DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Standards for the Growing, Harvesting, Packing and Holding of Produce for Human Consumption

Docket No. FDA-2014-N-2244
and FDA-2011-N-0921

RECORD OF DECISION

Final Environmental Impact Statement- Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption

Food and Drug Administration-
Center for Food Safety and Applied Nutrition
5100 Paint Branch Parkway
College Park, Maryland 20740

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Acronyms and Abbreviations

AMS- Agricultural Marketing Service

AZ- Arizona

BMP- Best Management Practices

BSA- Biological Soil Amendment

CA- California

CEQ- Council on Environmental Quality

CFR- Code of Federal Regulations

CFU- Colony Forming Unit

DEIS- Draft Environmental Impact Statement

DOL- Department of Labor

EA- Environmental Assessment

E. coli- Escherichia coli

EIS- Environmental Impact Statement

EPA- Environmental Protection Agency

ESA- Endangered Species Act

EST- Eastern Standard Time

FDA- Food and Drug Administration

FFDCA- Federal Food, Drug and Cosmetic Act

FEIS- Final Environmental Impact Statement

FR- Federal Register

FRIA- Final Regulatory Impact Analysis

FSMA- Food Safety Modernization Act

GAP- Good Agricultural Practices

GHP- Good Handling Practices

GM- Geometric Mean

HHS- Department of Health and Human Services

LGMA- Leafy Green Marketing Agreement

L. monocytogenes- Listeria monocytogenes

ml- milliliter

MPN- Most Probable Number

NASDA- National Association of State Departments of Agriculture

NASS- National Agricultural Statistics Service

NEPA- National Environmental Policy Act

NIFA- National Institute of Food and Agriculture

NOA- Notice of Availability

NOI- Notice of Intent

NOP- National Organic Program

NPDES- National Pollutant Discharge Elimination System

NRCS- Natural Resource Conservation Service

PSA- Produce Safety Alliance

PS PR- Produce Safety Proposed Rule

Pub. L.- Public Law

Q&A- Question and Answer

QAR- Qualitative Assessment of Risk

RIA- Regulatory Impacts Analysis

ROD- Record of Decision

spp- species

SAHCOD-Series Adverse Health Consequences or Death

SSA- Sprout Safety Alliance

STV- Statistical Threshold Value

T-GAPs- Tomato Good Agricultural Practices

USC- United States Code

USDA- United States Department of Agriculture

USFWS- United States Fish and Wildlife Service

USGS- United States Geological Service

Overview

The United States Food and Drug Administration (FDA or we) has completed and published a Final Environmental Impact Statement (FEIS or Final EIS) for the Proposed Rule: Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption ("the proposed rule") (78 Fed. Reg. 3504, January 16, 2013) (FDA, 2013a). This Record of Decision (ROD) states our decision with respect to provisions of the final rule (FDA, 2015a), identifies all alternatives we considered in reaching our decision, and identifies those means to avoid or minimize environmental harm from our decision that have been adopted, and if not, why not.

FDA prepared an FEIS to examine the potential environmental, and related socioeconomic, impacts of associated with establishing regulations aimed at reducing foodborne illness associated with the growing, harvesting, packing, and holding of produce intended for human consumption. In the FEIS, FDA identified those provisions that may significantly affect the quality of the human environment (hereinafter referred to as "potentially significant provisions"). The FEIS further examined alternatives for each of the potentially significant provisions in the rule as well as for the aggregate impacts of the rule and the No Action Alternative. In all, 22 different alternatives were considered including the No Action Alternative: 4 for standards directed at agricultural water, 8 for standards directed at treated and untreated biological soil amendments (BSA) of animal origin, 3 for standards directed at domesticated animals, 2 for standards directed at wild animal intrusion, and 4 for general provisions under which the combined impacts of all provisions were assessed in aggregate.

FDA used a two-step process to identify the preferred alternative for the FEIS. In the first step, FDA established a range of reasonable alternatives for each potentially significant provision. Each alternative reflects a science-based minimum standard established for the safe production and harvesting of those types of fruits and vegetables, including specific mixes or categories of fruits and vegetables, that are raw agricultural commodities, to minimize the risk of serious adverse health consequences or death (SAHCOD) (see 21 U.S.C. 350h(a)). At the second step, FDA selected the alternative for each provision for use in the aggregate analysis in Chapter 4.7 that FDA believes would best "fulfill its statutory mission and responsibilities, giving consideration to economic, environmental, technical and other factors" (46 Fed. Reg. 18026, March 23, 1981), with the exception of untreated BSAs of animal origin. FDA has previously indicated it would defer decision on a minimum application interval for untreated BSAs of animal origin and therefore has not identified an alternative that would best meet the statutory mission and responsibilities. For the purpose of the aggregate analysis, in the absence of a decision on the alternative which would fulfill the statutory mission, the impacts associated with the 0-day application interval were included as the environmental impacts associated with this alternative. Such impacts are indicative of current practice and any minor shifts in this practice that may be anticipated.

For each alternative FDA considered the potential impacts on a variety of environmental resources: specifically, water quality and availability; biological and ecological resources; soils; waste generation, disposal, and resources use; air quality; socioeconomics and environmental justice; and human health and safety.

Background

This document is the ROD, of the United States Food and Drug Administration regarding the final rule for Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption. The FDA Food Safety Modernization Act (FSMA) (Pub. L. 111-353) requires FDA to conduct a rulemaking to establish science-based minimum standards for the safe production and harvesting of those types of fruits and vegetables that are raw agricultural commodities for which we have determined such standards minimize the risk of SAHCOD (see section 419 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. § 350h). Further, FSMA requires FDA to adopt a final regulation based on known safety risks, setting forth procedures, processes, and practices that we determine to minimize the risk of SAHCOD, 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 FFDCA (21 U.S.C. § 342). On January 16, 2013, FDA published a proposed rule entitled, "Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption," which would establish science-based minimum standards for the safe growing, harvesting, packing, and holding of produce, meaning fruits and vegetables grown for human consumption ("the 2013 proposed rule") (78 Fed. Reg. 3504). The comment period for the proposed rule closed on November 22, 2013. In response to information we heard at public meetings, and based on a preliminary review of written comments submitted to the docket for the 2013 proposed rule, information available at that time, and our subsequent analysis of the proposed provisions in light of such information, FDA issued a supplemental notice of proposed rulemaking ("the supplemental proposed rule") and reopened the comment period to seek public comment on specific issues and amended and new proposed provisions (79 Fed. Reg. 58434; September 29, 2014). The comment period for the supplemental notice of proposed rulemaking closed on December 15, 2014. Taken together, these publications constituted FDA's proposed standards for the growing, harvesting, packing, and holding of produce for human consumption ("the Produce Safety Proposed Rule" (PS PR)). We are now finalizing this rule entitled, "Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption.".

National Environmental Policy Act (NEPA) Process

When FDA published the 2013 proposed rule, we relied on a categorical exclusion from the need to prepare an Environmental Assessment (EA) or EIS under 21 CFR 25.30(j) for the "issuance of CGMP regulations, HACCP regulations, establishment standards, emergency permit control regulations, GLP regulations, and issuance or denial of permits, exemptions, variances, or stays under these regulations." Based on further analysis and information, including comments received, FDA determined that the proposed action may significantly affect the quality of the human environment (21 CFR 25.22(b)) and, therefore, preparation of an EIS was necessary as part of the rulemaking process.

On August 19, 2013, FDA initiated the EIS process by publishing a Notice of Intent (NOI) to Prepare an Environmental Impact Statement for the Proposed Rule in the *Federal Register* (78 Fed. Reg. 50358). The NOI provided general information on the 2013 proposed rule and announced the beginning of the scoping process, the period during which FDA and the public collaborate to identify issues to be addressed in the EIS. Specifically, the NOI invited the public to submit comments for FDA's consideration during the preparation of the EIS and to aid FDA with determining the need to hold any public scoping meetings. FDA stated that it would receive such comments until the closing date, November 22, 2013.

Subsequently, FDA announced a comment period extension for the EIS on the PS PR that extended the comment period to March 15, 2014 (78 Fed. Reg. 69006, November 18, 2013). The extension was provided to allow interested parties more time to provide comments on the scope and significance of issues that FDA should consider in the EIS. The extension was also granted to allow FDA additional time to hold, as appropriate, one or more public scoping meetings.

On March 11, 2014, FDA announced a public scoping meeting on the EIS for April 4, 2014, in College Park, Maryland, and a second comment period extension for the EIS that extended the comment period from March 15, 2014, to April 18, 2014 (79 Fed. Reg. 13593). The comment period for the scope of the EIS ended on April 18, 2014. In addition to providing information on the proposed rule, the March 11, 2014, *Federal Register* publication announcing the public scoping meeting further included a summary (based on FDA's preliminary review of comments, currently available information, and further analysis of the 2013 proposed rule) of those provisions of the proposed rule that may significantly affect the quality of the human environment, and a range of potential alternatives for each provision for consideration in the EIS. FDA requested public comment on specific issues, alternatives, mitigation measures, or other information FDA should include for further analysis in the EIS.

Scoping – Public Outreach and Involvement

During the full scoping period for the EIS on the proposed rule (August 19, 2013, through April 18, 2014), FDA provided numerous ways that the public could participate in the EIS process. For example, the above-mentioned notices in the *Federal Register* provided instructions for submitting comments

electronically online via the Federal eRulemaking Portal at http://www.regulations.gov or by mail/hand delivery/courier (for paper or CD-ROM submissions).

The public scoping meeting was held on April 4, 2014, at the Harvey W. Wiley Federal Building Auditorium in College Park, Maryland, from 1 p.m. – 5 p.m. (EST). Public participants had the option of attending the meeting in person or via an interactive live webcast, a recording of which was made available after the meeting. The scoping meeting included a session that allowed individuals to review posters describing the issues under consideration for the EIS. During the poster session, FDA staff was on hand to answer questions and discuss poster content. The meeting included a presentation by FDA on the background of the PS PR and the scoping process, an overview of the NEPA process, proposed alternatives for provisions of the proposed rule that may significantly impact the quality of the human environment, and how the public may submit comment on the scope of the EIS. The scoping meeting also had an open microphone session where attendees were offered opportunities to provide comments, followed by a question and answer (Q&A) session between the audience and FDA officials. A court reporter was also available on-site throughout the entire meeting to transcribe oral comments.

FDA received more than 36,000 comments to the rulemaking docket in response to the 2013 proposed rule and the supplemental proposed rule, which included comments on the scope of the EIS, in response to the NOI and scoping public meeting. In the 2013 proposed rule, FDA stated that it was seeking comments on the potential environmental effects as part of the public comment period, including specific comments regarding agricultural water, BSAs of animal origin, and wildlife. FDA stated, in the August 19, 2013, NOI that these comments were still relevant to the environmental analysis. Consequently, FDA reviewed these comments on the 2013 proposed rule along with comments received as part of the EIS scoping process, in addition to other data and information, to determine the specific issues and alternatives FDA should include for analysis in the EIS.

Each of the notices in the *Federal Register* provided instructions for interested persons or agencies on how to access the rulemaking docket to read background documents or comments received.

Scoping – Agency Involvement, Consultation, and Cooperation

Pursuant to 40 CFR 1501.7(a)(1), as the lead agency, FDA is required to "invite the participation of affected Federal, State, and local agencies, any affected Indian tribe, the proponent of the action, and other interested persons (including those who might not be in accord with the action on environmental grounds)."

According to 40 CFR 1508.5, a "cooperating agency" is "any Federal agency other than a lead agency which has jurisdiction by law or special expertise with respect to any environmental impact involved in a proposal (or a reasonable alternative) for legislation or other major Federal action significantly affecting the quality of the human environment." In August of 2013, FDA sent letters to the Environmental Protection Agency (EPA), U.S. Department of Agriculture (USDA), and the U.S. Fish and Wildlife Service (USFWS) requesting their participation as cooperating agencies in the preparation of the EIS. At this time, FDA also sent letters to the State Departments of Agriculture inviting their comments to the docket and providing them the opportunity to request cooperating agency status, although not issuing a formal invitation.

