

## PROPOSED PRODUCE SAFETY RULE

Docket Number: [FDA-2011-N-0921](#); comments due by May 16, 2013

The U.S. Food and Drug Administration's (FDA's or the Agency's) proposed rule, "Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption" (Produce Rule), will establish science-based standards for growing, harvesting, packing, and holding produce on domestic and foreign farms. When finalized, the proposed rule will be the first national standard for on-farm practices related to produce safety.

The Agency stated that its proposed regulatory approach focuses on the likelihood of contamination of produce posed by the agricultural practices applied to crops, while exempting only the lowest-risk produce. Based on its qualitative assessment of risk (QAR) of hazards related to produce production and harvesting, the Agency determined that produce commodities are potentially subject to similar microbiological hazard pathways (e.g., direct exposure to contaminated water or soil amendment). In response to these similar hazard pathways, FDA is proposing to adopt a regulatory approach to minimize the risks associated with those hazards, while providing industry flexibility to adopt alternative approaches when appropriate.

View the [Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption Proposed Rule](#).

### KEY PRINCIPLES OF THE RULE

- Considers risk posed by practices over commodities
- Science- and Risk-based
  - Focus on identified routes of microbial contamination
  - Excludes certain produce rarely consumed raw
  - Excludes produce to be commercially processed (documentation required)
- Flexible
  - Phase in compliance dates based on farm size
  - Additional time for small farms to comply
  - Variances
  - Alternatives for some provisions

### Scope of Coverage

The proposed Produce Rule would apply to certain farm activities performed on certain produce for use as human food (importantly, the Agency states that produce intended for use as animal food would not be subject to the proposed rule). The Produce Rule will cover food that is a raw agricultural commodity (RAC), as defined in section 201(r) of the Federal Food, Drug, and Cosmetic Act (FDCA), which falls under the proposed definition of "produce." In the proposed rule, "produce" is defined as any fruit or vegetable (including specific mixes or categories of fruits and vegetables) grown for human consumption and includes mushrooms, sprouts (irrespective of seed source), peanuts, tree nuts, and herbs (which are included in the definition to leave no doubt as to the status of these foods).

Exempted from the Produce Rule are food grains—meaning the small, hard fruits or seeds of arable crops or the crops bearing these fruits or seeds—that are grown and processed for use as meal, flour, baked goods, cereals, and oils rather than for fresh consumption. Further, the proposed rule provides an exclusion for produce that is rarely consumed raw and includes an "exhaustive" list of specific fruits and vegetables that would be exempt, including the following: arrowhead, arrowroot, artichokes, asparagus, beets, black-eyed peas, bok choy, brussels sprouts, chickpeas, collard greens, crabapples, cranberries, eggplant, figs, ginger root, kale, kidney beans, lentils, lima beans, okra, parsnips, peanuts, pinto beans, plantains, potatoes, pumpkin, rhubarb, rutabaga, sugarbeet, sweet corn, sweet potatoes, taro, turnips, water chestnuts, winter squash (acorn and butternut squash), and yams.

Additionally, produce receiving commercial processing that adequately reduces the presence of microorganisms of public health significance (e.g., a “kill step”) would be eligible for exemption from the requirements of the Produce Rule as long as certain documentation is kept. One cited example of a product that receives commercial processing is green beans destined for a canning operation.

Under the proposed Produce Rule, a “farm” is defined as a facility in one general physical location devoted to the growing and harvesting of crops, the raising of animals (including seafood), or both. The term “farm” includes facilities that pack or hold food, provided that all food used in such activities is grown, raised, or consumed on that farm or another farm under the same ownership, and facilities that manufacture/process food, provided that all food used in such activities is consumed on that farm or another farm under the same ownership.

In addition, a “mixed-type facility” is defined as an establishment that engages in both activities that are exempt from registration under section 415 of the FDCA and activities that require the establishment to be registered. An example of such a facility is a “farm mixed-type facility,” which is an establishment that grows and harvests crops or raises animals and may conduct other activities within the farm definition but which also conducts activities that require the establishment to be registered.

The Produce Rule would apply to both domestic and imported covered produce. However, some farms would not be covered by the rule or would be eligible for a partial exemption based on factors including, but not limited to, the monetary value of their food sales and the types of persons or entities to whom they sell.

Additionally, the Produce Rule would not cover farms that have an average annual value of food sold during the previous three-year period of \$25,000 or less.

Finally, the Produce Rule would provide a qualified exemption and modified compliance requirements for farms that meet the following two requirements: (1) the farm must have food sales averaging less than \$500,000 per year during the last 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 as the farm or not more than 275 miles away.

