

# DEPARTMENT OF HEALTH AND HUMAN SERVICES

## Food and Drug Administration

### 21 CFR Part 112

[Docket No. FDA–2021–N–0471]

RIN 0910–AI49

### Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption Relating to Agricultural Water

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Proposed rule; supplemental notice of proposed rulemaking.

**SUMMARY:** The Food and Drug Administration (FDA, the Agency, or we) is proposing dates for compliance with the pre-harvest agricultural water provisions for covered produce other than sprouts in the “Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption Relating to Agricultural Water” proposed rule. We also are specifying the duration of the period during which we intend to exercise enforcement discretion for the harvest and post-harvest agricultural water requirements for covered produce other than sprouts in the produce safety regulation to provide covered farms, regulators, educators, and other stakeholders additional time to facilitate compliance with those provisions. The proposed compliance dates for pre-harvest agricultural water requirements and our exercise of enforcement discretion for the harvest and post-harvest agricultural water provisions are intended to facilitate successful implementation and optimize public health protections. We are reopening the comment period only with respect to the compliance dates for the proposed pre-harvest agricultural water provisions for covered produce other than sprouts.

**DATES:** Either electronic or written comments on the proposed rule must be submitted by September 19, 2022.

**ADDRESSES:** You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of September 19, 2022. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received 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–2021–N–0471 for “Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption Relating to Agricultural Water.” 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, 240–402–7500.

- **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 dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.govinfo.gov/content/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, 240–402–7500.

### 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, [samir.assar@hhs.fda.gov](mailto:samir.assar@hhs.fda.gov).

### SUPPLEMENTARY INFORMATION:

#### I. Executive Summary

##### A. Purpose of the Supplemental Notice of Proposed Rulemaking

This supplemental notice of proposed rulemaking proposes compliance dates for the pre-harvest agricultural water<sup>1</sup> provisions for covered produce other than sprouts in the proposed rule, “Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption Relating to

<sup>1</sup> Agricultural water for produce subject to the requirements of part 112 (covered produce) other than sprouts, using a direct application method during growing activities are commonly referred to as “pre-harvest agricultural water.” The produce safety regulation refers to pre-harvest agricultural water used during sprout production as “sprout irrigation water.”

Agricultural Water” (86 FR 69120, December 6, 2021) (2021 agricultural water proposed rule) and announces our intent to continue the policy of enforcement discretion for the relevant subpart E requirements in the produce safety regulation until this rulemaking is completed. Additionally, we are specifying the duration of our intended enforcement discretion policy for the harvest and post-harvest agricultural water<sup>2</sup> requirements for covered produce other than sprouts in the produce safety regulation.

In light of the revisions we are proposing to certain pre-harvest agricultural water requirements for covered produce (other than sprouts) in the 2021 agricultural water proposed rule, we are proposing to establish dates for compliance with the pre-harvest agricultural water provisions for covered produce other than sprouts as follows: 2 years and 9 months after the effective date of a final rule for very small businesses; 1 year and 9 months after the effective date of a final rule for small businesses; and 9 months after the effective date of a final rule for all other businesses (see table 3).

We are not proposing a compliance date extension for the harvest and post-harvest agricultural water requirements for covered produce other than sprouts because we did not propose to change those provisions. However, we are specifying the duration of our intended enforcement discretion policy for the harvest and post-harvest agricultural water provisions for covered produce other than sprouts in the produce safety regulation until January 26, 2025, for very small businesses; January 26, 2024, for small businesses; and January 26, 2023, for all other businesses (see table 3).

### *B. Summary of the Major Provisions of the Supplemental Notice of Proposed Rulemaking*

The 2021 agricultural water proposed rule, if finalized, would revise certain provisions in the produce safety regulation applicable to pre-harvest agricultural water.<sup>3</sup> The 2021 agricultural water proposed rule would not substantively alter the standards established in part 112, subpart E, for agricultural water used for sprouts, for which the compliance dates have passed, or for harvest and post-harvest

agricultural water, or for treatment of agricultural water.