USDA agreed to be an official cooperating agency, which entailed providing technical comments on the scoping of the EIS, the technical approach to the EIS, and a draft of the EIS. These comments were considered by FDA along with those received through stakeholder engagement during the scoping period, relevant stakeholder comments on the PS PR, and input received from other Federal agencies. Within USDA, FDA consulted with USDA Agricultural Marketing Service (AMS), which oversees the organic program; and the Natural Resource Conservation Service (NRCS), which develops and maintains the National Conservation Practice Standards. USDA did not review the Final EIS prior to publication. In addition, EPA answered questions from FDA on an as-requested basis and has responded to requests for formal opinions on various topics of the PS PR. USFWS also agreed to work with FDA through other appropriate channels, specifically with regards to the ESA. Having these agencies involved helped ensure

that environmental and conservation standards and policies established by these agencies were appropriately considered in developing the EIS for the PS PR.

Draft Environmental Impact Statement (EIS)

In accordance with 40 CFR 1503.1, FDA requested and obtained comments on the Draft Environmental Impact Statement (DEIS) from other Federal agencies with jurisdiction by law or special expertise in environmental standards, appropriate State and local agencies, sovereign Tribes, the regulatory community, and the public. The DEIS was published on FDA's Web site on January 12, 2015. The Notice of Availability (NOA) for the DEIS was published in the *Federal Register* on January 14, 2015 (80 Fed. Reg. 1852). On February 10, 2015, FDA held a public meeting at which FDA staff provided an overview of the findings described in the DEIS. The meeting was broadcast via webcast and was open to participants nationwide, and comments on the DEIS were obtained during the comment period. The comment period closed on March 13, 2015. FDA received 30 comments on the DEIS from interested parties, consumer groups, and a Native American Indian Tribe. All comments were considered by FDA, and certain revisions that the agency deemed appropriate are reflected in the FEIS.

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 until thirty (30) days after publication of the notice for a final environmental impact statement. However, § 1506.10(b) 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 § 1506.10(b) 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 proposed 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 below. The Produce Safety final rule establishes standards to minimize the risk of SAHCOD resulting from contaminated produce. This rule implements section 419 of Federal Food, Drug, and Cosmetic Act (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 SAHCOD, 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 (D'Lima, 2011). 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 (Merriweather, 2015). These outbreaks were associated with approximately 10 different produce commodities. The illness numbers cited above are the reported illnesses; CDC 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 ten years after publication of the rule, we expect benefits of the Produce Safety final rule to

be approximately 365,351 illnesses averted per year, valued at $977 million annually (See the Regulatory Impact Analysis accompanying the rule for additional information (FDA, 2013c)).

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 rule: one year after enactment of FSMA for a proposed rule (section 419(a)(1)(A) of the FD&C Act) and one 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 US 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 those covered under the rule to begin taking the steps that will safeguard public health and safety.

Alternatives Assessed in the Final EIS

The FDA considered various alternatives to determine if any were reasonable and environmentally preferable to the proposed action. Chapters 2.1 and 4.1 of the FEIS discuss in detail the No Action Alternative. Chapters 2.1 and 4.2 through 4.7 discuss in detail the potentially significant provisions (those provisions that FDA has determined may significantly affect the quality of the human environment and, therefore, included within the scope of the EIS). The FEIS contains a programmatic analysis of a comprehensive set of provisions aimed at reducing foodborne illness associated with the growing, harvesting, packing, and holding of produce for human consumption within the borders of the conterminous U.S., and also includes Alaska, Hawaii, and the EIS geographical areas (Puerto Rico, U.S. Virgin Islands, Guam, American Samoa, and the Northern Mariana Islands). The FEIS also considers corresponding transboundary effects in Canada and Mexico. FDA used USDA National Agricultural Statistics Service (NASS) survey data to identify the locations of farms that grow covered produce within the boundaries of the conterminous U.S., Alaska, Hawaii and Puerto Rico, and U.S. Geological Service

(USGS), institutional, and Congressional reports to identify regions where environmental resources (including the human environment) are shared transboundary. In terms of the geographic scope of the EIS, NASS data provides information on where produce commodities that are covered under the final rule are grown. NASS survey data were a major source of information on where produce commodities are grown. When combined with information on water quality, air quality and socioeconomic factors, as discussed in Chapters 2.3 and Chapter 3 of the FEIS, the data provided support the evaluation of potential impacts on a regional or national level. Where possible, FDA also considered environmental impacts at a state level when data and information were available.

Given the diverse nature of agricultural practices, the Final EIS analyzed the potential impacts of alternatives for each of the potentially significant provisions both individually and cumulatively. This allowed for a more comprehensive understanding of the role that each of the provisions plays in terms of both environmental impacts and human health benefits. These alternatives were developed based on the mandate established by Congress in FSMA and utilized the experience FDA has obtained during its involvement in foodborne illness outbreaks over time.

A brief summary of the alternatives follows.

Table 1. Potentially significant provisions and alternatives analyzed for the Produce Safety Rule

Potentially significant provisions and alternatives		
Subpart E Microbial Standard for Agricultural Water	**Alternative I.**	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 (Proposed § 112.44(c))
	Alternative II.	Generic *E.coli*: maximum of 235 CFU/100 ml for any single sample or a rolling GM of no more than 126 CFU per 100 ml
	Alternative III.	As proposed (i.e., Alternative I), along with an additional criterion establishing a maximum generic *E. coli* threshold
	Alternative IV.	Above three alternatives (considered separately), including drip-irrigated root crops: • IV-a: 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 (Proposed § 112.44(c)) • IV-b: Generic *E.coli*: maximum of 235 CFU/100 ml for any single sample or a rolling GM of no more than 126 CFU per 100 ml • IV-c: 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 (Proposed § 112.44(c)), along with an additional criterion establishing a maximum generic E. coli threshold
Subpart F Biological Soil Amendments of Animal Origin	**Untreated: Alt. I.**	9 month application interval of untreated BSAs of animal origin in a manner where there is a reasonable possibility that it will contact covered produce after the application (Originally proposed as § 112.56(a)(1)(i)-Decision Deferred)
	Untreated: Alt. II.	Zero days application interval
	Untreated: Alt. III.	90/120 days application interval
	Untreated: Alt. IV.	6 month application interval
	Untreated: Alt. V.	12 month application interval
	Treated: Alt. I.	Zero days application interval (Proposed § 112.56(a)(4)(i))

Potentially significant provisions and alternatives		
	Treated: Alt II.	45 days application interval
	Treated: Alt. III	90 days application interval
Subpart I Domesticated and Wild Animals	**Grazing: Alt. I.**	Adequate waiting period between grazing and harvest (Proposed §§112.82)
	Grazing: Alt. II.	Minimum waiting period of 9 months
	Grazing: Alt. III.	Minimum waiting period of 90/120 days
	Animal Intrusion: Alt I.	Monitoring for evidence of animal intrusion immediately prior to harvest and as needed during the growing season (Proposed §§ 112.83, and supplemental proposed 112.84)
	Animal Intrusion: Alt II.	Measures to exclude wildlife
Subpart A General Provisions	**Alternative I.**	$25,000 threshold (all produce), (Proposed §112.4)
	Alternative II.	$50,000 threshold (all food)
	Alternative III.	$100,000 threshold (all food)
	Alternative IV.	$25,000 threshold (covered produce only)

Alternatives Considered but Eliminated from Analysis in the EIS

In its Draft Qualitative Assessment of Risk to Public Health from On-Farm Contamination of Produce (QAR), FDA performed an assessment of potential routes of contamination and the likelihood of contamination on farms (FDA, 2013c). FDA evaluated the relative risk for 12 different classes of commodities during growing, harvest, and post-harvest. Contaminated water is a potential route of contamination when directly applied during irrigation, when applied for protection during growing, and when indirectly applied. Soil amendments were another identified route of contamination during the growing process. Workers, animals, and equipment were also identified as potential routes of contamination during growing. FDA identified water, workers, and equipment as potential routes of contamination during harvest; water, workers, equipment, and buildings were identified as potential routes of contamination during postharvest activities. Therefore, all of these routes are being evaluated for standards to reduce the potential for biological contamination and associated risk of foodborne illnesses.

The final rule focuses on biological hazards. While we acknowledge the potential for non-biological (physical or chemical (including radiological)) hazards in produce, we are not addressing such hazards in this rule. See section VI of the final rule for additional information.

Procedures, processes and practices in each of these on-farm routes of contamination have the potential to introduce biological hazards into or onto any covered produce. Therefore, FDA proposed an integrated approach to prescribe standards for each of these on-farm routes of contamination (see 78 Fed. Reg. 3504 at 3524-3529). These standards are the foundation that FDA used to establish requirements for the growing, harvesting, packing, and holding of produce for human consumption, in order to minimize the risk of SAHCOD, including those reasonably necessary to prevent the introduction of known or reasonably foreseeable biological hazards into or onto produce and to provide reasonable assurances that the produce is not adulterated on account of such hazards. This is the purpose of FDA's proposed action (see Chapter 1.2 of the FEIS). FDA is mandated to perform this action in accordance with FSMA (see Chapter 1.1 of the FEIS).

Alternatives or actions that FDA considered that did not meet the purpose of FDA's proposed action or that were deemed unreasonable were eliminated from further review (see Chapter 2.2 of the FEIS).

FDA considered a number of options and alternatives that were based on public comments received on the PS PR (see Chapter 1.8 of the FEIS), as well as the analysis FDA conducted as part of its Draft QAR (FDA, 2013c) and its 2013 Preliminary Regulatory Impact Analysis (PRIA) and 2014 Supplemental PRIA (FDA, 2013b and 2014). The options and alternatives FDA considered but eliminated include:

FDA considered but eliminated the following options:

(1) No new regulatory action (FDA, 2013b).

FDA considered under this option relying on current guidance such as GAPs guidance and other commodity-specific guidance, voluntary adoption of some or all provisions of the proposed regulation, current or enhanced State and local enforcement activity to bring about a reduction of potential harm from adulterated foods, or the tort system, with litigation or the threat of litigation serving to bring about the goals of the proposed rule.

However, FSMA requires FDA to conduct its rulemaking establishing produce safety standards. Moreover, FDA believes that these methods are unable to fully minimize the risk of SAHCOD from the use of, or exposure to, covered produce. The advantage of this option is that there would be no costs to the produce industry, but the disadvantage is that there would also be no benefits (in terms of illnesses prevented).

(2) Exclude commodities not associated with outbreaks from some or all of the provisions of the rule.

As discussed in greater detail in Chapter 1.6 of the FEIS, FDA considered and rejected the option to develop a framework that (based solely on a history of outbreaks or illnesses associated with the commodity) would be applicable to individual commodities or classes of commodities. Foodborne illness outbreaks have regularly been associated with commodities that have previously not been linked to outbreaks. In addition, because only a small percentage of outbreaks are both reported and assigned to a food vehicle, outbreak data may not provide a complete picture of the commodities upon which FDA needs to focus to minimize current and future risk of illness. Furthermore, FDA's Draft QAR (2013b) identifies common on-farm routes of contamination, which are not commodity-specific. These findings of the Draft QAR are also reiterated among the conclusions of the Final QAR, which FDA prepared taking into account peer reviewers' and public comment (FDA, 2015b)

(3) Require less-extensive standards (FDA, 2013b).

FDA considered that several of the proposed provisions could be combined to provide a less extensive set of controls than in the proposed rule. Certain prevention measures could be separated and put forth as stand-alone regulations. For example, provisions regarding agricultural water could be issued as a separate proposed rule. The various individual measures would, by themselves, generate lower costs than the integrated program outlined in the proposed rule.

As an alternative, FDA considered that certain provisions could be eliminated altogether, such that eliminating provisions for domesticated and wild animals and BSAs of animal origin would reduce the cost of the proposed rule; however, potential [healthcare related cost] benefits would also be reduced. FDA did not select this alternative because all requirements are important in reducing the level of contamination and human health burden associated with produce. Additionally, the likely reduction in costs from cutting these requirements would probably be outweighed the lost benefits from preventing foodborne illnesses.

(4) Apply a $10,000 limit to an average annual monetary value of "food" sold during the previous three-year period (FDA, 2013b).

