

MEMORANDUM

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RE: FDA Releases FSMA Final Rule on Produce Safety Standards

The Food and Drug Administration (FDA) has released its final rule on Standards for the Growing, Harvesting, Packing, and Holding Produce for Human Consumption under the FDA Food Safety Modernization Act (FSMA). Although the Produce Safety rule is primarily relevant to farms and other operations that grow, harvest, pack and hold produce, it is also relevant to food processors. An understanding of the scope and basic requirements of this rule is important for food companies conducting supplier verification activities under the Preventive Controls rules or under the Foreign Supplier Verification Program (FSVP). ^{1/} In addition, food companies that commercially process produce are subject to additional requirements under the Produce Safety rule, even if exempt from other FSMA requirements. This memorandum summarizes key components of the Produce Safety Rule of most interest to food manufacturers.

Overview

This final rule is FDA's first mandatory regulation of fresh produce. FSMA requires FDA to establish science-based minimum standards for the safe production and harvesting of those types of fruits and vegetables that are raw agricultural commodities (RACs) for which FDA has determined such standards are needed to minimize the risk of serious adverse health consequences or death. Rather than require specific standards for different commodities, ^{2/} the rule sets out safety standards to address six hazards that FDA considers to be potential routes of microbiological contamination of produce generally: agricultural water; biological soil amendments; worker hygiene; employee training; buildings, tools, and equipment; and, domesticated and wild animals. It also has separate standards for sprouts.

^{1/} See Hogan Lovells memorandum entitled "FDA Issues Foreign Supplier Verification Program Final Rule Under FSMA."

^{2/} The agency rejected a commodity based approach because "while different commodities may have different risk profiles at different stages of production, all commodities have the potential to become contaminated . . . especially if practices are poor and/or conditions are insanitary." In addition, the agency concluded that "an approach that relies on outbreak data, or certain commodity characteristics, to make determinations about which produce should be covered would be inconsistent with the prevention-based approach mandated by FSMA and that relying on outbreak data would be insufficient to protect the public because many foodborne illnesses are not linked to an outbreak and the patterns of outbreaks associated with produce commodities change over time."

Therefore, unless otherwise exempt, the rule covers all produce, both domestic and foreign. Further, it covers many operations not traditionally considered “farms” because for purposes of this rule, FDA uses the same definition of “farm” as in the Preventive Controls rule, which was revised to be broader in scope. As a result, the rule is far-reaching and covers many operations.

The rule focuses on biological hazards related to growing, harvesting, packing and holding produce. It does not establish standards for physical and chemical hazards. Those hazards continue to be addressed under the general prohibition on adulteration under the Federal Food, Drug, and Cosmetic Act.

SCOPE OF THE PRODUCE SAFETY RULE

Which Categories of Produce Are Covered?

The rule covers “produce” that is a raw agricultural commodity (RAC). “Produce” is defined in part as “any fruit or vegetable (including mixes of intact fruits and vegetables) and includes mushrooms, sprouts (irrespective of seed source), peanuts, tree nuts, and herbs.” It does not include food grains meaning “the small, hard fruits or seeds of arable crops, or the crops bearing these fruits or seeds, that are primarily grown and processed for use as meal, flour, baked goods, cereals and oils rather than for direct consumption as small, hard fruits or seeds (including cereal grains, pseudo cereals, oilseeds and other plants used in the same fashion).” The rule includes a list of commodities meeting the definition of produce.^{3/}

The following types of produce are not “covered produce” under the rule:

- (1) Specific produce commodities that are rarely consumed raw, such as potatoes, peanuts, and sweet corn; ^{4/} [Note that the exhaustive list of produce rarely consumed raw has changed from the proposed rule.]