We are reopening the comment period on the 2021 agricultural water proposed rule to seek public comment on the proposed compliance dates for the pre-harvest agricultural water provisions for covered produce other than sprouts. We are proposing to establish dates for compliance with the pre-harvest agricultural water provisions for covered produce other than sprouts as follows: 2 years and 9 months after the effective date of a final rule for very small businesses; 1 year and 9 months after the effective date of a final rule for small businesses; and 9 months after the effective date of a final rule for all other businesses. We are proposing these compliance dates in light of the proposed revisions to certain pre-harvest agricultural water requirements for covered produce (other than sprouts).

As the 2021 agricultural water proposed rule did not propose to change the requirements of the produce safety regulation that apply to harvest and post-harvest agricultural water for covered produce other than sprouts, we are not proposing a compliance date extension for those provisions. However, we are specifying the duration of our intended enforcement discretion policy for the harvest and post-harvest agricultural water provisions for covered produce other than sprouts in the produce safety regulation to provide covered farms, regulators, educators, and other stakeholders additional time to facilitate compliance with those requirements. (The compliance dates for harvest and post-harvest requirements are likely to occur before we complete this rulemaking, in which we have proposed to reorganize and replace subpart E in its entirety. In this document we refer to those provisions according to the section numbers in the produce safety regulation, recognizing that subpart E may be reorganized subsequently through this rulemaking.) We recognize that prior to the publication of the 2021 agricultural water proposed rule, stakeholders did not have clarity on whether additional substantive changes for the harvest and post-harvest agricultural water provisions would be proposed. In addition, we recognize that the intended benefits of the harvest and post-harvest requirements may not be fully realized unless accompanied by adequate training, technical assistance, and other preparations to support effective implementation by all parties. Therefore, we intend to exercise enforcement discretion for the harvest and post-harvest agricultural water

provisions for covered produce other than sprouts in the produce safety regulation until January 26, 2025, for very small businesses; January 26, 2024, for small businesses; and January 26, 2023, for all other businesses.

The proposed compliance dates for pre-harvest agricultural water provisions in the 2021 agricultural water proposed rule and enforcement discretion policy for the harvest and post-harvest agricultural water provisions in the produce safety regulation are intended to optimize public health by allowing for the proper foundation to be established for successful implementation. Additionally, these dates are informed by experience, information, and feedback on the inherent implementation challenges with agricultural water requirements given the scale and diversity of the produce sector and agricultural water systems and with a long-term view toward improving public-health outcomes.

At this time, we are not seeking comment on any other provisions of the previously published proposed rule that are not identified for public comment in this document. We will complete our review of public comments received thus far, and take into account comments received on the proposed compliance dates in response to this document, in issuing a final rule.

### *C. Legal Authority*

The proposed compliance dates for certain agricultural water provisions discussed in this document are consistent with our authority in sections 402, 419, and 701(a) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 342, 350h, and 371(a)) and sections 311, 361, and 368 of the Public Health Service Act (PHS Act) (42 U.S.C. 243, 264, and 271). We discuss our legal authority in greater detail in the 2021 agricultural water proposed rule (86 FR 69128–69129).

### *D. Costs and Benefits*

We have examined the impacts of this supplemental proposed rule. Annualized at either 3 percent or 7 percent, our primary estimates for the costs of this supplemental proposed rule are \$ 0.1 million. 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.

<sup>2</sup> Agricultural water used during harvesting, packing, and holding activities are commonly referred to as “harvest and post-harvest agricultural water.”

<sup>3</sup> The produce safety regulation refers to pre-harvest agricultural water used during sprout production as “sprout irrigation water.”

## II. Background

This pre-harvest agricultural water compliance dates proposal concerns one of the seven foundational rules that we have established as part of our implementation of section 105 of the FDA Food Safety Modernization Act (FSMA; Pub. L. 111–353): the “Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption” rule (80 FR 74354, November 27, 2015) (2015 produce safety final rule) (codified in 21 CFR part 112). FSMA, which was signed into law on January 4, 2011, is intended to allow FDA to better protect public health by helping to ensure the safety and security of the food supply.