FDA considered under this option to require that farms or farm mixed-type facilities with an average annual monetary value of food sold during the previous three-year period of more than $10,000 would be considered covered farms subject to the proposed rule. Therefore, as described in the 2013 PRIA (FDA, 2013b), more farms would be required to implement the standards outlined in the proposed rule, many of which were estimated to be very small farms. The result would have been approximately a 16 percent increase in costs to very small farms over the estimates provided in the 2013 proposed rule, but the estimated annual benefits (in terms of healthcare costs avoided) would have been very small compared to the overall cost to farms. FDA has not selected this alternative because the anticipated costs outweigh the potential benefits from eliminating all illnesses associated with these farms.

(5) Apply a $25,000 limit to an average annual monetary value of "food" as the threshold above which farms would be subject to the rule (79 Fed. Reg. 58434 at 58437).

FDA considered that farms with an average annual monetary value of food sold of $25,000 or less collectively account for 1.5 percent of covered produce acres, suggesting that they contribute little exposure to the overall produce consumption. Applying the $25,000 limit to an average annual monetary value of "produce" [rather than food, 2014 supplemental proposed § 112.4(a)] sold would account for an estimated total of 4 percent of covered produce acres and about 3.1 percent of all produce acres in the United States. The amended proposal would remove farms with produce sales of $25,000 or less from coverage, resulting in removal of an additional 2.1 percent (after removal of acres as a result of the provisions related to the qualified exemption, produce that is rarely consumed raw, and produce destined for commercial processing that eliminates pathogens of concern) of produce acres from coverage. Under this scenario, as with the previous proposed approach, such businesses would not contribute significantly to the volume of produce in the marketplace that could become contaminated and, therefore, would have little measurable public health impact. FDA determined that applying the $25,000 limit to "produce" sales would not adversely affect the level of public health protection that it proposes to accomplish.

(6) With respect to standards directed to agricultural water, applied to produce other than sprouts during growing using a direct water application method, no detectible *E. coli* per 100 ml (see Chapter 2.1 subpart E of the FEIS, and 79 Fed. Reg. 13593, March 11, 2014).

FDA considered an alternative to proposed § 112.44(c) (2013 proposed rule, 235 CFUs (or MPN) generic *E. coli* per 100 ml) for water applied to produce other than sprouts during growing using a direct water application method that would equate to no detectible *E. coli* per 100 ml. Water generally associated with no detectible *E. coli* is municipally treated drinking water. Many farms across the U.S. are not presently connected to such municipal systems due to the rural setting for most agriculture (water treatment plants generally reach to residential and commercial users in suburban and urban settings). In addition, if farms were connected to municipal supplies, it is likely they would not be permitted to draw all agricultural water needed from those supplies for irrigation due to the very large water demand that irrigation requires (irrigation water demand from surface and groundwater is detailed in Chapter 3.1.3 of the FEIS). Furthermore, there presently is no EPA-approved chemical treatment for contaminated water used to control pathogens in water directly applied to produce (EPA, 2014) (see Chapters 4.1 and 4.2 of the FEIS for a more detailed discussion). Therefore, FDA determined that this alternative is not a reasonable option at this time.

(7) Develop a manure standard that accounts for application of biological soil amendments that fall between fresh manure and composted material, such as the application of aged manures.

Public commenters requested that FDA analyze a manure standard for aged manures. FDA considers aged manures to fall within the spectrum of untreated BSAs of animal origin. In order to establish an alternative for "aged" manure or "aged" BSAs of animal origin, FDA would need to be able to identify specific parameters under which the microbial load of pathogens would scientifically be proven to consistently provide a level of protection greater than BSAs of animal origin which are not aged. There is no scientific evidence available to show that the process of aging BSAs of animal origin is sufficient to be safe without treatment nor to establish conditions under which that might be possible. FDA does not see aged manure offering different protections from the alternatives already proposed and considered. For this reason, a more flexible standard for biological soil amendments as proposed by the commenters, which may still result in a greater likelihood of pathogen transport, is not a reasonable alternative that meets the purpose and need of the proposed action.

Environmentally Preferable Alternative

The environmentally preferable alternative is that alternative that causes the least damage to the biological and physical environment. It is also the alternative which best protects, preserves and enhances historic, cultural, and natural resources. CEQ has recognized that the identification of the environmentally preferable alternative may involve difficult judgments, particularly when one environmental value must be balanced against another (CEQ, 1981). In identifying the environmentally preferable alternative, FDA was faced with balancing the public health impacts against impacts to natural resources. This requires a delicate balance between recognition of the importance of improving human health, while not discounting impacts to other portions of the human environment. Recognizing the importance that beneficial impacts to human health would play in determining the agency's preferred alternative, the decision was made to put greater emphasis on the potential for adverse impacts for each of the potentially significant provisions both individually and cumulatively on a number of potentially impacted environmental resources when identifying the environmentally preferable alternative. Based on this analysis, we identified the no action alternative as the environmentally preferable alternative.

Under the No Action Alternative, there would be a continued persistence of human health risks. An estimated 916,432 cases of domestic foodborne illnesses occur annually that are attributable to produce that would be covered by the final rule; FDA estimates that approximately $2.5 billion annually is spent on preventing illnesses associated with microbial contamination of covered produce (FDA, 2015c). If the present conditions are to continue, the total annual foodborne illnesses and associated costs are not expected to substantially decrease.

FDA is not choosing the environmentally preferable alternative because it does not meet the agency's purpose and need. As discussed in the FEIS, FDA does not consider a No Action Alternative to be a viable alternative. Section 105(a) of FSMA (21 U.S.C. 350h(a)) requires FDA to conduct rulemaking establishing minimum science-based produce safety standards. Congress specifically mandated through FSMA that " . . . the Secretary [of HHS, and by delegation, FDA], in coordination with the Secretary of Agriculture and representatives of State departments of agriculture (including with regard to the national organic program established under the Organic Foods Production Act of 1990), and in consultation with the Secretary of Homeland Security, shall publish a notice of proposed rulemaking to establish science-based minimum standards for the safe production and harvesting of those types of fruits and vegetables, including specific mixes or categories of fruits and vegetables, that are raw agricultural commodities for which the Secretary has determined that such standards minimize the risk of serious adverse health consequences or death" (section 419(a)(1)(A) of the FFDCA (21 U.S.C. § 350h(a)(1)(A)). Further, FSMA mandates that " . . . the Secretary [of HHS, and by delegation, FDA] . . . adopt a final regulation to provide for minimum science-based standards for those types of fruits and vegetables, including specific mixes or categories of fruits or vegetables, that are raw agricultural commodities, based on known safety risks, which may include a history of foodborne illness outbreaks" (section 419(b)(1) of FFDCA (21 U.S.C. § 350h(b)(1))).

Decision (Agency-Preferred Alternative)

As defined by the Council on Environmental Quality (CEQ), the "agency's preferred alternative" is the alternative which the agency believes will fulfill its statutory mission and responsibilities, giving consideration to economic, environmental, technical and other factors (CEQ, 1981). The concept of the "agency's preferred alternative" is different from the "environmentally preferable alternative," although in some cases an alternative may be both.

Based on the analysis in the EIS, and public comments on the DEIS and the PS PR, FDA has identified the standards that form the final rule. The final rule is the agency's preferred alternative.[1]

The standards as described below correlate to the following alternatives in the FEIS for the potentially significant provisions: Alternative IV-c for agricultural water (modified), Alternative I for treated BSAs of animal origin, Alternative I for domesticated animals (modified), Alternative I for wild animal intrusion, and Alternative I for Subpart A. The preferred alternative also includes all provisions that were excluded from detailed analysis in Chapter 2.2 of the FEIS. The preferred alternative is similar to the preferred alternative as laid out in the FEIS with the exception of the following modification to the standards for agricultural water and domesticated animals. FDA has also modified the list of produce that is considered to be rarely consumed raw and therefore exempt from regulation based on public comment and analysis of available data. As discussed in the FEIS, FDA has previously indicated it would defer decision on a minimum application interval for untreated BSAs of animal origin 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. Therefore, FDA has not identified an alternative that would best meet the statutory mission and responsibilities. (Note, however, that FDA is finalizing the provision for a minimum application interval of 0 days for untreated BSAs that are applied in a manner that does not contact covered produce during or after application.)

Alternative IV-c for agricultural water was modified in the final rule, in part, based on public comments in response to the supplemental proposed rule, in which FDA requested comment on any potential maximum generic *E. coli* threshold. Taking into account public comments and based on a review of available literature, we are adding a new limitation in § 112.45(b)(1)(i)(A) that a time interval of no more than four consecutive days may be applied between last irrigation and harvest to achieve the microbial quality criteria in § 112.44(b) as recommended by public comments. Farms may apply alternative scientifically supported die-off rates under § 112.45(b)(1)(i)(A) between last application and harvest or develop an alternative to the microbial quality criteria in § 112.44(b), as discussed in section XIII.F.2. of the final rule. Under the approach adopted in the final rule, FDA is not establishing a maximum generic *E. coli* threshold. The applied die-off rate along with the maximum time interval will result in a site-specific maximum log pathogen reduction. The environmental impacts of these would be comparable to the impacts from an FDA-established maximum threshold of generic *E. coli*. However, the ability to establish a higher die-off rate, if scientifically supportable, reduces potential impacts by reducing the need to change water source or chemically treat water in order to meet an FDA established maximum.

Alternative I for domesticated animals was modified in the final rule. Specifically, FDA removed the provision that would have required farms to apply an adequate waiting period between grazing and harvesting, and replaced it with revised requirements related to grazing and working animals in final § 112.83. As described in section XV.C. of the final rule, currently available science does not allow us to identify a specific minimum time period between grazing and harvesting that is generally applicable across various commodities and farming practices. Rather, the appropriate minimum time period between grazing and harvesting would need to be determined based on the specific factors applicable to the conditions and practices associated with growing and harvesting the commodity. We evaluated applying the strategy in proposed § 112.83 more broadly to grazing animals, working animals, and animal intrusion, and have concluded that such an approach was reasonable, scientifically sound, and simpler

[1] Note that the alternatives that make up the preferred alternative in this ROD vary somewhat from the agency's preferred alternatives as presented in the FEIS. Specifically, for subpart E, the FEIS identifies FDA's preferred alternative as Alternative IV-a, whereas the preferred alternative presented in this ROD is Alternative IV-c.

than establishing different requirements based on different types of animal activity. Therefore, we are removing the proposed requirements for a waiting period between grazing and harvesting in relation to grazing animals (proposed § 112.82(a)) and measures to prevent introduction of hazards from working animals into or onto covered produce (proposed § 112.82(b)), and we are adopting an approach that unifies the requirements addressing the potential for contamination from grazing animals, working animals, and animal intrusion. However, we encourage covered farms to voluntarily consider applying such waiting periods, as appropriate for the farm's commodities and operations. The term "adequate waiting period" was not defined by the PS PR or the DEIS. It was reasonable to assume that farmers could determine that an adequate waiting period was as little as zero days, although longer waiting periods were expected to be more common. The analysis in Alternative I is comparable to the impacts that will be seen if FDA's recommendation (rather than the previously proposed requirement) that an adequate waiting period be observed is implemented.

An exhaustive list of produce that is consumed raw and therefore not covered by the rule was included in the proposed rule and modified in the final rule. The following modifications were made. Removed from the exhaustive list were arrowhead; arrowroot; artichokes; black-eyed peas; bok choy; Brussel sprouts; crabapples; kale; parsnips; plantains; rhubarb; rutabaga; taro; turnips; and yams. Added to the list were beans, black; beans, great Northern; beans, navy; cashews; cherries, sour; cocoa beans; coffee beans; dates; dill (seed and weed); hazelnuts; horseradish; pecans and peppermint.

The exhaustive list of produce that is considered rarely consumed raw and therefore not covered by the final rule is as follows: asparagus; beans, black; beans, great Northern; beans, kidney; beans, lima; beans, navy; beans, pinto; beets, garden (roots and tops); beets, sugar; cashews; cherries, sour; chickpeas; cocoa beans; coffee beans; collards; corn, sweet; cranberries; dates; dill (seed and weed); eggplants; figs; ginger; hazelnuts; horseradish; lentils; okra; peanuts; pecans; peppermint; potatoes; pumpkins; squash, winter; sweet potatoes; and water chestnuts.

