$millions/year				7%	10 years		
					3%	10 years		
	Annualized Quantified				7%			
					3%			
	Qualitative	Clarity about proposed compliance dates for pre-harvest agricultural water provisions for covered produce other than sprouts in the 2021 Agricultural Water Proposed Rule						
Costs	Annualized Monetized \$millions/year	\$0.1	\$0.1	\$0.1		7%	10 years	Costs of reading this supplemental proposed rule
		\$0.1	\$0.1	\$0.1		3%	10 years	
	Annualized Quantified					7%		
						3%		
Transfer s	Federal Annualized Monetized \$millions/year					7%		
						3%		
	From/To	From:			To:			
	Other Annualized Monetized \$millions/year					7%		
						3%		
From/To	From:			To:				
Effects	State, Local or Tribal Government: None Small Business: None Wages: None Growth: None							

II. Preliminary Economic Analysis of Impacts

Acronyms, Initialisms, and Definitions in This Document

Term	What It Means
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Subpart E	Subpart E (21 CFR §§112.41-112.50) of “Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption”; agricultural water provisions
2021 Agricultural Water Proposed Rule	2021 FDA rulemaking entitled “Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption Relating to Agricultural Water,” published in December 2021
2021 Agricultural Water PRIA	FDA’s analysis of the impacts of the 2021 Agricultural Water Proposed Rule; “Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption Relating to Agricultural Water (Preliminary Regulatory Impact Analysis),” published in December 2021
Large farm	For the purposes of 2015 Produce Safety Final Rule requirements discussed in this document, “large farm” refers to a covered farm for which, on a rolling basis, the average annual monetary value of produce the farm sold during the previous 3-year period is more than \$500,000.
Small farm	For the purposes of 2015 Produce Safety Final Rule requirements discussed in this document, “small farm” refers to a covered farm for which, on a rolling basis, the average annual monetary value of produce the farm sold during the previous 3-year period is more than \$250,000 but no more than \$500,000, as defined in 21 CFR §112.3.
Very small farm	For the purposes of 2015 Produce Safety Final Rule requirements discussed in this document, “very small farm” refers to a covered farm for which, on a rolling basis, the average annual monetary value of produce the farm sold during the previous 3-year period is more than \$25,000 but no more than \$250,000, as defined in 21 CFR §112.3.

A. Background

The background for the 2021 Agricultural Water Proposed Rule is described in the 2021 Agricultural Water PRIA (Ref. 1). We use this section to describe the background for the specific change that would occur due to this supplemental proposed rule that proposes compliance dates for the pre-harvest agricultural water provisions for covered produce other than sprouts in the 2021 Agricultural Water Proposed Rule.

The 2021 Agricultural Water Proposed Rule preamble reminds stakeholders that the current compliance dates for the subpart E pre-harvest, harvest, and post-harvest agricultural water requirements for covered produce (other than sprouts) are January 26, 2024, for very small farms; January 26, 2023, for small farms; and January 26, 2022, for all other covered farms (84 FR 9706). Further, it explains that FDA intends to exercise enforcement discretion for these requirements while working to address compliance dates in a targeted manner through the rulemaking process, with the goal of completing the rulemaking as quickly as possible (86 FR 69147).

FDA is now issuing a supplemental notice of proposed rulemaking that proposes, for covered produce other than sprouts, the dates for compliance with the pre-harvest agricultural water provisions in the 2021 Agricultural Water Proposed Rule.¹ We recognize that covered farms would likely need time to prepare for compliance with the provisions we proposed to revise, if finalized. We also recognize that regulators, educators, and other stakeholders would also need time to develop education and outreach, training, and other tools to facilitate understanding and compliance by covered farms. This supplemental proposed rule proposes compliance dates for the pre-harvest agricultural water provisions in the 2021 Agricultural Water Proposed Rule for covered produce other than sprouts of:

- 2 years and 9 months after the effective date of a final rule for very small farms;
- 1 year and 9 months after the effective date of a final rule for small farms;
- 9 months after the effective date of a final rule for all other (large) farms.

¹ The supplemental proposed rule also specifies the duration of the period of enforcement discretion for the harvest and post-harvest agricultural water requirements for covered produce other than sprouts.

This supplemental proposed rule does not propose substantive changes to the provisions of the 2021 Agricultural Water Proposed Rule.

B. Need for Federal Regulatory Action

The 2021 Agricultural Water PRIA (Ref. 1) describes the need for federal regulatory action for the 2021 Agricultural Water Proposed Rule.

This supplemental proposed rule is needed to propose compliance dates for the pre-harvest agricultural water provisions for covered produce other than sprouts in the 2021 Agricultural Water Proposed Rule.

