Food

Fact Sheet on the FSMA Proposed Rule for Produce: Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption

Produce Safety Standards under the FSMA Main Page[1]

View the Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption Proposed Rule[2].
Docket Number: FDA-2011-N-0921[3]; comments due by May 16, 2013

See also:

- Preliminary Regulatory Impact Analysis
  Note: *On January 4th, the Produce Safety proposed rule and its accompanying Preliminary Regulatory Impact Analysis (PRIA) statement were posted on the site. An incorrect version of the PRIA statement was posted at that time. On January 16th, a corrected version of the PRIA statement was posted and is available in the docket folder, see FDA-2011-N-0921[4], as reference 265.*
- *What You Need to Know: Proposed Rule on Standards for Produce Safety Under the FDA Food Safety Modernization Act (FSMA)*[5]
- Fact Sheets on Subparts of the Rule
  - Equipment, Tools, Buildings, and Sanitation: Subpart L[6]
  - Biological Soil Amendments: Subpart F[7]
  - Domesticated and Wild Animals: Subpart I[8]
  - Personnel Qualifications, Training, and Health and Hygiene: Subparts C and D [9]
  - Agricultural Water: Subpart E [10]
  - Sprouts: Subpart M[11]

Summary

On January 4, 2013, FDA released for public comment its proposed rule to establish science-based standards for growing, harvesting, packing and holding produce on domestic and foreign farms. The proposed rule is one of five proposed rulemakings that would lay the cornerstone of the prevention-based, modern food safety system we need.

Section 105 of the Food Safety Modernization Act (FSMA) directs FDA to set science-based standards for the safe production and harvesting of fruits and vegetables that the Agency determines minimize the risk of serious adverse health consequences or death. FDA proposes to set standards associated with identified routes of microbial contamination of produce, including: (1) agricultural water; (2) biological soil amendments of animal origin (3) health and hygiene (4) animals in the growing area and (5) equipment, tools and buildings. The proposed rule includes additional provisions related to sprouts.

The proposed produce rule covers most fruits and vegetables while they are in their raw or natural (unprocessed) state. It would not apply to raw agricultural commodities that are rarely consumed raw, those produced for personal or on-farm consumption, and (with certain documentation) those destined for commercial processing, such as canning, that will adequately reduce microorganisms of public health concern.

Some farms would not be covered by the rule, or would be eligible for a partial exemption based on

factors including the monetary value of their food sales and to whom they sell. The partial exemption would still subject eligible farms to certain modified requirements, and could be withdrawn in certain circumstances.

FDA is proposing that the requirements be effective 60 days after a **final rule** is published in the Federal Register. Recognizing that small and very small businesses may need more time to comply with the requirements, compliance dates would be phased in based on business size.

In a separate Federal Register notice, FDA will be announcing a series of public meetings to explain the proposal and additional proposed rules and to provide additional opportunity for input.

Background

FSMA was signed into law by President Obama on January 4, 2011 to better protect public health by helping to ensure the safety and security of the food supply. FSMA embraces preventing food safety problems as the foundation of a modern food safety system.

It is widely recognized that produce is an essential component of a healthy diet, and the safe production and harvesting of fruits and vegetables helps consumers to maintain healthy diets. Foodborne illness outbreaks associated with contaminated produce over the last decade have caused a widespread recognition that we need a new, modern food safety system that prevents food safety problems in the first place--not a system that just reacts once they happen. FDA's analysis of available foodborne illness outbreak data document 131 outbreaks associated with contaminated produce between 1996 and 2010, causing more than 14,000 illnesses and 34 deaths. These foodborne illness outbreaks were caused mainly by biological hazards such as *Salmonella*, *E. coli* O157:H7, *Shigella*, Hepatitis A, and *Cyclospora*. Therefore, the proposed FDA produce rule focuses on setting enforceable standards that are reasonably necessary to prevent the introduction of known or reasonably foreseeable biological hazards and providing reasonable assurances that produce is not adulterated on account of these hazards.

The proposed rule builds on the more than 10 years of produce safety activities by the FDA, as well as the produce industry and other stakeholders, to put in place science-based best practices and standards for the growing, harvesting, packing and holding of fruits and vegetables. For instance, the FDA has issued guidance to the industry on Good Agricultural Practices (GAPs) and commodity-specific guidance on sprouts, and has also developed draft commodity-specific guidance that addresses food safety considerations for tomatoes, melons and leafy greens. Industry efforts have included development of numerous commodity-specific guidance documents that address on-farm food safety practices. Additionally, the industry, in collaboration with the U.S. Department of Agriculture and State departments of agriculture, has developed Leafy Greens Marketing Agreements in California and Arizona. In 2009, the Association of Food and Drug Officials published a Model Code for Produce Safety that was developed with input from industry, consumer groups, researchers, and state and local public health officials. Florida also passed state regulations for the safe production and handling of fresh market tomatoes. We also considered relevant international guidelines related to the safety of fruits and vegetables in developing this proposed rule.

Who is Covered by the Rule?