The impacts associated with the agency's preferred alternative and the agency's rationale for reaching this decision follows the discussion of the scope of coverage and key provisions that constitute the agency's final decision as outlined in the final rule. The agency's preferred alternative as laid out in the final rule is incorporated by reference, and summarized to the extent possible below.

Scope of Coverage of the Rule

The final rule applies to both domestic and imported produce. However, as explained in the remainder of this document, the rule contains several exemptions and limitations:

- The rule does not apply to certain specified produce commodities that are rarely consumed raw.
- The rule also does not apply to produce that is used for personal or on-farm consumption, or that is not a raw agricultural commodity.
- The rule provides an exemption for produce that receives commercial processing that significantly minimizes the presence of microorganisms of public health significance (e.g. via a "kill step") as long as certain disclosures are made and written assurances are received, with appropriate documentation.
- The rule does not cover farms that have an average annual value of produce sold during the previous three-year period of $25,000 or less.
- The rule provides a qualified exemption and modified requirements for farms that meet two requirements: (1) the farm must have food sales averaging less than $500,000 per year during the previous three years; and (2) the farm's sales to qualified end-users must exceed sales to others. A qualified end-user is either (a) the consumer of the food or (b) a restaurant or retail food establishment that is located in the same state or the same Indian reservation as the farm or not more than 275 miles away. Instead, these farms are required to include their name and complete business address either on the label of the produce that would otherwise be covered (if a label is required under the FFDCA and its implementing regulations) or to display the same information at the point-of-purchase. These farms are also required to establish and keep certain documentation. This exemption may be withdrawn in the event of an active investigation of an

outbreak that is directly linked to the farm, or if it is necessary to protect the public health and prevent or mitigate an outbreak based on conduct or conditions on the farm that are material to the safety of the produce.

The rule also permits states, Tribes, or foreign countries to submit a petition, along with supporting information, to FDA requesting a variance(s) from the requirements of this rule.

Summary of the Major Provisions of the Rule

The final rule establishes science-based minimum standards for the safe growing, harvesting, packing, and holding of produce on farms. Based on the findings of the DEIS, and the Final QAR, we are focusing the provisions of this rule on five major routes of contamination. We are finalizing requirements in the following major areas:

- Worker Training and Health and Hygiene
  - Establish qualification and training requirements for all personnel who handle (contact) covered produce or food-contact surfaces and their supervisors (§§ 112.21, 112.22, and 112.23);
  - Require documentation of required training and corrective actions (§ 112.30); and,
  - Establish hygienic practices and other measures needed to prevent persons, including visitors, from contaminating produce with microorganisms of public health significance (§§ 112.31, 112.32, and 112.33).
- Agricultural Water
  - Require that all agricultural water must be safe and of adequate sanitary quality for its intended use (§ 112.41). Agricultural water is defined in part as water that is intended to, or is likely to, contact the harvestable portion of covered produce or food-contact surfaces (§ 112.3(c));
  - Establish requirements for inspection, maintenance, and certain other actions related to the use of agricultural water, water sources, and water distribution systems associated with growing, harvesting, packing, and holding of covered produce (§§ 112.42 and 112.48);
  - If a farm chooses to treat agricultural water to meet relevant requirements for its intended use, establish requirements related to methods of treatment and monitoring such treatment (§ 112.43);
  - Establish specific requirements for the microbial quality of agricultural water that is used for certain specified purposes, including provisions requiring periodic analytical testing of such water (with exemptions provided for use of public water supplies, under certain specified conditions, and treated water), and requiring certain actions to be taken when such water is not safe or of adequate sanitary quality for its intended use and/or does not meet the microbial quality requirements (§§ 112.44, 112.45, 112.46, and 112.47); and provide for alternative requirements for certain provisions under certain conditions (§§ 112.12 and 112.49); and,
  - Require certain records, including documentation of inspection findings, water testing results, scientific data or information relied on to support the adequacy of water treatment methods, treatment monitoring results, scientific data or information relied on to support microbial die-off or removal rates or any permitted alternatives to requirements, time intervals or log reductions applied, and corrective actions (§ 112.50).
- Biological Soil Amendments
  - Establish requirements for determining the status of a biological soil amendment of animal origin as treated or untreated, and for their handling, conveying, and storing (§§ 112.51 and 112.52);
  - Prohibit the use of human waste for growing covered produce except in compliance with EPA regulations for such uses or equivalent regulatory requirements (§ 112.53);
  - Establish requirements for treatment of biological soil amendments of animal origin with scientifically valid, controlled, biological, physical and/or chemical processes that satisfy

certain specific microbial standards (§§ 112.54 and 112.55), including examples of such processes;
    - Establish application requirements and minimum application intervals for untreated and treated biological soil amendments of animal origin (§ 112.56); and,
    - Require certain records, including documentation from suppliers of treated biological soil amendments of animal origin, documentation that process controls were achieved, and corrective actions (§ 112.60).
- Domesticated and Wild Animals
    - If there is a reasonable probability that grazing animals, working animals, or animal intrusion will contaminate covered produce, require measures to assess as needed relevant areas during growing and, if significant evidence of potential contamination is found, take measures reasonably necessary to assist later during harvest when the farm must identify, and not harvest, covered produce that is reasonably likely to be contaminated with a known or reasonably foreseeable hazard (§§ 112.83 and 112.112).
- Equipment, Tools, and Buildings
    - Establish requirements related to equipment and tools that contact covered produce and instruments and controls (including equipment used in transport), buildings, domesticated animals in and around fully-enclosed buildings, pest control, hand-washing and toilet facilities, sewage, trash, plumbing, and animal excreta (§§ 112.121-134); and,
    - Require certain records related to the date and method of cleaning or sanitizing equipment used in growing operations for sprouts, and in covered harvesting, packing, or holding activities, and corrective actions (§ 112.140).
- Sprouts
    - Establish scope of applicability of sprout provisions (§ 112.141);
    - Establish measures that must be taken related to seeds or beans for sprouting (§ 112.142);
    - Establish measures that must be taken for the growing, harvesting, packing, and holding of sprouts (§ 112.143);
    - Require testing the growing environment for *Listeria* spp. or *L. monocytogenes*, and testing each production batch of spent sprout irrigation water or sprouts for *E. coli* O157:H7, *Salmonella* species and, under certain conditions, other pathogen(s), and taking appropriate follow-up actions (§§ 112.144 - 112.148); and,
    - Require certain records, including documentation of treatment of seeds or beans for sprouting, a written environmental monitoring plan and sampling plan, test results, certain test methods used, and corrective actions (§ 112.150).

Rationale for Decision

As discussed in the EIS, the agency's stated purpose and need was to conduct a rulemaking to establish science-based minimum standards for the safe production and harvesting of those types of fruits and vegetables that are raw agricultural commodities for which we have determined such standards minimize the risk of SAHCOD, as required by FSMA (Pub. L. 111-353). Further, FSMA requires FDA to adopt a final regulation based on known safety risks, setting forth procedures, processes, and practices that we determine to minimize the risk of SAHCOD, 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 FFDCA (21 U.S.C. § 342).

FDA weighed the adverse impacts that a final rule will have against the anticipated public health benefits and determined that the provisions as outlined above, and laid out in full in the final rule, best meet the agency's stated purpose and need while attempting to reduce environmental impacts to the extent possible. FDA has promoted co-management throughout the rulemaking and EIS process. As required by section 419(a)(3)(D) of the FFDCA (21 U.S.C. § 350h(a)(3)(D)), in developing produce safety standards and consistent with ensuring enforceable public health protection, FDA took into consideration conservation and environmental practice standards and policies established by Federal natural resource conservation, wildlife conservation, and environmental agencies. In developing the PS PR, FDA consulted with USDA's National Organic Program (NOP) and NRCS, USFWS, and the EPA to take into

consideration conservation and environmental practice standards and policies established by those agencies. Furthermore, FDA consulted with the USFWS throughout the rulemaking and NEPA process in order to more accurately predict potential impacts that may result from habitat destruction activities, with particular emphasis on potential impacts to threatened and endangered species.

FDA is establishing the produce safety standards described in the final rule as part of our implementation of FSMA to minimize the risk of SAHCOD from consumption of contaminated produce. The regulatory framework we adopted in the final rule focuses on the likelihood of contamination of produce posed by the agricultural practices applied to the crop, while exempting the lowest-risk produce. This integrated approach provides the most appropriate balance between public health protection, flexibility, and appropriate management of different levels of risk. The primary benefits of the provisions in this rule are an expected decrease in the incidence of illnesses related to microbial contamination of produce. Annualizing benefits over the first ten years after the effective date of the final rule at seven percent, benefits are expected to derive from averting approximately 331,964 illnesses per year (362,059 at three percent), valued at $925 million annually ($976 million at three percent). Similarly, annualized costs, estimated at seven percent, are expected to be approximately $366 million annually ($387 million at three percent). Additionally, annualized costs for foreign farms are estimated to be approximately $138 million annualized at seven percent ($146 million at three percent) (FDA, 2015c).

Many of the changes made between the 2013 proposed rule and the final rule have increased the flexibility of, or deferred decision on, potentially significant provisions, and clarified the agency's requirement on key environmental issues. These changes have minimized the impacts associated with the final action compared to the 2013 proposed rule.

The criteria for microbial quality of agricultural water have been revised to allow for microbial die-off between last irrigation and harvest and between harvest and end of storage. These changes greatly reduced the likelihood that covered farms would either switch water sources or chemically treat their water to bring it into compliance, thereby reducing potential impacts on water quality and availability, soil and air quality, biological and ecological resources, and associated socioeconomic impacts.

By deferring decision on a minimum application interval for untreated BSAs of animal origin until such time as necessary for us to pursue certain steps, including a risk assessment and research to supplement the science on an appropriate interval, we have reduced the potential for adverse impacts experienced over current conditions that would be associated with establishing an application interval. Impacts associated with the untreated BSA provisions as finalized are indicative of current practice and any minor shifts in this practice that may be anticipated are not significant.

In response to comments received on the 2013 proposed rule, FDA proposed and is now finalizing § 112.84 to clarify that nothing in the regulation authorizes the "taking" of threatened or endangered species as that term is defined by the Endangered Species Act (ESA) (16 U.S.C. 1531–1544) (i.e., to harass, harm, pursue, hunt, shoot, wound, kill, trap, capture, or collect, or to attempt to engage in any such conduct), in violation of the ESA. Nor does the regulation require covered farms to take measures to exclude animals from outdoor growing areas, or to destroy animal habitat or otherwise clear farm borders around outdoor growing areas or drainages. FDA further clarified in the preamble to the supplemental proposed rule (79 Fed. Reg. 58434 at 58464) that growers of produce should be aware that clearing or manipulation of habitats, including activities affecting water resources, groundwater or natural vegetative cover, can affect species listed as threatened and endangered.

With the exception of the alternatives for Subpart A (general provisions) and Subpart E (agricultural water), the alternative for each of the potentially significant provisions that were used to form the agency's preferred decision has the least environmental impact when compared to the other alternatives considered for the respective provision. The impacts are greater than the environmentally preferable alternative in resource areas, with the exception of benefits to human health. With regard to Subpart A, the adverse impacts from the selected alternative ($25,000 threshold (all produce)) are greater than those associated with the other alternatives considered for this provision. However, the beneficial impacts on human health are also greater than those associated with the other alternatives. Applying the alternative

thresholds of 50,000 or 100,000 based on sales of produce would remove a larger number of farms, from coverage providing less public health protection. We find it difficult to quantitatively determine the extent to which businesses with an average annual monetary value of "covered produce" sold of more than $25,000 would contribute to the overall produce market, or the public health impact of not covering such farms. However, it can be reasonably expected that applying the $25,000 threshold to covered produce sales (rather than to total produce sales) would remove more produce acres from coverage and, therefore, a larger volume of product potentially associated with foodborne illness. Although applying these alternative thresholds is expected to have fewer environmental impacts, such thresholds would result in less public health protection and, therefore, do not align with the public health goals of the final rule.