In the preamble of the 2015 produce safety final rule, we stated that the 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 2015 produce safety final rule, 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 in 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.<sup>4</sup> 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.

**TABLE 1—AS STATED IN THE 2015 PRODUCE SAFETY FINAL RULE (80 FR 74461), 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 years beyond the compliance date based on size of farm
§ 112.41. § 112.42. § 112.43. § 112.45(a) with respect to safe and adequate standard. § 112.46(a). § 112.46(b)(1) with respect to untreated surface water. § 112.47. § 112.48. § 112.49. § 112.50.	§ 112.44. § 112.45(a) with respect to § 112.44(a) criterion. § 112.45(b). § 112.46(b)(1) with respect to untreated ground water. § 112.46(b)(2) and (b)(3). § 112.46(c).

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 four of the seven foundational rules that we have established as part of our implementation of FSMA, including the 2015 produce safety final rule (§ 112.2(b)(3)). In that final rule, we also clarified the compliance dates for certain agricultural water testing provisions as originally established in the 2015 produce safety final rule.

In 2017, we issued a proposed rule, “Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption; Extension of Compliance Dates for Subpart E” (82 FR 42963, September 13, 2017) (2017 proposed compliance date extension), in which we proposed to extend, for covered produce other than sprouts, the dates for compliance with the pre-harvest, harvest, and post-harvest agricultural water provisions contained in subpart E of the 2015 produce safety final rule. We proposed to extend the compliance dates, which we later finalized in a final rule (84 FR 9706, March 18, 2019) (2019 final compliance date extension), 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 protect public health. In that final rule we also finalized a uniform compliance date structure such that all the compliance dates for subpart E provisions as applied to non-sprout covered produce would occur at the same time, retaining date-staggering based on farm size. That final rule extended the compliance dates for the agricultural water requirements in subpart E for non-sprout covered produce to January 26, 2024, for very small businesses; January 26, 2023, for small businesses; and January 26, 2022, for all other businesses. See table 2.

**TABLE 2—AS STATED IN THE FINAL RULE EXTENDING COMPLIANCE DATES FOR SUBPART E (84 FR 9706), COMPLIANCE DATES FOR REQUIREMENTS IN SUBPART E FOR COVERED ACTIVITIES INVOLVING COVERED PRODUCE (EXCEPT SPROUTS SUBJECT TO SUBPART M)**

Size of covered farm	Compliance date
Very Small Business .....	January 26, 2024.
Small Business .....	January 26, 2023.

<sup>4</sup> Under the produce safety regulation, a farm is a very small business if, on a rolling basis, the average annual monetary value of produce it sold

during the previous 3-year period is no more than \$250,000. A farm is a small business if, on a rolling basis, the average annual monetary value of

produce it sold during the previous 3-year period is no more than \$500,000, and the farm is not a very small business. See § 112.3.

TABLE 2—AS STATED IN THE FINAL RULE EXTENDING COMPLIANCE DATES FOR SUBPART E (84 FR 9706), COMPLIANCE DATES FOR REQUIREMENTS IN SUBPART E FOR COVERED ACTIVITIES INVOLVING COVERED PRODUCE (EXCEPT SPROUTS SUBJECT TO SUBPART M)—Continued

Size of covered farm	Compliance date
All Other Businesses .....	January 26, 2022.

The 2021 agricultural water proposed rule explains that we intend 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). At public meetings to discuss the proposed rule, we reiterated our commitment to work diligently to address the agricultural water compliance dates for covered produce other than sprouts. The comment period for the 2021 agricultural water proposed rule closed on April 5, 2022.