Instead, these farms would be required to include their names and complete business addresses either on the label of the produce that would otherwise be covered (if a label is required under the FDCA and related regulations) or at the point of purchase. However, FDA may withdraw this exemption 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 proposed rule would establish science-based minimum standards 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 (proposed §§ 112.21, 112.22, and 112.23);
- Require documentation of required training (proposed § 112.30); and
- Establish hygienic practices and other measures needed to prevent persons including visitors, from contaminating produce with microorganisms of public health significance (proposed §§ 112.31, 112.32, and 112.33).
- Requirements include
  - Training
  - Preventing contamination by ill persons
  - Toilet facilities
  - Avoiding contact with non-working animals and minimizing contact with produce when using working animals
  - Hand washing and maintaining gloves appropriately (if used)

Regardless of the nature of a farm's workers, FDA proposes that each worker receive training upon hiring and at the beginning of each growing season, with periodic training updates as necessary in order to prevent contamination of covered produce

### **Agricultural Water**

- Require that all agricultural water must be of safe and sanitary quality for its intended use (proposed § 112.41). Agricultural water is defined in part as water that is intended to, or likely to, contact the harvestable portion of covered produce or food-contact surfaces (proposed § 112.3(c));
- Establish requirements for inspection, maintenance, and follow-up actions related to the use of agricultural water, water sources, and water distribution systems associated with growing, harvesting, packing, and holding of covered produce (proposed §§ 112.42 and 112.46);
- Require treatment of agricultural water if you know or have reason to believe that the water is not safe and of adequate sanitary quality for its intended use, including requirements for treating such water and monitoring its treatment (proposed § 112.43);
- Establish specific requirements for the 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 or treated water), and requiring certain actions to be taken when such water does not meet the quality standards (proposed §§112.44 and 112.45); and provide for alternative requirements for certain provisions under certain conditions (proposed § 112.12); and
- Require certain records, including documentation of inspection findings, scientific data or information relied on to support the adequacy of water treatment methods, treatment monitoring results, water testing results, and scientific data or information relied on to support any permitted alternatives to requirements (proposed § 112.50).
- Specific requirements for the quality of water used for specific purposes and follow-up action when water does not meet the quality standards
  - 0 detectable generic E. coli standard (highest risk uses)
  - 235 CFU generic E. coli standard (direct contact with covered produce other than sprouts during growing)

FDA's proposed definition of "agricultural water" in the Produce Rule is different from its definition of "agricultural water" in the Agency's Good Agricultural Practices Guide—both because such water is not limited in the proposed Produce Rule to water in the growing environment and because FDA proposes to exclude water that does not contact covered produce from this definition based on the information in the Agency's QAR.

### **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 (proposed §§ 112.51, 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 (proposed § 112.53);
- Establish requirements for treatment of biological soil amendments of animal origin with scientifically valid, controlled, physical and/or chemical processes or composting processes that satisfy certain specific microbial standards (proposed §§ 112.54 and 112.55); and provide for alternative requirements for certain provisions under certain conditions (proposed § 112.12);
- Establish application requirements and minimum application intervals for untreated and treated biological soil amendments of animal origin (proposed § 112.56); and provide for alternative requirements for certain provisions under certain conditions (proposed § 112.12); and
- Require certain records, including documentation of application and harvest dates relevant to application intervals; documentation from suppliers of treated biological soil amendments of animal origin, periodic test results, and scientific data or information relied on to support any permitted alternatives to requirements (proposed § 112.60).

The proposed produce safety rule establishes certain processes that are acceptable for treating biological soil amendments of animal origin if they are validated to meet listed microbial validation standards. Such treatments include "chemical processes, physical processes, combinations of chemical and physical processes, and composting."

Each type of treatment process is linked to application requirements that would need to be followed in using the treated biological soil amendment of animal origin to grow covered produce (including manner of application requirements and application intervals, as applicable). In addition, the proposed rule prescribes application requirements for untreated biological soil amendments of animal origin (both a manner of application requirement and a 9 month, and for certain situations, 0 day application intervals). The economic analysis of the rule provides an example: raw manure is an untreated biological soil amendment of animal origin.

The proposed rule also requires biological soil amendments of animal origin to must be handled, conveyed, and stored in a manner and location such that they do not become a potential source of contamination and in a manner and location that minimizes the risk that treated biological soil amendments of animal origin will become contaminated by an untreated or in process biological soil amendment of animal origin. Contaminated biological soil amendments of animal origin must be handled, conveyed and stored as though they were untreated. This proposed rule also prohibits the use of human waste for growing covered produce except sewage sludge biosolids used in accordance with relevant EPA regulations or equivalent regulatory requirements. Lastly, the proposed rule establishes recordkeeping requirements with respect to the use of biological soil amendments of animal origin.

### **Domesticated and Wild Animals**

- If animals are allowed to graze or are used as working animals in fields where covered produce is grown and under the circumstances there is a reasonable probability that grazing or working animals will contaminate covered produce, require, at a minimum, an adequate waiting period between grazing and harvesting for covered produce in any growing area that was grazed, and measures to prevent the introduction of known or reasonably foreseeable hazards into or onto covered produce (proposed § 112.82); and
- If under the circumstances there is a reasonable probability that animal intrusion will contaminate covered produce, require monitoring of those areas that are used for a covered activity for evidence of animal intrusion immediately prior to harvest and, as needed, during the growing season (proposed § 112.83).

The Produce Rule would not prohibit the use of on-farm domesticated working animals, but it would require covered farms to take measures to prevent the introduction of known or reasonably foreseeable hazards into or onto covered produce if working animals are used in a growing area where a crop has been planted and when, under the circumstances, there is a reasonable probability that animals will contaminate covered produce.

