

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 112

[Docket No. FDA-2014-N-2244]

RIN 0910-AG35

Final Environmental Impact Statement and Record of Decision for the Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification of availability.

SUMMARY: The Food and Drug Administration (FDA or we) has made available for public review the Final Environmental Impact Statement (EIS) and Record of Decision (ROD) for the standards for the growing, harvesting, packing, and holding of produce for human consumption. FDA prepared the Final EIS after taking into account public comment received on the corresponding Draft EIS and is publishing the ROD at the time of our decision. The Final EIS and ROD documents are available in Docket No. FDA-2014-N-2244.

DATES: FDA announces the availability of the EIS and ROD on November 27, 2015.

FOR FURTHER INFORMATION CONTACT: Annette McCarthy, Center for Food Safety and Applied Nutrition (HFS-205), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240-402-1057.

SUPPLEMENTARY INFORMATION:

I. Background

The FDA Food Safety Modernization Act (FSMA) (Pub. L. 111-353), signed into law by President Obama on January 4, 2011, enables FDA to better protect public health by helping to ensure the safety and security of the food supply. FSMA amends the Federal Food, Drug, and Cosmetic Act (the FD&C Act) to establish the foundation of a modernized, prevention-based food safety system. As part of our implementation of FSMA, we published the proposed rule: Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption (hereafter referred to as “the 2013 proposed rule”) on January 16, 2013, to establish science-based minimum standards for the safe growing, harvesting, packing, and holding of produce (78 FR 3504). On September 29, 2014, FDA issued a

supplemental notice of proposed rulemaking (“the supplemental proposed rule”), amending certain specific provisions of the 2013 proposed rule (79 FR 58434). Taken together, these publications constitute FDA’s proposed standards for the growing, harvesting, packing, and holding of produce for human consumption (“the Produce Safety proposed rule”).

FDA announced a “Notice of Intent” (NOI) to prepare an EIS to evaluate the potential environmental effects of the Produce Safety Proposed Rule in the **Federal Register** on August 19, 2013 (78 FR 50358). In the NOI, FDA also announced the beginning of the scoping process and solicited public comments to identify issues to be analyzed in an EIS. The NOI asked for public comment by November 15, 2013, and FDA later extended the deadline for the comment period to March 15, 2014 (78 FR 69006; November 18, 2013), and then April 18, 2014 (79 FR 13593; March 11, 2014).

A public scoping meeting was held on April 4, 2014, in College Park, MD. FDA prepared a Draft EIS for the Produce Safety proposed rule and, on January 14, 2015, published a “Notification of public meeting” in the **Federal Register** to: (1) Announce the availability of the Draft EIS for public review and comment and (2) announce a public meeting to inform the public of the findings in the Draft EIS, provide information about the EIS process, solicit oral stakeholder and public comments on the Draft EIS, and provide clarification, as needed, about the contents of the Draft EIS (80 FR 1852). The public meeting was held on February 10, 2015, in College Park, MD. The comment period on the Draft EIS closed on March 13, 2015. FDA is now announcing the availability of the Final EIS, which FDA prepared, taking into account public comment received on the Draft EIS, and the ROD, which details FDA’s final decision, taking into account the findings of the Final EIS and the Agency’s stated purpose and need.

In the Produce Safety proposed rule, FDA proposed science-based minimum standards for the safe production and harvesting of produce. As discussed in the Final EIS (Ref. 1), out of these standards, we identified four provisions that could potentially significantly affect the quality of the human environment, if finalized (hereinafter referred to as “potentially significant provisions”). For each of the potentially significant provisions, FDA then identified alternative provisions to consider. The potentially significant provisions are: (1) Standards directed to agricultural water, (2) standards

directed to biological soil amendments (BSA) of animal origin, (3) standards directed to domesticated and wild animals, and (4) general provisions (*i.e.*, cumulative impacts). Additionally, an overarching “No Action” alternative was considered for the purpose of evaluating conditions in the absence of any final rule.