Under Subpart E, the anticipated impacts from the modified Alternative IV-c are slightly greater than those that would be seen in Alternatives I or IV-a, but less than those expected from Alternatives II, III, IV-b and the unmodified IV-c. Only 5 crops—dry bulb onions, green onions, carrots, garlic and radishes—were not considered to be included in Alternative I. Producers of these crops account for roughly 5.8% of all covered farms. The PRIA assumed that 50% of all covered farms would use low-flow irrigation methods. This represents a minor increase in the number of farms impacted by this provision. Chemical treatments may have similar but slightly greater effects compared to Alternative I due to the increased types of covered produce, in terms of environmental quality and related costs, but these differences are limited due to the small number of impacted farms. The impacts on groundwater and from chemical treatments would be increased relative to Alternatives I and IV-a by establishing a maximum time interval between last irrigation and harvest to achieve the microbial quality criteria as this limitation is expected to limit the number of farms that can utilize microbial die-off. However, as Alternative I required an adequate waiting period to allow for die-off, and the 4-day limitation allows for a 2-log reduction in pathogens, the number of impacted farms is expected to be minimal. Moreover, in the final rule, FDA is providing the option for farms to use alternative microbial quality criteria (in lieu of the FDA-established criteria in 112.44(b)) and alternative microbial die-off rate and an accompanying maximum time interval (in lieu of those FDA established in 112.45(b)(1)(i)).

The impacts analyzed in the FEIS are not expected to be significantly different as a result of the revisions to the exhaustive list of produce that is rarely consumed raw. These changes would have an impact on the cost of the implementation of the rule as shown in Table 2 below.

FDA weighed the anticipated environmental impacts against the anticipated benefits to human health and believes that the beneficial impacts to human health outweigh the potential adverse environmental impacts, and that Alternative I under Subpart A best fits with the agency's purpose and need to reduce foodborne illness.

Resource Impacts Associated with the Preferred Alternative

The impacts described here include the combined anticipated impacts associated with all potentially significant provisions as well as the impacts, primarily socioeconomic, associated with the preferred alternatives described in Chapter 2.2 of the FEIS which were excluded from detailed analysis.

Water Resources

- Significant current and ongoing adverse impacts such as reduced water availability, water-table declines, soil subsidence and increased costs for finding and maintaining access to water, resulting from groundwater withdrawals, are presently experienced in regions B, C, D, I, J, and U (see Figure 1.7-4 in Chapter 1.7 of the FEIS for a regional map showing where covered produce are grown). These impacts represent the current condition, absent of any final rule, and are the result of many factors that include agricultural practices nationwide, development, and other factors unrelated to FDA's action. Any action (personal, Federal, state, local, etc.) in these regions that would cause a farmer or any entity to draw from groundwater instead of surface water could exacerbate the current environmental conditions. Under such conditions, individuals on Native American reservations in

regions B and C may be disproportionately adversely impacted as a result of continued groundwater drawdown.

- The flexibility in meeting the water quality standard is likely to reduce the need to use chemical treatment of a water source with poor water quality. It is also likely that a farmer might add a post-harvest mechanism to allow for added microbial die-off or removal in lieu of treating the water source.
- It is not likely that a farmer will change the water source or cease growing covered produce because, among the regions that are potentially most affected (B, C, D, I, J, and U (see Figure1.7-4 in the FEIS)), many farmers have entered into marketing agreements that establish numeric standards that are the same as, or are more stringent than, those in the final rule. In general, the existence of these marketing agreements, particularly in produce growing regions currently experiencing water impacts, minimizes the severity of potential impacts on resource components, as the number of farms that may need to alter their current management practices is less than the total number of covered farms. In addition, reactions and verbal comments from some industry and trade groups that FDA received on the supplemental proposed rule suggest that the provisions for microbial die-off and/or removal to achieve the microbial quality standard considerably reduce the perceived need to change the water source in order to comply with modified Alternative IV-c. Any action that may lead to increases in groundwater drawdown would be considered a significant environmental impact. Regions that may be most impacted in terms of potential land subsidence, including any additive effects by switching to groundwater sources, include the regions that already experience the highest groundwater withdrawals; these are regions B, C, D, I, J, and U (see Figure1.7-4 in the FEIS), as well as corresponding areas in the northeastern and northcentral reaches of Mexico that share an aquifer with region D, I, or J in the United States.
- The majority of the 285 covered sprouting operations draw from municipal water already. Only minimal adverse, not significant impacts may occur from water treatment effluent, and no nationwide or regional impacts are anticipated to water availability from those few operations that may connect to municipal water supplies.
- With respect to water quality and impacts considered under subpart F (untreated or treated BSAs), if a farmer is permitted to use an application interval of 0 days between the application of untreated or treated BSAs and harvest, there would be no substantial change from the baseline condition that would result in additional impacts to water quality or availability.

Biological and Ecological Resources

- Adverse effects to biological and ecological resources relevant to groundwater drawdown are not expected (discussed above). A high number of growers in key growing regions, such as California, Arizona, and Florida (regions C, D, and U) already participate in marketing agreements that have more stringent numeric water quality standards than what FDA has proposed, and are already using water that would be in compliance with the proposed standard.
- With respect to both grazing/working animals and animal intrusion, the most likely management decision in response to the rule's requirements would be to evaluate whether produce can be harvested safely and, as appropriate, not harvest a field or part of a field that is reasonably believed to be contaminated from wildlife intrusion. We would not expect environmental impacts to water resources, waste generation, disposal, and resource use, and air quality associated with this management decision.
- Also with respect to subpart I, any measures, however unlikely, taken to exclude animals (including measures to clear land to facilitate monitoring) may involve the use of herbicides, rodenticides, or other materials that may have short-term toxic effects to water resources, biological resources and ecosystems directly adjacent to the farm, and soils. These impacts may be reduced through proper use and handling of such chemicals in accordance with labeling requirements, which would be a reasonably foreseeable use (see Chapters 4.1 and 4.2 of the FEIS). In proper use and handling of chemicals in accordance with labeling requirements are done, then the use of such chemicals is not expected to result in significant impacts to the environment. Water quality conditions would be expected to recover to ambient conditions. Wildlife, vegetation and wetlands would be resilient to the effects of the chemicals at a regional or national level. The quantities of air emissions and GHGs related to fencing or other exclusion measures are not expected to result in public health concerns because there would be no measureable change to the air quality environment over existing

conditions. In addition, all of these aforementioned impacts take into consideration the very small number of farms potentially affected by this provision where such impacts may occur (at most 8 percent of covered farms). Measures that may be employed to reduce any other potential adverse effects that may otherwise be significant include preparing pest management plans (see Chapter 4.3 of the FEIS). Additionally, § 112.84 does not require covered farms to destroy animal habitat or otherwise clear farm borders around outdoor growing areas or drainages. The alternative and more likely management decision that a farmer may make is to monitor the fields and evaluate whether produce can be harvested safely. Any unharvested portions of the field may provide non-significant beneficial impacts to wildlife species as a result of added short-term cover and forage area.

- Hunting, trapping, and animal poisoning are other methods that are sometimes used to manage wildlife species at or adjacent to farm fields. Hunting and trapping are often accomplished in accordance with state or county permit requirements and in accordance with state wildlife regulations, which factor in species population levels before determining the number of licenses/permits that can be issued without adversely impacting the species survivability.

Soils

- Considering the most likely alternatives and management decisions carried forward for aggregate analysis (see Chapter 4.7 of the FEIS), the added flexibility in meeting the proposed water quality standard is likely to reduce the need to change the water source; therefore, the aggregate impacts should not have significant effects on soils.
- However, as described in FEIS Chapter 3.3.3.4, the USGS finds that more than 80 percent of the identified land subsidence in the nation is a consequence of groundwater exploitation. In many areas of arid western regions and in more humid areas underlain by soluble rocks such as limestone, gypsum, or salt, land subsidence is an often overlooked environmental consequence of land- and water-use practices. Chapter 3.1, Figures 3.1-23 and 3.1-24 of the FEIS show the extent of excessive groundwater pumpage of aquifer systems throughout the U.S., which correlate to areas where land subsidence is most likely to occur. Actions that would increase reliance on groundwater would potentially also impact soils. An impact on soils resulting from groundwater drawdown may result in impacts that are in addition to, but related to, irreversible compaction or subsidence, such as reduced ability to partition water for groundwater recharge and for use by plants and soil organisms. Regions where groundwater withdrawal may have the highest influence on land subsidence, and thus permanent damage to soils, are B, C, D, I, J, and U, as well as regions in the northeastern and northcentral reaches of Mexico that share an aquifer with regions D, I, or J. Therefore, the environmental effects on groundwater resources, where steps are not taken to reduce the impacts as discussed in the FEIS, may result in irreversible impacts on soils and corresponding impacts on the ability of those soils to filter nutrients, chemicals and pathogens.
- With respect to soil health and impacts related to subpart F (untreated or treated BSAs), a minimum application interval of 0 days between the application of the BSA and harvest, as provided in the final rule (i.e., for untreated BSAs that are applied in a manner that does not contact covered produce during or after application; certain treated BSAs that are applied in a manner that minimizes contact with covered produce during and after application; and certain other treated BSAs that are applied in any manner) would not represent a substantial change from the baseline condition, and, therefore, would not result in additional impacts to soil resources.
- With respect to subpart I, in most cases, covered dual- or multi-purpose operations already have fields that are dedicated pasturelands and would not, under normal conditions, be rotated in for crop land. No significant impacts from grazing are expected.

Waste Generation, Disposal and Resource Use

- Approximately 12.5 percent of produce farms use BSAs of animal origin, and of those that use BSAs of animal origin, only roughly 18.5 percent use untreated manure (this is 820 farms nationally, or 2.3 percent of the covered produce farms), and 10.2 percent of covered produce farms use treated BSAs of animal origin (this is 3,618 covered farms nationally). Therefore, a relatively small number of farms nationwide are expected to be impacted by the BSA provisions of the rule.

- (Untreated BSAs) A minimum application interval of 0 days between the application of untreated manure and harvest would not represent a substantial change from the baseline condition. Therefore, we do not expect additional impacts to waste generation, disposal, or use of the resource. The alternative will impose a requirement to apply untreated BSAs in a manner that does not contact covered produce during application and minimizes contact thereafter.
- (Treated BSAs) A minimum application interval of 0 days between application and harvest for treated BSAs of animal origin (e.g., compost) will be similar to the existing condition. Impacts similar to those occurring existing conditions will be associated with this alternative and corresponding management decisions. The use of chemical fertilizers in place of treated BSAs of animal origin as a nutrient source is unlikely to occur under this alternative because the alternative does not restrict the timing of the use of BSAs, but will impose a requirement to apply in a manner that minimizes contact covered produce during and after application for certain types of treated BSAs.

Air Quality and Greenhouse Gases

- There are minimal adverse environmental impacts (not significant) associated with air quality and GHGs because the most likely alternatives and management decisions are not expected to contribute to air emissions of criteria pollutants or GHG emissions that may result in considerable public health concerns at a regional or national level.

Socioeconomic and Environmental Justice

Major cost summary

Anticipated socioeconomic impacts related to the socioeconomic resource component that are associated with meeting the requirements for the provisions of the final rule stem from economic costs that result from management decisions to comply with the standards. In addition, FDA considered estimates prepared by FDA in the 2014 supplemental PRIA (FDA, 2014a) in its consideration of environmental alternatives (see 40 CFR 1502.23). The 2014 supplemental PRIA put the total cost of implementing the provisions of the PS PR at $386.23 million nationwide for businesses with an average annual monetary value of produce sold during the previous three-year period of more than $25,000 (FDA, 2014a). These estimates have been updated for the final rule (FDA, 2015c) in Table 2 which breaks down these costs by provision and by size class of farm.