### **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 (proposed §§ 112.121-134); and
- Require certain records related to the date and method of cleaning and sanitizing equipment used in growing operations for sprouts, and in covered harvesting, packing, or holding activities (proposed § 112.140).

Additional examples of equipment and tools provided in the Produce Rule are knives, implements, mechanical harvesters, waxing machinery, cooling equipment (including hydrocoolers), grading belts, sizing equipment, palletizing equipment, and equipment used to store or convey harvested covered produce (such as containers, bins, food-packing material, dump tanks, flumes, and vehicles or other equipment used for transport).

Additional examples of buildings provided in the Produce Rule are any fully or partially enclosed buildings used for covered activities, including minimal structures that have roofs but do not have any walls. FDA explained that fully enclosed buildings are typically used to grow covered produce, such as sprouts and mushrooms, and may be used to grow a variety of covered produce indoors to create or extend the growing season in a particular geographic area. FDA also explained that partially enclosed buildings can be used to grow covered produce, such as tomatoes, and are often used to pack covered produce. Buildings that are subject to the requirements of the Produce Rule would also include storage sheds, buildings, or other structures used to store food-contact surfaces (such as harvest containers and food-packing materials).

## **Sprouts**

- Establish measures that must be taken related to seeds or beans for sprouting (proposed § 112.141);
- Establish measures that must be taken for the growing, harvesting, packing, and holding of sprouts (proposed § 112.142);
- Require that you test the growing environment for *Listeria* spp. or *L. monocytogenes* and that you test each production batch of spent irrigation water or sprouts for *E. coli* O157:H7 and *Salmonella* species and take appropriate follow-up actions (proposed §§ 112.143, 112.144, 112.145, 112.146); and
- Require certain records, including documentation of your treatment of seeds or beans for sprouting, a written environmental monitoring plan and sampling plan, test results, and certain methods used (proposed § 112.150).

Because sprouts have been frequently associated with foodborne illness outbreaks, FDA proposed minimal standards specifically for them. FDA explained that sprouts present a special concern with respect to human pathogens, as compared with other covered produce, because of the warm, moist, and nutrient-rich conditions required to produce sprouts—the same conditions that are also ideal for the proliferation of pathogens if present. FDA is seeking comment on whether, or to what extent, the proposed requirements in the Produce Rule should be applied to soil-grown sprouts.

### **Growing, Harvesting, Packing and Holding Activities**

- Proposal includes science-based, minimum standards related to growing, harvesting, packing and holding
- Requirements include:
  - Separating covered and excluded produce and cleaning and sanitizing as necessary
  - Not distributing covered produce that drops to the ground before harvest unless it receives commercial processing
  - Food-packing material must be appropriate for use

### **Record Keeping Required**

- The proposed rule would require certain records, for example to document that certain standards are being met
  - Example: agriculture water testing results
- Records already kept for other purposes need not be duplicated
- Electronic records would be acceptable but not required
- Offsite storage of records is permitted after 6 months following the date the record was made if such record can be retrieved and provided onsite within 24 hours of request for official review. Records must be kept for two years after the date the record was created.

### **Inspections**

- Inspections will, of necessity, be targeted to those farms that present the greatest risk based, in part, on their association with past outbreaks or contamination events and the risk associated with the agricultural practices they apply in the growing, harvesting, packing, and holding of covered produce.
- Proposed § 112.193 provides that under Section 419(b)(2)(A) of the FD&C Act, FDA coordinates education and enforcement activities by State, Territorial, tribal, and local officials. As described above, FDA plans to work closely with State, Territorial, tribal, and local partners to develop the education and enforcement tools and training programs needed to facilitate consistent inspection and regulatory activities associated with the requirements proposed in subparts A through O.

### **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).

As proposed in § 112.12(a), you may establish alternatives to the following requirements:

- (1) the requirements in § 112.44(c), for testing water, and taking action based on test results, when agricultural water is used during growing operations for covered produce (other than sprouts) using a direct water application method;
- (2) the composting treatment processes required in § 112.54(c)(1) and (2);
- (3) the minimum application interval established in § 112.56(a)(1)(i) for an untreated biological soil amendment of animal origin; and
- (4) the minimum application interval established in § 112.56(a)(4)(i) for a biological soil amendment of animal origin treated by a composting process.

### **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.

### **How do I comment on the proposed rules?**

These are **proposed draft rules** and not final regulation. Stakeholders are encouraged to comment on aspects of the rules they object to or do not understand.

**Submit either electronic or written comments by May 16, 2013.**

**Electronic Submissions:** Submit electronic comments in the following way:

- Federal eRulemaking Portal: <http://www.regulations.gov>. Insert the docket number into the “search” box and follow the instructions for submitting comments.

**Written Submissions:** Submit written submissions in the following ways:

- Mail/Hand delivery/Courier (for paper or CD-ROM submissions): Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

All submissions received must include the Agency name and Docket No. FDA-2011-N-0921 and Regulatory Information Number RIN 0910-AG35 for this rulemaking.

**Questions? Contact Gwendolyn Wyard**  
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