The proposed rule would establish science-based minimum standards for the safe growing, harvesting, packing, and holding of produce in its raw or natural (unprocessed) state on farms. For the purposes of this proposed rule, produce means fruits and vegetables grown for human consumption. This would include, for example, lettuce, spinach, cantaloupe, tomatoes, sprouts, mushrooms, onions, peppers, cabbage, citrus, strawberries, and walnuts. The FDA proposed produce safety rule considers both the commodity and the practices associated with growing, harvesting, packing and holding produce as well as how produce will be used and consumed after it leaves the farm. The proposed produce rule provides growers flexibility in their approach to on-farm food safety, so that food safety practices being taken by farmers can be appropriate for the scale of production and type of agricultural practices being used.

Farm mixed-type facilities (farms that are also engaged in activities outside the definition of "farm" that require food facility registration), may be subject to both the proposed produce safety rule and the forthcoming preventive controls proposed rule, depending on whether any exemptions apply. An example is an establishment that grows and harvests produce but also conducts activities

such as processing fresh-cut produce that requires the establishment to be registered. In such cases, only the establishment's "farm" activities would be subject to the proposed produce safety rule.

Limitations on Coverage of the Proposed Rules

As required by Congress, farms would be partially exempt from the proposed rule if they meet two requirements. First, they must have food sales averaging less than $500,000 per year during the last three years (adjusted for inflation). Second, their sales to qualified end-users must exceed their sales to others during the same period. A qualified end-user is either a consumer (in any location) or a restaurant or retail food establishment located in the same State as the farm or not more than 275 miles away from the farm. However, FDA may withdraw this partial exemption if the farm is directly linked to an outbreak, or if FDA determines it is necessary to protect the public health and prevent or mitigate an outbreak based on conditions or conduct that create the potential for the farm's produce to cause an outbreak.

If a farm qualifies for this partial exemption, certain labeling requirements would apply. That is, if a label is otherwise required on the produce that would otherwise be covered (tomatoes packaged in a clam shell are an example) then the label must include the name and business address of the farm where the produce was grown. If a label is not required then the name and business address of the farm where the produce was grown must be displayed at the point of purchase (such as on a poster, for example).

In addition, the proposed rule excludes certain produce that constitute the lowest risk with respect to biological hazards. Examples include produce that is rarely consumed raw, such as potatoes, or that is destined for further processing that includes a kill step (with certain documentation), such as green beans destined for a canning operation.

The proposed rule also would not apply to produce for personal or on-farm consumption.

FDA also is proposing that the smallest farms—those with an average annual value of food sold during the previous three-year period of $25,000 or less—would not be covered.

Highlights of the Proposed Rule

FDA is proposing to establish science-based minimum standards for the safe growing, harvesting, packing, and holding of produce on farms. The proposed rule focuses on identified routes of microbial contamination of produce, including:

- **Agricultural Water.** Water used for produce production presents different microbial quality demands depending on its use. Water can be a carrier of many different microorganisms of public health concern. The proposed rule would require that all agricultural water be safe and of adequate sanitary quality for its intended use. "Agricultural water" would be defined in part as water that is intended to, or likely to, contact covered produce or food-contact surfaces. The proposed rule would require that, at the beginning of the growing season, the agricultural water system components under a farm's control be inspected to identify conditions that are reasonably likely to introduce pathogens to produce or food-contact surfaces. FDA is proposing that specific criteria for the quality of agricultural water be established for water that is used for certain purposes, with proposed requirements for periodic analytical testing.
- **Biological Soil Amendments of Animal Origin.** Biological soil amendments of animal origin, such as composted manure, may contain pathogens of public health concern. To address this, the rule proposes three types of measures to reduce the risk: types of treatment, methods of application, and time intervals between the application of a biological soil amendment of animal original and crop harvest. The proposed rule also has provisions pertaining to the handling and storage of biological soil amendments of animal origin.
- **Health and Hygiene.** Bacteria, viruses, and parasites are frequently transmitted from person to person and from person to food, particularly through the fecal-oral route. The proposed rule would require that farm personnel use hygienic practices, including hand washing and maintaining adequate personal cleanliness.
- **Domesticated and Wild Animals.** Pathogens can be introduced into fruit and vegetable

production systems via animal feces. Where there is a reasonable probability that animals will contaminate produce, the rule proposes certain requirements, such as an adequate waiting period between grazing of domesticated animals and harvesting produce from that growing area. Similarly, for working animals used where a produce crop has been planted, farms would be required to take measures to prevent pathogens from being introduced onto the produce. In addition, farms would be required to monitor for significant wild animal intrusion events both immediately before harvest, and, as needed during the growing season, and not harvest produce that is visibly contaminated with animal excreta.

- **Equipment, tools and buildings.** Among other things, the proposed rule also would set standards for certain equipment and tools, buildings, and sanitation used for produce operations on farms.

Other areas addressed in the standards include:

- **Sprouts.** Sprouts present a unique risk because the warm, moist, and nutrient-rich conditions required to produce sprouts are the same conditions that are also ideal for the growth of pathogens. The proposed rule would require treating seed before sprouting, testing spent sprout irrigation water (or sprouts, in some cases) for pathogens and monitoring the growing environment *for Listeria species* or *Listeria monocytogenes*.
- **Training.** The proposed rule would require training for farm personnel who handle the produce or food-contact surfaces, and for supervisors.