Table 2. Summary of costs for the Produce Safety Rule (in millions)

Cost Sections	Not Covered	Very Small	Small	Large	Total
Personnel Qualifications and training	$0.00	$41.14	$54.08	$92.16	$187.38
Health and Hygiene	$0.00	$28.11	$13.59	$93.91	$135.61
Agricultural water	$0.00	$18.41	$4.21	$14.45	$37.07
Biological soil amendments of animal origin	$0.00	$0.44	$0.31	$1.72	$2.47
Domesticated and wild animals	$0.00	$2.36	$2.05	$11.45	$15.86
Growing, harvesting, packing, and holding activities	$0.00	$0.92	$0.35	$0.98	$2.25
Equipment, tools, buildings, and sanitation	$0.00	$19.49	$13.91	$85.29	$118.69
Sprouting operations	$0.00	$0.82	$0.94	$5.00	$6.77
Recordkeeping	$5.71	$10.71	$3.78	$7.29	$27.49
Administrative cost to learn the rule	$1.82	$10.63	$4.00	$6.80	$23.25
Corrective steps	$0.00	$0.73	$0.43	$2.08	$3.25

Cost Sections	Not Covered	Very Small	Small	Large	Total
Variances	$0.00	$0.00	$0.00	$0.11	$0.11
Total Costs (annual in millions)	$7.53	$133.76	$97.65	$321.24	$560.19
Average Cost per Farm	$101	$5,872	$24,683	$38,741	$15,992

The average projected per-farm cost of complying with the provisions of the rule is approximately $16,000, though this estimate is much lower (i.e., approximately $6,000) for very small farms. Small and very small farms may not be able to afford the added cost burden of complying with the provisions of the final rule. It is anticipated that these farms, if they are not able to qualify for an exemption to reduce the cost of compliance, will be the most likely to make management decisions that would result in them not being subject to the provisions of the rule.

As discussed under Chapter 4.2 of the FEIS, based on the comments FDA has received in response to the 2013 proposed rule and supplemental proposed rule, FDA does not expect farmers to decide to cease growing covered produce as a preferred management decision except in select instances which are often driven by outside pressures such as a program run by the State of California that pays farmers to keep land fallow in order to divert water to the cities. This is not a re-zoning of the land; rather, that land is essentially reserved for future alternative agricultural uses.

If non-covered produce or other agricultural crops that are not produce are grown, requirements to maintain certain water quality conditions would be dependent on any existing state regulations or industry marketing agreements. The type of crop a farmer may select to grow would also be dependent upon the region's climate, soils, and water availability, and may involve a decision whether the existing farm's equipment and infrastructure would be sufficient or would need to be updated, modified, or bought to accommodate a new type of crop.

Under certain conditions, where very small farms are involved and costs may be a larger factor, some farms may decide to stop growing crops altogether. However, this scenario would be most likely for very small farms as well as livestock operations that grow small amounts of covered produce (although many such diversified farming-livestock operations would likely not be covered based on the monetary threshold for excluded farms applied to sales of produce only rather than sales of food). There are no data to suggest under what conditions specifically such a management decision may occur, and there are no data available to quantify or qualify any related indirect impacts.

Under subpart F, since there is no substantial change from the existing conditions, we do not expect additional costs associated with this provision.

Environmental Justice

Minority groups

The overall cost of compliance for farms could potentially result in higher produce prices for consumers, including minority consumers. However, we expect that demand for produce commodities would eventually be met by other growers in the region, growers in other regions, or international suppliers. As a result, we expect commodity prices to stabilize.

As discussed in Chapters 1.9, 3.7, and 4.1 of the FEIS, Environmental Justice impacts related to the final rule are assessed for minority principal operators and minority farmworkers. Therefore, the discussion of anticipated socioeconomic impacts in the FEIS was limited to principal farm operators and farmworkers.

When considering the thresholds established in Chapter 3.7 of the FEIS for identifying potential impacts to minority principal operators, regions that are important for identifying potential impacts to minority principal operators are regions A, B, C, D, W, and V (see Figure 1.7-4 in the FEIS). Of these regions,

regions B and C are major produce growing regions (see Chapter 1.7 of the FEIS). Information for minority farmworkers is provided below.

Principal operators

Like all principal operators, minority principal operators will need to make management decisions regarding whether to comply with the provisions of the final rule or to cease growing covered produce. As noted above, very small farms are more likely than larger farms to decide to stop growing covered produce altogether if the farm manages livestock operations and also grows small amounts of covered produce; many such diversified farming-livestock operations would likely not be covered based on the proposed monetary threshold applied to sales of produce only rather than sales of food. Based upon the "meaningfully greater" threshold FDA established for minority populations of principal operators potentially affected by the rule, regions where minority principal operators manage very small farms that are more likely to make a management decision to cease growing covered produce are regions A, B, C, D, W, and V (see Figure1.7-4 in the FEIS).

Minority farmworkers

Based on the information on farmworkers reported by the DOL through surveys taken by that agency (see Chapter 3.7.3 of the FEIS), regions where there are potentially populations of minority farmworkers that may be impacted by the rule include regions C, D, I, and J (see Figure1.7-4 in the FEIS). Costs incurred by farms of all sizes may result in the farm either increasing the costs of their produce for consumers, or may involve the farm principal operator terminating the employment of full-time, part-time, or seasonal worker(s) in order to defray operating costs. FDA has no data to determine where in the nation or under what specific circumstances such decisions may occur as they are highly specific to the individual farm; however, with respect to the scope of this EIS, regions where such actions may adversely disproportionately affect minority farmworkers due to employment-related impacts include regions C, D, I and J.

Native American operators

Of all farms that are operated by Native American principal operators, whether located on or off reservations, 5.5 percent report growing vegetables, 2.4 percent report growing fruits and tree nuts, and 15 percent report growing combination crops. There may be farms that produce crops in multiple of these categories, and these categories include both covered and non-covered crops. Therefore, based on a very conservative estimate, no more than 22.9 percent of farms—the sum of these three categories—that are operated by Native American principal operators may be growing covered produce (USDA NASS, 2014). Based on USDA NASS data (2014), 78 percent of all Native American farms sell less than $10,000 in total sales, annually, meaning that, at most, 22 percent of farms with a Native American principal operator are covered farms under the rule. If it is assumed that these trends are consistent across all commodities, this means that, at most, 5 percent of farms with a Native American principal operator are covered by the rule (22 percent of 22.9 percent is approximately 5 percent). Moreover, farms that sell less than $25,000 annually in produce—not $10,000—are not covered by the rule. An additional 14 percent of farms with a Native American principal operator sell less than $49,999, meaning there is a reasonable likelihood that additional farms with a Native American principal operator would not be covered by the rule. It is not possible to estimate what percent of farms lie between $10,000 and $49,999 average annual sales. An additional 5 percent of Native American operated farms have less than $249,999 in total sales.

Despite the low number of total Native American owners/operators covered by the rule, there is a potential that added operating costs associated with the rule will impact a disproportionate number of Native American farmers compared to farmers as a whole, given that the average income for a farm for which a Native American is the principal operator is 30 percent lower than a farm for which the principal operator is not a Native American (per the 2007 Agricultural census). The average reported agricultural product sales for Native American operated farms are $40,331, compared to an average of $134,807 for all farms. The average anticipated per farm cost of approximately $6,000 for very small farms could be disproportionally burdensome for farms with a Native American principal operator, as this cost will comprise approximately 15 percent of average annual sales, compared to 4 percent of the average

annual sales of all farms.[2] However, the potential impacts for very small and small farms may be entirely mitigated to the extent these farms are eligible for a qualified exemption.

Low-income

As discussed in Chapter 3.7.3 and 4.7 of the FEIS, this class includes any persons whose median household income is at or below the HHS poverty guidelines (see 77 Fed. Reg. 4034, January 26, 2012). The HHS poverty guideline for a family of four in 2012 was set at $23,050. According to the USDA Agricultural Resource Management Survey data sheet, *Principal farm operator household finances, by ERS farm typology,* in 2012, median principal farm operator household income (an average of the farm and off-farm household incomes of residence farms, intermediate farms, and commercial farms) was $68,298.[3] This exceeds the $23,050 guideline as well as all other 2012 HHS poverty guidelines for families up to eight members (see Table 3.7-17 in the FEIS). While FDA acknowledges that there still may be low-income principal operators that may be adversely impacted by the costs associated with the rule, based on the aforementioned available information, we cannot reasonably identify low-income populations on a national or regional level that could be affected by the rule.

Low-income farmworkers: As discussed under minority farmworkers, impacts may involve the farm principal operator terminating the employment of full-time, part-time, or seasonal worker(s) in order to defray operating costs. FDA has no data to determine where in the nation, or under what specific circumstances such decisions may occur as they are highly specific to the individual farm. Based on data provided by the Department of Labor (DOL) (information reported for California) (DOL, 2000 and 2005), region C (see Figure1.7-4 in the FEIS) has populations of low-income farmworkers that may be disproportionately impacted by the rule.

Foodborne Illnesses Prevented

FDA estimated, in the 2015 Final Regulatory Impact Analysis (FRIA) to the final rule, that the number of foodborne illnesses prevented when considering the rule as finalized, all provisions, is 504,966, annually (FDA, 2015c). This represents a significant beneficial outcome to human health because the rule is likely to minimize the risk of SAHCOD from covered produce.

Human Health Impacts

Under subpart E (Chapter 4.2) of the FEIS, EPA-registered pesticide products were evaluated to determine potential environmental effects and potential impacts to human health specific to their use. With respect to the use of chemical pesticides, FIFRA mandates that EPA regulate the use and sale of pesticides to protect human health and preserve the environment. There is the possible risk of chemical exposure to site workers that may have to handle pesticides prior to application, but these risks are minimized when using proper handling techniques including using recommended personal protective equipment in accordance with labeling requirements or product recommendations (e.g., chemically resistant gloves to avoid exposures that may otherwise cause significant health effects) as described by the manufacturer. We do not expect impacts to human health and safety to be significant from the use of these products.

Resource Impacts Associated with Cumulative Analysis

In addition to the analysis relating to each potentially significant provision, the FEIS provided a cumulative impact analysis for the final rule (see 40 CFR 1508.7). The cumulative impacts analysis included impacts that would have resulted from the provisions of the proposed rule as well as any impacts that would result from Federal, state or industry standards or practices that have relevancy to the production of covered produce and that set guidelines that are important to reducing hazards associated with foodborne illness. The cumulative impacts analysis also considered other environmental, industry, or private actions nationwide that may contribute to the incremental adverse effects of the action. This included

[2] $6,000 divided by $40,331 equates to approximately 15 percent.
[3] There is limited data for principal farm operator income other than on a national level.

consideration of past, present, and reasonably foreseeable actions, and an analysis of whether, and to what extent, those actions contribute to the cumulative effects to the environment when combined with the potential environmental impacts associated with the proposed rule. The following discussion updates the analysis from the FEIS to incorporate the standards established in the final rule.

A cumulative impact is defined as "the impact on the environment which results from the incremental impact of the action when added to other past, present, and reasonably foreseeable future actions regardless of what agency (Federal or non-Federal) or a person undertakes such other actions. Cumulative impacts can result from individually minor but collectively significant actions taking place over a period of time" (40 CFR §1508.7). CEQ's guidance for considering cumulative effects further states that NEPA documents "should compare the cumulative effects of multiple actions with appropriate national, regional, state, or community goals to determine whether the total effect is significant" (CEQ, 1997).

Past, Present and Reasonably Foreseeable Future Actions

The actions that were identified as past, present and reasonably foreseeable future actions can be divided into 3 categories. These include related FSMA actions, comparable federal and non-federal actions and non-specific actions.

The related FSMA actions include the final rules for:

- Intentional Adulteration,
- Sanitary Transportation of Human and Animal Food,
- Preventive Controls for Human Food,
- Preventive Controls for Animal Food,
- Foreign Supplier Verification Programs for Importers of Food for Humans and Animals, and
- Third Party Accreditation.

Comparable Federal and non-federal actions include similar Federal and state/private efforts to manage pathogen transport on fresh produce commodities. The actions analyzed include:

- FDA Guidance to Industry: Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables (the GAPs Guide),
- USDA AMS GAP&GHP audit program,
- USDA organic regulations,
- USDA-NRCS Conservation Technical and Financial Assistance,
- The Fair and Equitable Tobacco Reform Act of 2004,
- Tomato Good Agricultural Practices (T-GAPs) and Best Management Practices Manual (BMP),
- Leafy Greens Marketing Agreements,
- Industry-Wide Food Safety Standards for Fresh Mushroom Growing, Harvesting, and Shipping,
- FDA Draft Guidance for Industry: Guide to minimize food safety hazards of tomatoes,
- FDA Draft Guidance for Industry: Guide to Minimize Microbial Food Safety Hazards of Melons,
- FDA Draft Guidance for Industry: Guide to Minimize Microbial Food Safety Hazards of Leafy Greens,
- California cantaloupe program, and,
- State specific agricultural water quality standards and nutrient management standards.