C. Purpose of the Proposed Rule

The 2021 Agricultural Water PRIA (Ref. 1) describes the purpose of the 2021 Agricultural Water Proposed Rule. The purpose of this supplemental proposed rule is to propose compliance dates for the subpart E pre-harvest agricultural water provisions for non-sprout covered produce in the 2021 Agricultural Water Proposed Rule. This supplemental proposed rule proposes compliance dates for the pre-harvest agricultural water requirements for covered produce other than sprouts of:

- 2 years and 9 months after the effective date of a final rule for very small farms;
- 1 year and 9 months after the effective date of a final rule for small farms;
- 9 months after the effective date of a final rule for all other (large) farms.

D. Benefits of the Proposed Rule

We estimate benefits of the 2021 Agricultural Water Proposed Rule in the 2021 Agricultural Water PRIA (Ref. 1).

The benefit of this supplemental proposed rule is clarity to stakeholders about the proposed compliance dates for the pre-harvest agricultural water provisions for covered produce other than sprouts described in the 2021 Agricultural Water Proposed Rule.

E. Costs of the Proposed Rule

We estimate costs of the 2021 Agricultural Water Proposed Rule in the 2021 Agricultural Water PRIA (Ref. 1). The costs of this supplemental proposed rule are the costs of reading this supplemental proposed rule.

We assume that all covered farms will read and understand the supplemental proposed rule; we include the estimated cost of reading the rule in the year of publication. To calculate costs of reading the rule, we draw on Bureau of Labor Statistics (BLS) 2020 wage data² for “Farmers, Ranchers, and Other Agricultural Managers” (11-9013) from the National Industry-Specific Occupational Employment and Wage Estimates (Ref. 2) to yield a mean hourly wage rate of approximately \$36.93. Following guidelines from the Department of Health and Human Services (HHS) (Ref. 3), we double the wage rate to account for overhead and benefits, yielding a fully-loaded hourly cost of labor of \$73.86. Table 2 presents estimates of the cost of reading this supplemental proposed rule by reading speed.

Table 2: Cost of Reading and Understanding the Supplemental Proposed Rule (in Millions 2020\$)

² Costs in this document are estimated in 2020 dollars unless noted otherwise

	Low	Primary	High
Average reading speed (words per minute)	250	225	200
Total words in rule	5,617	5,617	5,617
Hours to read rule	0.37	0.42	0.47
Hourly cost of labor of farm operators	\$73.86	\$73.86	\$73.86
Cost per farm	\$28	\$31	\$35
Number of farms that read the rule	35,029	35,029	35,029
Total cost of reading and understanding rule	\$1.0	\$1.1	\$1.2
Annualized, 3%	\$0.1	\$0.1	\$0.1
Annualized, 7%	\$0.1	\$0.1	\$0.1

III. Initial Small Entity Analysis

The Regulatory Flexibility Act requires Agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because this supplemental proposed rule proposes compliance dates without imposing additional costs to farms (except reading the rule), we still anticipate that the 2021 Agricultural Water Proposed Rule as amended by this supplemental proposed rule will not have a significant economic impact on a substantial number of small entities. If the proposed rule is finalized, we may, if appropriate, certify that the final rule does not have a significant impact on a substantial number of small entities. This analysis, as well as other sections in this document, serves as the Initial Regulatory Flexibility Analysis, as required under the Regulatory Flexibility Act.

A. Description and Number of Affected Small Entities

The 2021 Agricultural Water PRIA (Ref. 1) describes the number of small entities potentially affected by the 2021 Agricultural Water Proposed Rule, which would not be changed by this supplemental proposed rule.

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

The 2021 Agricultural Water PRIA (Ref. 1) discusses the potential impacts of the 2021 Agricultural Water Proposed Rule on small entities. This supplemental proposed rule proposes compliance dates for the pre-harvest agricultural water provisions for non-sprout covered produce for all farms, including small farms. The only cost to farms we estimate resulting from this supplemental proposed rule is the cost of reading the rule; our primary estimate of this cost is \$31 per farm.

C. Alternatives to Minimize the Burden on Small Entities

Because we do not believe the 2021 Agricultural Water Proposed Rule as amended by the supplemental proposed rule will have a significant impact on a substantial number of small entities, we do not include alternatives to minimize the burden on small entities.

IV. References

1. **FDA**, Standards for the Growing, Harvesting, Packing and Holding of Produce for Human Consumption Relating to Agricultural Water; Preliminary Regulatory Impact Analysis. 2021. Available from: [Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption Relating to Agricultural Water \(Proposed Rule\) Preliminary Regulatory Impact Analysis | FDA](#).
2. **U.S. Bureau of Labor Statistics**, May 2020 National Occupational Employment and Wage Estimates United States, Farmers, Ranchers, and Other Agricultural Managers. 2020. Available from: <https://www.bls.gov/oes/current/oes119013.htm>.
3. **U.S. Department of Health and Human Services**, Guidelines for Regulatory Impact Analyses. 2016. Available from: https://aspe.hhs.gov/system/files/pdf/242926/HHS_RIAGuidance.pdf.