Alternatives and Variances

The proposed rule would provide that farms may establish alternatives to certain requirements related to water and biological soil amendments of animal origin if the alternative is scientifically established to provide the same amount of protection as the requirement in the proposed rule without increasing the risk of adulteration.

The proposed rule also would allow a state or foreign country to request a variance from some or all provisions of the proposed rule, if the state or country determines that it is necessary in light of local growing conditions, and practices under the proposed variance provide the same level of public health protection as the requirements of the proposed rule without increasing the risk of adulteration. The proposed rule provides a process by which FDA would consider such requests and approve or deny them, and also provides that FDA may specify that an approved variance applies to other farms (for example, those with similar agricultural conditions).

Recordkeeping

The proposed rule would require certain records, for example, to document that certain of the standards are being met. However, it would not require duplication of records already kept for other purposes.

Effective and Compliance Dates and Definitions for Small and Very Small Businesses

FDA is proposing the following effective and compliance dates. The effective date is the date on which the rule would be codified in the Code of Federal Regulations. Recognizing that the farming community, especially small and very small farms, would need time to comply with the provisions of the rule, FDA is proposing extended times compliance dates.

- **Effective Date:** 60 days after a final rule is published.
- **Compliance Dates:** For farms that would be covered by the proposed rule, the following definitions and compliance dates would apply:
    - **Very Small Businesses**—a very small business is defined as having, on a rolling basis, an average annual monetary value of food sold during the previous three years of no more than $250,000. These farms would have four years after the effective date to comply; for some of the water requirements, they would have six years.
    - **Small Businesses**—a small business is defined as having, on a rolling basis, an average annual monetary value of food sold during the previous three years of no more than $500,000. These farms would have three years after the effective date to comply; for some of the water requirements, they would have five years.

- **Other Businesses**—other businesses would have to comply two years after the effective date. For some of the water requirements, they would have four years to comply.

Risk Assessment

In a separate document cited as a reference to the proposed rule, FDA is issuing a draft qualitative assessment of risk that provides a scientific evaluation of potential adverse health effects resulting from human exposure to hazards in produce, with a focus on the public health risk associated with on-farm microbial contamination of produce. This document helps to inform the proposed produce rule.

Economic Impact of the Proposed Rule

The proposed rule on produce safety is aimed at reducing the public health burden of foodborne illness associated with contaminated produce. We estimate the number of foodborne illnesses that would be prevented by this proposed rule to be 1.75 million, with an associated benefit of $1.04 billion, annually. We estimate the annualized costs of the proposed rule to be $459.56 million annually for domestic farms, and $170.62 million annually for foreign farms covered by the rule (for a grand total of $630.18 million annually). The proposed rule would cover an estimated 40,496 domestic farms and 14,927 foreign farms.
An estimated 75,716 domestic farms that engage in direct farm marketing to qualified end-users would be partially exempted from this proposed rule but will be subject to a labeling requirement. It is estimated that the annual total cost of the labeling requirement will be $3.82 million.

Additionally, an estimated 34,433 farms that grow, harvest, pack or hold produce that have an average annual monetary value of food sold during the previous three-year period of $25,000 or less will not be covered by this proposed rule.

However, the vast majority (approximately 90%) of covered produce acreage grown and consumed by Americans would either be covered by this proposed regulation, consumed cooked, or sent to food processing plants that have processes designed to address biological hazards associated with produce.

Rulemaking Process and Submitting Comments

FDA issues proposed rules in the Federal Register so that the public can review them and submit comments. The official title of the proposed rule is "Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption."

FDA will consider comments received during the comment period on the proposed rule and then consider revising the rule based on its review of the comments before issuing a final rule. The proposed rule and supporting documents are filed in FDA's official docket on http://www.regulations.gov[12] and also can be accessed on the FSMA website[13]. When a final rule is available, the rule and its supporting documents will be available in the same place.

FDA has conducted extensive outreach to the produce industry, the consumer community, other government agencies and the international community to gain input and perspective on this and other proposed rules required by FSMA. That input and perspective helped shape the proposed regulations in a way that will help to ensure the proposed rules are practical and flexible, as well as effective. FDA will be holding several additional meetings, including regional public meetings, during the comment period for these rules.

Assistance to Industry

Assistance to Industry
FDA intends to publish guidance documents, including guidance that explains the requirements of the rule in plain language to help businesses, particularly small and very small businesses, comply with the produce safety requirements. In addition, FDA is working with its partners through the Produce Safety Alliance and the Sprouts Safety Alliance to develop training materials and to disseminate information on produce safety to help industry, particularly small and very small businesses, comply with the a final rule.

For Additional Information

- Video: The Rulemaking Process: A Primer by FDA[14]
- Video: FDA Food Safety Modernization Act, A Primer by FDA[15]
- Fact sheet: The Food Safety Law and the Rulemaking Process: Putting FSMA to Work [16]

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Note: If you need help accessing information in different file formats, see Instructions for Downloading Viewers and Players.

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