The proposed pre-harvest agricultural water compliance dates and enforcement discretion policy for harvest and post-harvest requirements are intended to optimize public health by allowing for the proper foundation to be established for successful implementation that will benefit all stakeholders, as described in sections III and IV. These dates are informed by experience with produce safety rule implementation, together with information and stakeholder feedback on the inherent implementation challenges with agricultural water requirements given the scale and diversity of the produce sector and agricultural water systems and with a long-term view toward improving public-health outcomes. Fully realizing the anticipated benefits to consumers of the agricultural water requirements (including the pre-harvest requirements, if finalized) will require a solid foundation for implementation to ensure that regulators and industry are adequately trained and understand how to apply the agricultural water requirements effectively on individual covered farms and, for regulators, also necessitates ensuring that the requirements are applied consistently.

We note that the compliance dates for provisions of the produce safety regulation not related to agricultural water have passed, and all compliance dates for provisions related to sprouts, including for agricultural water have passed (see table entitled “Compliance Dates for the Produce Safety Regulation Under this Final Rule (21 CFR part 112)” in the 2019 final compliance date extension at 84 FR 9709).

**III. Proposed Pre-Harvest Agricultural Water Compliance Dates for Covered Produce Other Than Sprouts**

In the 2021 agricultural water proposed rule, we proposed to revise certain provisions in the produce safety regulation applicable to pre-harvest agricultural water for covered produce other than sprouts. In the proposed rule, we did not propose to revise the requirements established for harvest and post-harvest agricultural water. Specifically, the proposed rule would replace the microbial criteria and testing requirements for pre-harvest agricultural water for covered produce (other than sprouts) with provisions for systems-based agricultural water assessments that are designed to be more feasible to implement across the wide variety of agricultural water systems, uses, and practices, while also being adaptable to future advancements in agricultural water quality science, and achieving improved public health protections. Additionally, we proposed to require expedited mitigation for hazards related to certain activities associated with adjacent and nearby lands, in light of findings from several recent produce outbreak investigations. The proposed revisions in the 2021 agricultural water proposed rule are intended to address stakeholder concerns about complexity and practical implementation challenges with certain agricultural water provisions while more comprehensively addressing a known route of contamination that can lead to preventable foodborne illness that is a significant public health problem.

We recognize that covered farms will 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 may also need time to develop education and outreach, training, and other tools to facilitate understanding and compliance by covered farms. FSMA acknowledges the importance of education and outreach in obtaining compliance with the produce safety rule, which established the first-of-its-kind Federal produce safety requirements. A key pillar of FSMA implementation has been to ensure that industry has the appropriate knowledge and training to effectively

comply, making it important for compliance dates to account for remaining outreach, education, and training needs.

FSMA further recognizes a critical role for FDA’s State regulatory partners in enforcing the regulation in coordination with FDA. To this end, FDA has established the FDA-State Produce Safety Implementation Cooperative Agreement Program<sup>5</sup> (FDA-State Produce CAP), through which most states have developed produce safety programs. The FDA-State CAP has various program objectives—including assessment and planning to guide the development of produce programs; providing education, outreach, and technical assistance to produce farms; developing inspection regulatory programs; and establishing compliance and enforcement programs—all of which can take significant time, resources, and planning to successfully administer. Due to the valuable role of FDA’s State regulatory partners in the integrated food safety system—in particular, their essential participation in produce safety rule education and enforcement under section 419(b)(2)(A) of the FD&C Act—we recognize that States need adequate time to fully prepare for implementation of their program components and that coordination efforts are taken between state and Federal regulators to ensure consistent implementation across all regulated industry. Therefore, we consider it appropriate to propose compliance dates for the proposed pre-harvest agricultural water requirements for covered produce other than sprouts and to exercise enforcement discretion for the relevant pre-harvest requirements in the produce safety regulation until this rulemaking is completed in order to give covered farms and other stakeholders adequate time to prepare for compliance.

This supplemental notice of proposed rulemaking does not address the underlying requirements in subpart E, and we are reopening the comment

<sup>5</sup> See “FDA-State Produce Safety Implementation Cooperative Agreement Program at <https://www.fda.gov/federal-state-local-tribal-and-territorial-officials/grants-and-cooperative-agreements/fda-state-produce-safety-implementation-cooperative-agreement-program>.

period only with respect to the pre-harvest agricultural water compliance dates identified in this document.