For standards directed to agricultural water, we considered the following alternatives: (1) As proposed by FDA, *i.e.*, a statistical threshold value (STV) not exceeding 410 colony forming units (CFU) of generic *Escherichia coli* per 100 milliliters (ml) of water and a geometric mean (GM) not exceeding 126 CFU of generic *E. coli* per 100 ml of water, along with options to achieve the standard by applying either a time interval between last irrigation and harvest using a microbial die-off rate of 0.5 log per day and/or a time interval between harvest and end of storage using an appropriate microbial die-off or removal rates, including during activities such as commercial washing (proposed 21 CFR 112.44(c)); (2) a microbial quality standard of no more than 235 CFU (or most probable number (MPN), as appropriate) generic *E. coli* per 100 ml for any single sample or a rolling GM (n=5) of more than 126 CFU (or MPN, as appropriate) per 100 ml of water, as was proposed in the 2013 proposed rule; (3) as proposed (*i.e.*, Alternative 1), but with an additional criterion establishing a maximum generic *E. coli* threshold; and (4) for each of the previous alternatives, consider the environmental impacts if each alternative includes root crops that are irrigated using low-flow methods.

For standards directed to BSAs of animal origin, FDA considered standards for both untreated and treated BSAs. For untreated BSAs of animal origin, the alternatives considered included a range of minimal application intervals (the time between application and harvest) when the BSA is applied in a manner that does not contact covered produce during application and minimizes the potential for contact with covered produce after application. The alternative application intervals evaluated were: (1) 9 months; (2) 0 months; (3) 90 and 120 days; consistent with the National Organic Program’s regulations in 7 CFR 205.203(c)(1); (4) 6 months; and (5) 12 months. For standards directed to treated BSAs, the alternatives considered included a range of application intervals when the BSA is composted in accordance with the requirements proposed in § 112.54(c) and applied in a manner that minimizes the potential for contact with covered produce during and after application.

The application intervals evaluated were: (1) As proposed by FDA, 0 days (proposed § 112.56(a)(4)(i)); (2) 45 days; and (3) 90 days.

For standards directed at domesticated animals, we considered alternatives under which, if working animals are used in a growing area where a crop has been planted, measures would be required to prevent the introduction of known or reasonably foreseeable hazards into or onto covered produce with the waiting period between grazing and harvesting varying by alternative. The following alternatives were evaluated: (1) As proposed by FDA, an adequate waiting period between grazing and harvesting for covered produce in any growing area that was grazed to ensure the safety of the harvested crop (proposed § 112.82(a)); (2) a minimum waiting period of 9 months; and (3) a minimum waiting period of 90 days and 120 days before harvest, depending upon whether the edible portion of the crop contacts the soil (applying the timeframes for raw manure set forth in the National Organic Program's regulations in 7 CFR 205.203(c)(1)). For standards directed to wild animals, we considered alternatives to the proposed requirement that under circumstances when there is a reasonable probability that animal intrusion will contaminate covered produce, the grower would be required to monitor those areas that are used for a covered activity for evidence of animal intrusion: (1) As needed during the growing season based on (i) the grower's covered produce and (ii) the grower's observations and experience; and (2) immediately prior to harvest. The alternatives evaluated were: (1) As proposed by FDA, if animal intrusion occurs—as made evident by observation of significant quantities of animals, animal excreta, or crop destruction via grazing—the grower must evaluate whether the covered produce can be harvested in accordance with the requirements of proposed § 112.112 (proposed § 112.83(a) and (b)); and (2) if animal intrusion is reasonably likely to occur, the grower must take measures to exclude animals from fields where covered produce is grown.

The cumulative impacts of the proposed rule were considered using a range of alternatives to the general provision in proposed § 112.4, which would specify the farms that would be covered under the rule based on the farm's annual sales of produce. The alternatives evaluated were to cover those farms that have: (1) As proposed by FDA, an average annual monetary value of produce sold during the previous 3-year period of more than

\$25,000 (on a rolling basis) (proposed § 112.4); (2) an average annual monetary value of food sold during the previous 3-year period of more than \$50,000 (on a rolling basis); (3) an average annual monetary value of food sold during the previous 3-year period of more than \$100,000 (on a rolling basis); and (4) an average annual monetary value of covered produce sold during the previous 3-year period of more than \$25,000 (on a rolling basis).