Non-specific actions include:

- Oil and gas exploration and development,
- Residential and commercial development,
- Groundwater drawdown,
- Land subsidence, and
- Climate change.

The "cumulative impacts" on the environment are those that result from the incremental impact of FDA's action when added to other past, present, and reasonably foreseeable future actions presented above.

Therefore, the potential environmental impacts discussed below, in some cases, may be more severe than the impacts that were described for the agency's preferred alternative. Likewise, certain agency and/or industry actions may have beneficial effects, and thus may reduce the potential severity of a potential environmental impact. These relationships are discussed below.

Water Resources

The potential cumulative impacts are described in more detail in Chapter 5.5 of the FEIS and are summarized in the following statements.

Water availability

Groundwater withdrawals, as discussed in Chapter 3.1.3.11 and Chapter 4.1 of the FEIS, continue to have significant adverse effects on the amount of water in aquifers that is available for agricultural use, human consumption, and industrial and commercial use across the nation. Significant current and ongoing adverse impacts such as reduced water availability, water-table declines, soil subsidence and increased costs for finding and maintaining access to water resulting from groundwater withdrawals are presently experienced in regions B, C, D, I, J, and U (compare Figure 1.7-4 with Figures 3.1-12 and 3.1-13 in the FEIS). These impacts are absent of any final rule. Any action (personal, Federal, state, local, etc.) in regions B, C, D, I, J, and U that would cause a farmer or any entity to draw from groundwater instead of surface water could exacerbate the current environmental conditions, generally, or in corresponding regions in the northeastern and northcentral reaches of Mexico that share an aquifer with regions D, I, or J. FDA does not anticipate the final rule to result in the management decisions being that farms switch to groundwater sources (Chapter 4.7 of the FEIS). However, some limited number of farms may switch to groundwater sources, and therefore, would exacerbate the significant impacts currently occurring to this resource.

Sprouting operations – water availability

The majority of the 285 covered sprouting operations draw from municipal water already; only minimal adverse (not significant) impacts may occur from water treatment effluent; and no nationwide or regional impacts are anticipated to water availability from those few operations that may connect to municipal water supplies. This small number of operations nationwide is not anticipated to significantly contribute to cumulative impacts nationwide or regionally.

Water quality

As discussed in Chapter 4.7 of the FEIS, the added flexibility in meeting FDA's water quality standard is likely to limit the need to use chemical treatment of a water source with poor water quality. It is also likely that a farmer might add a post-harvest mechanism to allow for added pathogen die-off or removal. Similar to water availability (discussed immediately above), water quality is a current and ongoing problem throughout the U.S. and is exacerbated by all the same influences as is water availability. As discussed under the No Action Alternative (Chapter 4.1 of the FEIS), decreasing water flow and supply tends to worsen the concentrations of water contaminants that may otherwise be diluted under higher water flow conditions.

While FDA does not anticipate the environmental impacts of the final rule associated with water quality to significantly contribute to water quality concerns (see Chapter 4.7 of the FEIS), current conditions are expected to be somewhat worsened. However, sustained, long-term water treatment may not be required because the added flexibility to account for die-off and/or removal is anticipated to result in few, intermittent impacts that are not significant because any steps taken to comply with the rule may be as simple as allowing sufficient time between final application of agricultural water in the field and harvest. Water quality would be expected to return to ambient conditions. Regions that are important under these ongoing conditions for water quality issues and covered produce, include regions A, B, C, L, R, T, and U (see Chapter 4.1 of the FEIS).

Biological and Ecological Resources

As discussed in Chapter 4.7 of the FEIS, adverse effects to biological and ecological resources relevant to groundwater drawdown are not expected. Although the potential cumulative effects from groundwater drawdown relative to existing and expected ongoing conditions may potentially be significant, it is important to also consider the context of human influences along with conservation measures that exist and that are expected to continue.

In addition to water availability, potential cumulative effects on biological and ecological resources will include the pressures of climate change, human development (residential and commercial and its associated environmental effects), and the continued increase in invasive plants and animals that so often disrupt regional ecosystems and species populations (see Chapter 3.2.1 of the FEIS). Energy development, such as oil and gas exploration activities nationwide, has an additive adverse effect to biological diversity, productivity, and fertility that results from increased levels of toxins contributed to the environment and loss of habitat that provides food and cover for all types of species.

With respect to water quality, potential adverse effects may occur from the use of disinfectants to treat poor quality water in certain areas (as follows). Disinfectants may be useful for reducing hazards that may cause foodborne illnesses; however, many of these disinfectants may form harmful byproducts. EPA-registered pesticide products are evaluated to determine potential environmental effects and potential impacts to human health specific to their use. The persistence of chemicals (e.g., antimicrobials or disinfectants) in the environment may adversely influence non-target systems (e.g., wetlands and riparian ecology) and have further indirect effects to flora and fauna coming into contact with those chemicals. If a grower were to choose to use chemical treatment to bring water into compliance, sustained, long-term water treatment may not be required because the added flexibility to account for die-off. Providing that any pesticide that is EPA-registered and is handled and applied in accordance with labeling requirements, which we have determined to be the reasonably foreseeable use of such products, the use of such products should not result in significant environmental impacts to vegetation, wildlife, and wetland resources. There would be no anticipated impact to the sustainability of vegetation or wildlife at the regional or national level. Impacts to wetlands or waters would not be significant because water quality conditions would be expected to return to ambient conditions. Additionally, as long as the pesticides are handled and applied according to label directions, which we have determined to be a reasonably foreseeable use (see Chapter 4.1 and 4.2, and Appendix E of the FEIS), we do not expect significant environmental impacts to result. Any potentially adverse effects that are associated with the proper use of pesticides may be somewhat limited because a high number of growers in key growing regions, such as California, Arizona, and Florida (Regions C, D, and U), already participate in marketing agreements that have more stringent numeric water quality standards than what FDA has proposed, and are already using water that would be in compliance with the proposed standard. As a result, such impacts would not be the result of the final rule.

With respect to both grazing/working animals and animal intrusion, the most likely management decision would be to evaluate whether produce can be harvested safely and, as appropriate, not harvest a field or part of a field that is reasonably believed to be contaminated from wildlife intrusion. We would not expect environmental impacts to water resources, waste generation, disposal, and resource use, and air quality associated with this management decision.

Any measures taken to exclude wildlife (including measures to clear land to facilitate monitoring) may involve the use of herbicides, rodenticides, or other materials that may have short-term toxic effects to water resources, biological resources and ecosystems directly adjacent to the farm, and soils. These impacts may be reduced through proper use and handling in accordance with labeling requirements, which we determined to be a reasonably foreseeable use; therefore, we do not expect significant impacts vegetation or wildlife (see Chapter 4.1 and 4.2, and Appendix E of the FEIS). Impacts to wetlands or waters would not be significant because water quality conditions would be expected to return to ambient conditions. In addition, given the very low number of farms that could be affected (between 1.5 and 8 percent of covered farms), there would be no anticipated impact to the sustainability of vegetation or wildlife or to water quality at the regional or national level. Through the use of pest management plans

and wildlife removal in accordance with state and local regulations (such as through hunting and trapping permits) (see Chapter 4.6 on hunting and trapping permit discussions), adverse cumulative effects may be effectively minimized and considered not significant.

Soils

Land subsidence

In Chapter 4.7 of the FEIS, we concluded that significant adverse impacts related to groundwater drawdown and the related adverse impacts to soils are anticipated as a result of the produce rule (although the added flexibility in meeting FDA's water quality standard and in light of public comments on the supplemental rule that indicate that because of the added flexibility, a management decision to switch to groundwater sources is not anticipated to be the preferred management decision). When one considers the potential significant adverse effects related to groundwater drawdown (these effects are ongoing, see USGS, 2013), it may be reasonable to predict continued adverse impacts related to land subsidence. Regions that may be most impacted by land subsidence (as discussed in Chapter 4.1 of the FEIS) include regions B, C, D, I, J and U (see Figure1.7-4 in the FEIS), as well as corresponding regions in the northeastern and northcentral reaches of Mexico that share an aquifer with regions D, I, or J. Therefore, impacts on groundwater resources, where steps are not taken to reduce the impacts as discussed in Chapter 3.1.3.11 of the FEIS, may result in irreversible impacts on soils and corresponding impacts on the ability of those soils to filter nutrients, chemicals and pathogens.

Soil quality

With respect to soil health and impacts related to subpart F, a minimum application interval of 0 days between the application of the BSA and harvest, as provided in the final rule (i.e., for untreated BSAs that are applied in a manner that does not contact covered produce during or after application; certain treated BSAs that are applied in a manner that minimizes contact with covered produce during and after application; and certain other treated BSAs that are applied in any manner) would not represent a substantial change from the baseline condition, and, therefore, would not result in additional impacts to soil resources.

With respect to subpart I, in most cases, covered dual- or multi-purpose operations already have fields that are dedicated pasturelands and would not, under normal conditions, be rotated in for crop land. Any impacts to soils in these areas are most likely already occurring, and therefore, no significant impacts from grazing are expected.

Waste Generation, Disposal, and Resource Use

For untreated BSAs of animal origin, a minimum application interval of 0 days between the application of untreated BSA and harvest when the untreated BSA is applied in a manner that does not contact covered produce during or after application, would not represent a substantial change from the baseline condition. Therefore, we do not expect additional impacts to waste generation, disposal, or use of the resource. No impacts will be associated with this provision and corresponding management decisions. The use of chemical fertilizers in place of treated or untreated BSAs of animal origin as a nutrient source is unlikely to occur under this alternative because the alternative does not restrict the timing of the use of BSAs, but will impose certain requirements to apply some types of BSAs in a manner that does not contact or minimizes contact with covered produce.

Air Quality and Greenhouse Gases

Air quality (and related greenhouse gas and energy usage) impacts from agriculture that are already occurring include the generation of methane from animal operations (including distribution/transportation of manure, composting, and use on fields), use of fuels to manage farming operations (including equipment, vehicles, and facilities), and use of chemical fertilizers. Criteria pollutants and other greenhouse gases are generated daily by commercial and residential development, oil and gas exploration, and other human activities. The net generation of criteria pollutants and other greenhouse gases are not expected to change considerably at a regional or national level as a result of the final rule because the preferred alternative and related most likely management decisions are not expected to

contribute to air emissions of criteria pollutants or GHG emissions that may result in considerable public health concerns at a regional or national level.

No new methane production is expected (the general same amount of animal waste that is generated today is not expected to change as a result of the rule).

Socioeconomics and Environmental Justice

With respect to cumulative impacts, farms all over the U.S. are subjected to pressures from water availability and water quality as a result of competing commercial, residential, and industrial water interests, and the interests of public and private oil and gas exploration efforts. Farms, like the rest of U.S. businesses and residents, are subject to increasing costs for goods (equipment) and services (power and water for example). The result has been an overall increase in operating costs, and an overall decrease in farming (see trends as discussed in Chapter 1.9 of the FEIS). Farms have been very adaptable, finding new and innovative methods to plant and harvest crops, regulate the use of water, and apply nutrients to soils (through the use of nutrient management plans – which when accompanied with regular soil testing as most plans accomplish, allow the farmer to better manage nutrient application in a more efficient manner to different parts of even the same field).

FDA considered the economic costs of the PS PR to covered farms when considering the environmental alternatives and associated socioeconomic impacts in the FEIS. The average projected per-farm cost of complying with the provisions of the PS PR was estimated at approximately $4,477 for very small farms, $12,384 for small farms, and $29,545 for all other covered farms. FDA has updated these numbers in the FRIA that accompanies the final rule, and, as such, the projected per-farm cost for very small farms is $5,872 $24,683for small farms and $38,741 for all other covered farms (FDA, 2015c). While small and very small farms may not be able to afford this added cost burden, FDA anticipates that for these farms, if they are not able to qualify for an exemption to reduce the cost of compliance, they would be the most likely to make management decisions which would either result in them not being subject to the provisions of the final rule or that would make them exempt from the provisions. As discussed in Chapters 4.7 and 4.2 of the FEIS, based on the comments FDA has received, FDA does not expect that individual primary farm operators would cease growing covered produce as a preferred management decision except in select instances which are often driven by outside pressures unrelated to this rule (an example cited in Chapter 4.7 of the FEIS includes the state of California that pays farmers to keep land fallow in order to divert water to the cities).