In this supplemental notice of proposed rulemaking, we are proposing compliance dates for the pre-harvest agricultural water provisions for covered produce other than sprouts, in the 2021 agricultural water proposed rule. We are not proposing to extend the compliance dates for the harvest and

post-harvest agricultural provisions that we are not proposing to change, although we intend to exercise enforcement discretion for those requirements in the produce safety regulation (see section IV) for covered produce (other than sprouts). We also propose that any final rule establishing the compliance dates for the pre-harvest agricultural water requirements for covered produce (other than sprouts)

would become effective 60 days after the date of publication of the final rule in the **Federal Register**.

Specifically, we are proposing compliance dates for the pre-harvest agricultural water provisions for covered produce other than sprouts such that the subpart E compliance dates for non-sprout covered produce would be those in table 3.

**TABLE 3—COMPLIANCE DATES FOR REQUIREMENTS IN SUBPART E FOR COVERED ACTIVITIES INVOLVING COVERED PRODUCE (EXCEPT SPROUTS SUBJECT TO SUBPART M)**

Size of covered farm	Provisions related to harvest and post-harvest agricultural water	Provisions related to pre-harvest agricultural water
	Compliance date	Proposed compliance date
Very Small Business .....	January 26, 2024 .....	2 years and 9 months after the effective date of a final rule.
Small Business .....	January 26, 2023 .....	1 year and 9 months after the effective date of a final rule.
All Other Businesses .....	January 26, 2022 .....	9 months after the effective date of a final rule.

We recognize that stakeholders may benefit from additional clarity to aid in their understanding of the compliance date structure in table 3. As such, table 4 summarizes the subpart E provisions as stated in the 2021 agricultural water proposed rule that would apply for agricultural water used during growing and during harvesting, packing, or

holding for covered produce (other than sprouts). (As discussed above, the compliance dates for harvest and post-harvest requirements are likely to occur before we complete this rulemaking, in which we have proposed to reorganize and replace subpart E in its entirety. While the discussion regarding our intended exercise of enforcement

discretion for the harvest and post-harvest requirements refers to those provisions according to section numbers in the produce safety regulation, table 4 reflects the relevant proposed provision numbers in the 2021 agricultural water proposed rule.)

**TABLE 4—SUMMARY OF THE PROVISIONS IN SUBPART E THAT WOULD APPLY FOR AGRICULTURAL WATER USED DURING GROWING ACTIVITIES AND DURING HARVESTING, PACKING, OR HOLDING ACTIVITIES FOR COVERED PRODUCE OTHER THAN SPROUTS**

If you use agricultural water for this covered activity for covered produce other than sprouts	Then you must meet these requirements		If applicable, you also must meet these requirements	
Pre-harvest activities .....	§ 112.41 .....	(quality standard) .....	§ 112.43(d) .....	(testing for assessment purposes).
	§ 112.42 .....	(inspections and maintenance) ...	§ 112.45 .....	(measures).
	§ 112.43 .....	(agricultural water assessment) ...	§ 112.46 .....	(treatment).
	§ 112.50 .....	(records) .....	§ 112.47 .....	(who may test).
	§ 112.161 .....	(records review) .....	§ 112.151 .....	(test methods).
Harvest and post-harvest activities.	§ 112.41 .....	(quality standard) .....	§ 112.12 .....	(alternatives).
	§ 112.42 .....	(inspections and maintenance) ...	§ 112.44(b) .....	(testing untreated ground water).
	§ 112.44(a) .....	(microbial quality criterion) .....	§ 112.45 .....	(measures).
	§ 112.44(d) .....	(additional management and monitoring).	§ 112.46 .....	(treatment).
	§ 112.50 .....	(records) .....	§ 112.47 .....	(who may test).
	§ 112.161 .....	(records review) .....	§ 112.151 .....	(test methods).
			§ 112.12 .....	(alternatives).