In the Final EIS, FDA identifies the "Agency's preferred alternative," *i.e.*, the alternative which the Agency believes will fulfill its statutory mission and responsibilities for this rulemaking, giving consideration to economic, environmental, technical, and other factors. Slight modifications to the preferred alternative were made in the ROD to reflect the Agency's final action. The Agency's preferred alternative, as described in the ROD, is comprised of the following alternatives for each of the potentially significant provisions listed previously:

For agricultural water and including root crops irrigated using low-flow methods, generic *E. coli*: GM of 126 CFU/100 ml and STV of 410 CFU/100 ml, with additional flexibility for microbial die-off and/or removal (§§ 112.44(b) and 112.45(b));

For treated biological soil amendments of animal origin, 0 day application interval (§ 112.56(a)(2)); and
For domesticated animals (grazing and working) and animal intrusion, visual assessment for significant evidence of animal potential contamination as needed during the growing season to identify and not harvest produce that is or is likely to be contaminated (§§ 112.83, 112.84, and 112.112).

As discussed in the supplemental proposed rule, FDA has chosen to defer decision on a minimum application interval for untreated BSAs of animal origin that are applied in a manner that does not contact covered produce during application and minimizes the potential for contact with covered produce after application (79 FR 58434) and, therefore, has not identified an alternative that would best meet the statutory mission and responsibilities. For the purpose of the aggregate environmental impact analysis in the Final EIS, in the absence of a decision on the alternative that would fulfill the statutory mission, the impacts associated with the 0-day application interval were included as the environmental impacts associated with this alternative.

FDA has made the Final EIS and ROD available for public review in Docket

No. FDA-2014-N-2244 (see Ref. 1 and 2).

Waiver of 30-Day Review of Final EIS

Under CEQ regulation 40 CFR 1506.10(b)(2), no decision on the proposed action shall be made or recorded by a Federal Agency under 40 CFR 1505.2 until 30 days after publication of the notice for a Final EIS. However, 40 CFR 1506.10(b)(2) also provides the following exception from the rules of timing: An agency engaged in rulemaking under the Administrative Procedure Act or other statute for the purpose of protecting the public health or safety, may waive the time period in paragraph (b)(2) and publish a decision on the final rule simultaneously with publication of the notice of the availability of the final environmental impact statement.

Consistent with the circumstances in 40 CFR 1506.10(b)(2) under which a waiver may be used, FDA is waiving the 30-day time period between the publication of the Final EIS and FDA's decision on the Produce Safety final rule. FDA is publishing this notice of availability of the Final EIS simultaneously with the publication of the Produce Safety final rule and ROD. FDA considers the use of the waiver to be appropriate, in order to enhance food safety and protect public health, consistent with the purpose of FSMA and the Produce Safety final rule and the urgency for its release. We explain our reasons as follows:

The Produce Safety final rule establishes standards to minimize the risk of serious adverse health consequences or death (SAHCOD) resulting from contaminated produce. This rule implements section 419 of the FD&C Act (21 U.S.C. 350h), which requires FDA to adopt a final produce safety regulation based on known safety risks, that sets forth procedures, processes, and practices to minimize the risk of serious adverse health consequences or death, including those that are reasonably necessary to prevent the introduction of known or reasonably foreseeable hazards into produce and to provide reasonable assurances that produce is not adulterated under section 402 of the FD&C Act (21 U.S.C. 342).

The history of foodborne illness outbreaks, including outbreaks resulting in severe illnesses and death associated with contaminated produce, make clear that produce-related outbreaks are a serious and ongoing food safety problem. From 1996 to 2010, approximately 131 produce-related reported outbreaks occurred, resulting in 14,132 outbreak-related illnesses; 1,360 hospitalizations; and 27 deaths.

These outbreaks were associated with approximately 20 different produce commodities (Ref. 3). Even after enactment of FSMA outbreaks from produce continue to occur, between January 2011 and 2014, there were 44 outbreaks; 3,120 illnesses; 735 hospitalizations; and 42 deaths associated with produce (Ref. 4). These outbreaks were associated with approximately 10 different produce commodities. The illness numbers cited previously are the reported illnesses; the Centers for Disease Control estimates that only a fraction of foodborne illness is reported (<http://www.cdc.gov/foodborneburden/estimates-overview.html>).