^{3/} Fruits and vegetables such as almonds, apples, apricots, apriums, Artichokes-globetype, Asian pears, avocados, babacos, bananas, Belgian endive, blackberries, blueberries, boysenberries, brazil nuts, broad beans, broccoli, Brussels sprouts, burdock, cabbages, Chinese cabbages (Bok Choy, mustard, and Napa), cantaloupes, carambolas, carrots, cauliflower, celeriac, celery, chayote fruit, cherries (sweet), chestnuts, chicory (roots and tops), citrus (such as clementine, grapefruit, lemons, limes, mandarin, oranges, tangerines, tangors, and uniq fruit), cowpea beans, cress-garden, cucumbers, curly endive, currants, dandelion leaves, fennel- Florence, garlic, genip, gooseberries, grapes, green beans, guavas, herbs (such as basil, chives, cilantro, oregano, and parsley), honeydew, huckleberries, Jerusalem artichokes, kale, kiwifruit, kohlrabi, kumquats, leek, lettuce, lychees, macadamia nuts, mangos, other melons (such as Canary, Crenshaw and Persian), mulberries, mushrooms, mustard greens, nectarines, onions, papayas, parsnips, passion fruit, peaches, pears, peas, peas-pigeon, peppers (such as bell and hot), pine nuts, pineapples, plantains, plums, plumcots, quince, radishes, raspberries, rhubarb, rutabagas, scallions, shallots, snow peas, soursop, spinach, sprouts (such as alfalfa and mung bean), strawberries, summer squash (such as patty pan, yellow and zucchini), sweetsop, Swiss chard, taro, tomatoes, turmeric, turnips (roots and tops), walnuts, watercress, watermelons, and yams

^{4/} The following is the exhaustive list of the types of produce that would be exempted on this basis: 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 (seeds and weed); eggplants; figs; ginger; hazelnuts; horseradish; lentils; okra; peanuts; pecans; peppermint; potatoes; pumpkins; squash, winter; sweet potatoes; and water chestnuts.

- (2) Produce of any kind that is produced for personal consumption or consumption on the farm or another farm under the same ownership;
- (3) Produce that is not a RAC; and,
- (4) Produce that receives commercial processing that adequately reduces the presence of microorganisms of public health significance (e.g., a “kill step”), as long as certain conditions are met (e.g., oranges used to make pasteurized orange juice; cucumbers used in pickle production).^{5/}

To be eligible for the commercial processing exemption, the following conditions must be met:

- The farm must disclose in documents accompanying the produce that it is “not processed to adequately reduce the presence of microorganisms of public health significance”;
- The farm must obtain an annual written assurance from the customer that performs the commercial processing that it has established and is following procedures identified in the written assurance that adequately reduce the presence of microorganisms of public health significance;
 - If the farm’s customer is not the processor, then it must obtain documentation from the customer that some other party in the distribution chain will process the produce and that the customer
 - Will make the requisite disclosure in documentation accompanying the produce, and
 - Will only sell to an entity that agrees in writing either:
 - To follow procedures (identified in a written assurance) that adequately reduce the presence of microorganisms of public health significance OR
 - Obtain a similar written assurance from its customer.
- The farm must keep documentation of its disclosures and annual written assurances; and,
- Commercial processors must:
 - Provide annual written assurances identifying the procedures they have established and will implement to adequately reduce microorganisms of public health significance; and,
 - Document compliance with those procedures.

It is important to note that this requirement for commercial processors applies to any entity that agrees to provide the written assurance, even if the entity is exempt from compliance with the Preventive Controls rule (e.g., processors in compliance with juice HACCP). This is a significant documentation and recordkeeping burden that should be carefully examined by both farms and commercial processors.

^{5/} FDA gives the following examples of such commercial processing: processing in accordance with the requirements of 21 CFR part 113 (low-acid foods), part 114 (low-acid canned foods), or part 120 (juice HACCP); treating with a validated process to eliminate spore-forming microorganisms (such as processing to produce tomato paste or shelf-stable tomatoes); and processing such as refining or distilling or otherwise manufacturing/processing produce into products such as sugar, oil, spirits, wine, beer or similar products. On its website, FDA explains that “Blanching and/or freezing processes may qualify [as commercial processing that adequately reduces the presence of pathogens] if they are validated to ensure that the specific procedures followed adequately reduce pathogens in the food.”

Which Farms Are Covered?

The rule applies to all domestic and foreign farms that grow, harvest, pack, or hold covered produce with average produce sales during the previous 3-year period of \$25,000 or more. Farms with average sales of produce of less than \$25,000 during the previous 3-year period are completely excluded from the rule's coverage.