We acknowledge that some requirements that apply for pre-harvest agricultural water (for example, § 112.42, which includes requirements for inspections and maintenance of agricultural water sources and distribution systems) remain unchanged in the 2021 agricultural water proposed rule. However, we anticipate that maintaining compliance dates for all

pre-harvest agricultural requirements on the same interval would be important for effective implementation of the systems-based approach we are proposing for pre-harvest agricultural water. To bifurcate compliance dates for the pre-harvest agricultural water requirements based on whether changes have been proposed would result in a compliance date structure similar to that

originally established in the 2015 produce safety final rule—*i.e.*, based on specific provisions of subpart E, as opposed to being based on the covered activity that agricultural water is being used for (compare table 1 with table 3). In consideration of the feedback received from stakeholders during rulemaking for the 2019 final compliance date extension, we do not

consider that this would be a wise or workable approach to pursue. Accordingly, we are proposing to maintain compliance dates for all pre-harvest agricultural water requirements on the same interval, regardless of whether changes have been proposed.

As the comment period for the 2021 agricultural water proposed rule closed on April 5, 2022, we are reopening the comment period solely to request comments on the proposed compliance dates for the proposed pre-harvest agricultural water provisions for covered produce other than sprouts. This action does not seek comment on other provisions of the previously published proposed rule.

Our goal is to complete this rulemaking as quickly as possible, and in the meantime, we intend to exercise enforcement discretion for the pre-harvest agricultural water requirements in the produce safety regulation for covered produce other than sprouts. We note that produce remains subject to the other applicable provisions of the produce safety regulation and the applicable provisions of the FD&C Act notwithstanding this proposed compliance date extension. The Agency encourages farms to focus their attention on good agricultural practices to maintain and protect the quality of their water sources. (See, e.g., FDA's "Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables," at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-guide-minimize-microbial-food-safety-hazards-fresh-fruits-and-vegetables>).

#### **IV. Intended Enforcement Discretion for the Harvest and Post-Harvest Agricultural Water Requirements for Covered Produce Other Than Sprouts**

As we are not proposing to change the requirements that apply for harvest and post-harvest agricultural water through this rulemaking, we are not proposing a compliance date extension for those provisions for covered produce other than sprouts. However, we recognize that prior to the publication of the 2021 agricultural water proposed rule, stakeholders did not have clarity on whether FDA would be proposing substantive changes to requirements that apply for agricultural water used during harvest and post-harvest activities. Because the intended benefits of the harvest and post-harvest requirements may not be fully realized unless accompanied by adequate training, technical assistance, and other preparations to support effective implementation by all parties, we are

specifying the duration of our intended exercise of enforcement discretion with an understanding that covered farms will likely need this additional time to prepare for compliance with the harvest and post-harvest agricultural water provisions, and that regulators, educators, and other stakeholders may also need time to develop education and outreach, training, and other tools to facilitate understanding and compliance by covered farms. Moreover, due to the valuable role of FDA's State regulatory partners in the integrated food safety system—in particular, their essential participation in produce safety rule education and enforcement under section 419(b)(2)(A) of the FD&C Act—we recognize that States may need the additional time to prepare for implementation of their program components, and that coordination efforts are taken between State and Federal regulators to provide for consistent implementation across all regulated industry. (See also discussion in section III of this document). We understand that some of these parties may have been awaiting FDA action before developing or deploying such training, technical assistance, or other implementation materials.

Additionally, we recognize that many covered farms may already be aware of, and have received education and training on, the harvest and post-harvest agricultural water requirements established in the produce safety regulation, which we are not proposing to change. (See, for example, the standardized curriculum developed by the Produce Safety Alliance, which covers fundamental food safety topics as they relate to produce and the requirements of the produce safety regulation, including those for agricultural water used during harvesting, packing, and holding of covered produce.) However, we understand that even with education and training on these requirements, covered farms will still need to apply the knowledge to their operations by taking steps to implement those requirements on-farm, such that covered farms may need additional time to come into compliance with those provisions.