This history of produce-related outbreaks was the impetus for Congress, in FSMA, to require Federal produce safety standards to establish requirements for prevention-focused regulation in a sector of the food industry that had previously seen little Federal food safety oversight and underscores the urgent public health need for implementation of FDA produce safety standards to begin. Annualizing benefits over the first 10 years after publication of the rule, we expect benefits of the Produce Safety final rule to be approximately 362,059 illnesses averted per year, valued at \$976 million annually (see the Regulatory Impact Analysis accompanying the rule for additional information (Ref. 5)).

There is a public health need to publish the Produce Safety final rule and begin implementation of the produce safety standards. Congress conveyed its sense of urgency in the timeframes established in FSMA for the Produce Safety final rule: 1 year after enactment of FSMA for a proposed rule (section 419(a)(1)(A) of the FD&C Act) and 1 year after the close of the comment period for a final rule (section 419(b)(1) of the FD&C Act). Congress recognized the urgent need to establish standards for produce safety to prevent SAHCOD hazards and, therefore, included specific timeframes for issuance of the proposed and final produce safety rules within the statute. Although FDA was unable to meet these statutory timeframes, FDA has nonetheless acted as swiftly as possible to complete the rulemaking process to

establish the produce safety regulation in 21 CFR part 112.

Formulating the produce safety standards involved highly complex scientific, regulatory, and practical considerations. For example, establishing the appropriate microbial quality criteria for agricultural water that is used during growing activities involved extensive review of scientific literature on pathogen presence, transmission, and survival under various conditions; other relevant national and international standards; diverse uses and methods of application of water; and the wide array of commodities and practices that affect potential risk of contamination of produce. As another example, we considered various options before adopting a regulatory framework that is based on practices, procedures, and processes associated with growing, harvesting, packing, and holding of all covered produce, rather than one that (based solely on a history of outbreaks or illnesses associated with the commodity) would be applicable to individual commodities or classes of commodities. FDA's integrated approach to produce safety standards draws on our past experiences and appropriately reflects the need to tailor requirements to specific on-farm routes of contamination. Through this rule (along with other FSMA rules) FDA is putting in place a framework for food safety that is modern and brings to bear the most recent science on provisions to enhance food safety, that is risk-based and focuses effort where the hazards are reasonably likely to occur, and that is flexible and practical given our current knowledge of food safety practices.

The rule notably sets standards in an area that is extremely diverse. Therefore, FDA has spent considerable time to achieve the right balance in establishing standards that would adequately protect public health and yet be flexible and practicable to be implemented successfully by the highly diverse produce industry. This necessitated enormous outreach, including numerous farm visits all over the United States, throughout the rulemaking process, to solicit and consider stakeholder input in preparing the final rule. We believe we have acted responsibly in taking the time to craft a

regulation that provides critical public health protection and also is implementable by the produce industry. Implementation of the produce safety standards by covered farms engaged in the growing, harvesting, packing, and/or holding of produce is critical to achieve the public health goals set out in FSMA and, therefore, we set reasonable timeframes for compliance with the rule. It is important for FDA to finalize the rule as quickly as possible to enable farmers, packers, handlers, and others covered under the rule to begin taking the steps that will safeguard public health and safety.

II. References

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

1. Final Environmental Impact Statement for the Proposed Rule: Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption, <http://www.fda.gov/food/guidanceregulation/fsma/ucm396564.htm>.
2. Record of Decision. Final Environmental Impact Statement—Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption, October 2015.
3. D'Lima, C., K. Vierk, and FDA, "Memorandum to the Record", 2011.
4. Merriweather, C., T. C. Cloyd, C. Robinson, D. Gubernot, and FDA, 2011–2014 Produce Related Outbreaks and Illnesses [Memorandum]. May 8, 2015.
5. FDA, "Final Regulatory Impact Analysis: Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption," <http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm334114.htm>.

Dated: October 30, 2015.

Leslie Kux,

Associate Commissioner for Policy.

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