With respect to subpart F, since there is no substantial change from the existing conditions, there are no additional costs associated with this provision that may result in impacts to farm employment or loss of income.

Environmental Justice

The overall cost of compliance for farms could potentially result in higher produce prices for consumers, including minority consumers. However, we expect that demand for produce commodities would eventually be met by other growers in the region, growers in other regions, or international suppliers. As a result, we expect commodity prices to stabilize. Therefore, we do not expect significant impacts to disadvantaged populations as a result of the rule's impact to consumer costs. As discussed in Chapter 1.9 of the FEIS, FDA considers potential impacts to minority principal farm operators and farmworkers (see also Chapter 3.7.3 of the FEIS). USDA NASS survey data provides information on principal operators of farms. Available information related to farmworkers is less extensive, and FDA relied on statistics provided by USDA ERS and the U.S. Department of Labor. Increases in farm operating costs may result in adverse impacts to farmworkers, but such costs may also be transferred to consumers.

Minority groups

When considering the "meaningfully greater" threshold of 11.6 percent (see Chapters 3.7 and 4.1 of the FEIS), regions that are important for identifying potential impacts to minority primary operators are regions A, B, C, D, W, and V (see Figure 1.7-4 in the FEIS).

Principal operators

FDA is not aware of any Federal or state programs that have been implemented or that are presently being considered that may adversely or disproportionately affect minority operators, except that the same economic pressures that are discussed in Chapters 1.9 and 5 of the FEIS apply to all farmers. Minority primary operators manage farms of all size classes affected by the provisions of the rule and will need to make the same management decisions as primary operators generally regarding whether to comply with the rule or to cease growing covered produce based on cost considerations. As discussed in Chapter 4.7, of the FEIS, because of the greater added costs proportional to the amount of sales, primary operators for very small farms are generally more likely than primary operators of larger farms to make management decisions to stop growing crops altogether if the farm manages livestock operations that also grow small amounts of covered produce, although many such diversified farming-livestock operations would not likely be covered based on the new monetary threshold for excluded farms applied to sales of produce only rather than sales of food, or may be eligible for qualified exemptions (in the very small and small farm categories). Because of the monetary threshold based on sales and the qualified exemption that may be available to very small and small farms, and because there are management decisions available to all covered farms that may reduce the impacts related to employment or income (e.g.,switch to a non-covered crop), we do not expect there to be disproportionate cumulative impacts to minority primary operators covered by the rule. As noted above, potentially adverse impacts to minority primary operators are more likely to occur in regions A, B, C, D, W and V (see Figure 1.7-4 in the FEIS).

Minority farmworkers

As discussed in Chapters 3.7 and 4.7 of the FEIS, and above, regions where there are populations of minority farmworkers that may be impacted by the rule include regions C, D, I, and J (see Figure1.7-4 in the FEIS). Costs incurred by farms of all sizes may result in the farm either increasing the costs of their produce for consumers, or may involve the farm primary operator terminating the employment of full-time, part-time, or seasonal worker(s) in order to defray their operating costs. Regions were such actions may adversely disproportionately affect minority farm workers include regions C, D, I, and J.

Native American operators

As discussed in Chapter 4.7 of the FEIS, based on available data, it appears that no more than 5 percent of farms with a Native American principal operator will be covered by the rule. Despite this relatively low number of total Native American owners/operators who may be covered by the rule, there is a potential that added operating costs associated with the rule will impact a disproportionate number of Native American farmers compared to farmers as a whole, given that the average sales for a farm with a Native American principal operator is 30 percent lower than a farm with a non-Native American principal operator (per the 2007 Agricultural census). The average reported agricultural product sales for Native American operated farms are $40,331, compared to an average of $134,807 for all farms. The average potential per farm cost of approximately $6,000 could be disproportionally burdensome for Native American operated farms as it will comprise approximately 15 percent of their average annual sales, compared to 4 percent of the average annual sales of all farms.[4] However, the potential impacts for very small and small farms may be entirely mitigated to the extent these farms are eligible for a qualified exemption; therefore, potential incremental cumulative impacts may also be mitigated and would not be considered significant. It is assumed that large farms would be able to absorb any additional costs of complying with the provisions of the rule.

Water availability-related impacts

As discussed in Chapter 4.7 of the FEIS and the discussion above related to water availability, individuals on Native American reservations in regions B and J (see Figure1.7-4 in the FEIS) may be disproportionately adversely impacted as a result of continued groundwater drawdown. These conditions are a result of current and projected ongoing impacts related to water use throughout the U.S. and are anticipated to occur even if a final rule were not enacted.

[4] $6,000 divided by $40,331 equates to approximately 15 percent.

Low-income farmworkers

As discussed in Chapter 4.7 of the FEIS, impacts may involve the farm principal operator terminating the employment of full-time, part-time, or seasonal worker(s) in order to defray their operating costs. FDA has no data to determine where in the nation, or under what specific circumstances may occur as such decisions are highly specific to the individual farm.

Human Health and Safety

Foodborne illnesses prevented

FDA has revised estimates of the number of foodborne illnesses prevented when considering the rule as finalized in the FRIA. The number of illnesses prevented for all provisions is 331,964 million annually (FDA, 2015b). This represents a significant beneficial outcome to human health.

Human health impacts

Any management decision that may adversely affect primary operator and farm worker health would potentially be related to chemical treatment of irrigation water. FIFRA mandates that EPA regulate the use and sale of pesticides to protect human health and preserve the environment. The risks to worker health are minimized when using proper handling techniques including using recommended personal protective equipment in accordance with labeling requirements or product recommendations (e.g., chemically resistant gloves to avoid exposures that may otherwise cause significant health effects) as described by the manufacturer. We have determined that the proper use of pesticides is a reasonably foreseeable use (see Chapter 4.1, 4.2, and Appendix E of the FEIS).

Mitigation

In accordance with 40 CFR 1502.14(f) and 1502.16(h), the FEIS identifies a variety of mitigation measures that are intrinsically part of FDA's determination of the level of impacts. A mitigating factor of particular importance is FDA's development of a compliance strategy that will be used for the implementation of the final rule. Education and technical assistance (including FDA-issued guidance documents) are the principal components of the compliance strategy. FDA believes that a comprehensive compliance strategy focused on education and technical assistance for farmers can help alleviate any uncertainty about requirements of the final rule, which, in turn, can help ensure that the provisions of the final rule are appropriately followed.

FDA has diligently been working toward this effort since FSMA was enacted. For example, in May 2014, FDA published the "Operational Strategy for Implementing the Food Safety Modernization Act (FSMA): Protecting Public Health by Strategic Implementation of Prevention-Oriented Food Safety Standards," which describes the guiding principles for implementing all aspects of FSMA, including produce safety standards. In addition, FDA held a two-day public meeting entitled "FDA Food Safety Modernization Act: Focus on Implementation Strategy for Prevention-Oriented Food Safety Standards" on April 23-24, 2015, to present FDA's current implementation plans. The meeting was announced in the *Federal Register* on March 24, 2015, and included information on how to submit comments to a docket established to obtain comments on the FSMA implementation work plans (80 Fed. Reg. 15612).

With respect to education and technical assistance, FDA firmly believes that compliance cannot be effectively achieved based on FDA's efforts alone. Rather, FDA is building a network of partners that can assist with providing education and technical assistance to the farming community. This network involves collaboration with various institutions primarily via cooperative agreements, partnerships, and alliances—each of which is, in turn, described more fully below.

One of the key members of the network is the National Association of State Departments of Agriculture (NASDA), in which all 50 U.S. State Departments of Agriculture and the territories of American Samoa, Guam, Puerto Rico, and the U.S. Virgin Islands participate. In September 2014, FDA announced that a new cooperative agreement has been established between FDA and NASDA that will provide critical information on local produce growing, harvesting, packing, and holding, in an effort to assist states with

aligning their requirements with the final rule. Specifically, the cooperative agreement will "provide the funding and support necessary to determine the current foundation of state law, the resources needed by states to implement the produce safety rule, as well as develop a timeline for successful implementation once the rule is finalized" (FDA, 2014b).

While education and technical assistance will be available to everyone in the farming community who must comply with the final rule, special focus has been put on farmers with small operations. Accordingly, in January 2015, FDA announced that it has formed a collaborative partnership with the USDA's National Institute of Food and Agriculture (NIFA) to administer and manage the "National Food Safety Training, Education, Extension, Outreach, and Technical Assistance Program," a grant program that will provide funding so that small farms receive adequate training, education, and technical assistance.

The announcement also lists training grant application types that will be prioritized: "Priority will be given to those submitting grant applications to train owners and operators of small and medium-size farms; farmers just starting out in business; socially disadvantaged farmers; small food processors; small fruit and vegetable wholesalers; and farms that lack access to food safety training and other educational opportunities" (FDA, 2015d). The NIFA-FDA program will also award grants to establish one national coordination center that will coordinate the overall program and four regional centers that will reach out to the local communities. Moreover, the regional centers will coordinate with each other through the national coordination center which will further make certain that the information is provided throughout all areas of the country. In addition to NIFA, FDA is partnering with multiple other organizations to assist with the implementation of the final rule such as land grant University Cooperative Extension Services, community based organizations, and food safety professional organizations.

Currently, FDA is also working with the Produce Safety Alliance (PSA) and the Sprout Safety Alliance (SSA) to develop training to help the farming community understand and comply with the final rule. The PSA, a collaborative effort with Cornell University, is currently developing training materials on the rule's requirements. The SSA, centered at the Illinois Institute of Technology, is also developing training materials specifically designed to assist sprout growers. In addition to classroom training, FDA is collaborating with NASDA to develop a voluntary on-farm assessment program. These assessments are intended to be conducted before the compliance period is in effect to assist farmers in understanding what the rule requires before the mandatory compliance date arrives.

Along with education and technical assistance, FDA-issued guidance documents round out the principal components of our implementation strategy. Section 419(e) of the FFDCA requires FDA to issue guidance documents to assist the farming community with rule compliance. FDA anticipates that the principle guidance document for compliance with the rule will be published in 2016, with other guidance documents following as resources allow. FDA will provide opportunity for public comment on the draft guidance documents so FDA can gain input from the affected community before issuing final guidance.

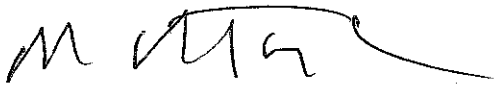
Tiering

Under the final rule, variances may be requested by states, Tribes, or foreign governments by submitting to FDA a citizen petition using the process described in 21 CFR 10.30, specifically identifying the standard or standards from which the requesting entity is requesting a variance and identifying the specific growing conditions and science-based procedures or practices that will support the use of a variance. Variances may be requested for one or more requirements of the rule. For example, these variances may include (1) variances from the microbial quality criteria when agricultural water is used during growing activities for covered produce (other than sprouts) using a direct water application method, established in § 112.44(b); (2) variance from the microbial die-off rate that is used to determine the time interval between last irrigation and harvest, and/or the accompanying maximum time interval, established in § 112.45(b)(1)(i); and (3) variance from the approach or frequency for testing water used for purposes that are subject to the requirements of § 112.44(b), established in § 112.46(b). FDA expects requests for variances to be supported by relevant and scientifically valid information or materials specific to the covered produce or covered activity to support the petitioner's determination that the variance requested is reasonably likely to ensure that the produce is not adulterated and to provide the same level of public

health protection as the relevant requirement. For example, this could include information about the crop, climate, soil, and geographical or environmental conditions of a particular region, as well as the processes, procedures, or practices followed in that region.

An FDA action to grant or deny a particular variance request is independent from the final rule, which establishes the procedures that must be followed for any variance requests. A decision by FDA to grant or deny a variance request would be a "major Federal action" (as defined in 40 CFR 1508.18). Therefore, FDA will evaluate, independent of the final rule, its obligations under NEPA for a decision to grant or deny a particular variance request submitted consistent with such required procedures. Therefore, FDA does not need to consider environmental impacts related to the administrative procedural requirements for variances in the Final EIS.

Certification/ Signature



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