In light of these considerations, we intend to exercise enforcement discretion for the harvest and post-harvest agricultural water provisions in the produce safety regulation for covered produce other than sprouts until January 26, 2025, for very small businesses; January 26, 2024, for small businesses; and January 26, 2023, for all other businesses. In the meantime, covered farms (other than sprout operations) should focus their attention

on good agricultural practices to maintain and protect the quality of their water source. (See, e.g., FDA's "Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables," at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-guide-minimize-microbial-food-safety-hazards-fresh-fruits-and-vegetables>). We note that produce remains subject to the other applicable provisions of the produce safety regulation and the applicable provisions of the FD&C Act.

#### **V. Preliminary Economic Analysis of Impacts**

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.

We have developed a comprehensive Preliminary Economic Analysis of Impacts (PRIA) that assesses the impacts of the supplemental proposed rule (Ref. 1). 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” (2021 agricultural water PRIA) (Ref. 2). 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. The costs of the supplemental proposed rule are the costs of reading this rule. Annualized at either 3 percent or 7 percent, our primary estimates of this supplemental proposed rule are \$0.1 million. 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. The full preliminary analysis of economic impacts is available in the docket for this proposed rule and at <https://www.fda.gov/about-fda/reports/economic-impact-analyses-fda-regulations>.

## VI. Analysis of Environmental Impact

The Agency has carefully considered the potential environmental effects of this action. FDA has concluded that the action will not have a significant impact on the human environment, and that an environmental impact statement is not required. The Agency’s finding of no

significant impact, including a supplement to the finding of no significant impact, and the evidence supporting that finding may be seen in the Dockets Management Staff (see **ADDRESSES**) between 9 a.m. and 4 p.m., Monday through Friday (Refs. 3 to 5). Under FDA’s regulations implementing the National Environmental Policy Act (21 CFR part 25), an action of this type would require an EA under 21 CFR 25.31a(a).

## VII. Paperwork Reduction Act of 1995

FDA tentatively concludes that this supplemental notice of proposed rulemaking contains no collection of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

## VIII. 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.

## IX. Consultation and Coordination With Indian Tribal Governments

We have analyzed this proposed rule in accordance with the principles set forth in Executive Order 13175. We have tentatively determined that the rule does not contain policies that would have a substantial direct effect 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. The Agency solicits comments from tribal officials on any potential impact on Indian Tribes from this proposed action.

## X. References

The following reference is on display at 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; it is 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, “Supplemental Notice of Proposed Rulemaking: Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption Relating to Agricultural Water; Preliminary Regulatory Impact Analysis,” 2022. Available at: <https://www.fda.gov/about-fda/reports/economic-impact-analyses-fda-regulations>.
2. FDA, “Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption Relating to Agricultural Water; Preliminary Regulatory Impact Analysis,” 2021. Available at: <https://www.fda.gov/about-fda/reports/economic-impact-analyses-fda-regulations>.
3. FDA, “Environmental Assessment for the Proposed Rule: Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption Relating to Agricultural Water,” November 9, 2021.
4. FDA, “Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption Relating to Agricultural Water: Finding of No Significant Impact,” November 9, 2021.
5. FDA, “Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption Relating to Agricultural Water: Supplement to the Finding of No Significant Impact.”

Dated: July 11, 2022.

**Robert M. Califf,**

*Commissioner of Food and Drugs.*

[FR Doc. 2022–15134 Filed 7–18–22; 8:45 am]

BILLING CODE 4164–01–P

## DEPARTMENT OF JUSTICE

### Drug Enforcement Administration

#### 21 CFR Part 1308

[Docket No. DEA–945]

#### Schedules of Controlled Substances: Removal of Fenfluramine From Control

**AGENCY:** Drug Enforcement Administration, Department of Justice.  
**ACTION:** Notice of proposed rulemaking.

**SUMMARY:** The Drug Enforcement Administration proposes to remove fenfluramine (chemical name: *N*-ethyl- $\alpha$ -methyl-3-(trifluoromethyl)phenethylamine), including its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts is possible, from the schedules of the Controlled Substances Act (CSA). This scheduling action is pursuant to the CSA which