The rule also provides a "qualified exemption" with modified requirements for farms with average food sales during the previous 3-year period of \$500,000 or less that sell primarily to consumers, retail food establishments, or restaurants located within the same state or a 275 mile radius of the farm. The exemption would apply even if the category of produce grown by the "qualified farm" is otherwise covered by the rule. The modified requirements applicable to such farms include disclosing the name and the complete business address of the farm where the produce was grown either on the label of the produce or at the point of purchase and establishing and keeping certain documentation. Further, these farms would remain subject to the compliance and enforcement provisions of the produce safety rule.

SUMMARY OF STANDARDS FOR SIX SPECIFIC HAZARDS AND SPROUTS

Below we summarize the proposed requirements for each of the six specific hazards and for sprouts:

- **Worker Training Provisions:**
 - Establish qualification and annual training requirements for all personnel who handle (contact) covered produce or food-contact surfaces and their supervisors, including training on the importance of health and hygiene and on the produce safety standards.
 - Establish special training requirements for workers engaged in harvesting, such as recognizing produce that cannot be harvested and inspecting harvesting containers and equipment.
 - Require documentation of required training and corrective actions.
- **Health and Hygiene Provisions:**
 - Establish hygienic practices and other measures needed to prevent persons, including visitors, from contaminating produce with microorganisms of public health significance, including communicable diseases; personal cleanliness; avoiding contact with animals; hand washing; maintaining gloves in an intact and sanitary condition; and no eating, chewing gum, or using tobacco products.
- **Agricultural Water Provisions:**
 - Establish requirements for the safe and adequate sanitary quality of water; the inspection of the water system under farm's control; water treatment, if a farm chooses to treat water; a tiered approach to water testing based on source, and specific microbial criteria for water used for certain purposes. They also require corrective measures and certain records.
- **Biological Soil Amendment Provisions:**
 - Establish standards for "treated" (stabilized compost) and "untreated" (raw manure), as well as restrictions on application method depending on treatment status.
 - Establish requirements for the treatment of biological soil amendments of animal origin with scientifically valid, controlled, biological, physical and/or chemical processes that satisfy certain specific microbial standards.
 - Require certain records, including documentation from suppliers.

- **Domesticated and Wild Animals Provisions:**
 - Establish requirements such that if there is a reasonable probability that grazing animals, working animals, or animal intrusion will contaminate covered produce, then the farm must take measures to assess as needed relevant areas during growing. If significant evidence of potential contamination is found, then the farm must evaluate whether covered produce can be harvested and take measures reasonably necessary throughout the growing season to ensure covered produce that is reasonably likely to be contaminated will not be harvested (e.g., identify contaminated areas with flags).

- **Growing, Harvesting, Packing or Holding Provisions:**
 - Establish requirements to keep covered produce separate from excluded produce and to adequately clean and sanitize food contact surfaces that contact excluded produce before using them for covered produce.
 - Prohibit harvesting produce that is likely to be contaminated, including that visibly contaminated with animal excreta and require a visual assessment of the growing area.
 - Prohibit distribution of dropped produce.
 - Require food packaging materials to be appropriate for use.

- **Buildings, Tools, and Equipment Provisions:**
 - Requirements include:
 - Equipment/tools must be designed and constructed to allow adequate cleaning and maintenance.
 - Food contact surfaces of equipment and tools must be inspected, maintained, cleaned, and sanitized as necessary.
 - Buildings must be of a size, design and construction to facilitate maintenance and sanitary operations.
 - Toilet and hand-washing facilities must be adequate, and readily accessible during covered activities.
 - Require certain records related to the date and method of cleaning or sanitizing equipment and corrective actions.

- **Sprout Provisions:**
 - Establish measures that must be taken related to seeds or beans for sprouting.
 - Establish measures that must be taken for the growing, harvesting, packing, and holding of sprouts.
 - Require testing the growing environment for *Listeria* species or *Listeria 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 pathogens, and taking appropriate follow-up actions .
 - 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.

COMPLIANCE DATES

Farms other than small or very small businesses will have two years to comply with most provisions of the produce safety rule. Small businesses, which are farms where the average annual monetary value of produce sold during the previous 3-year period is more than \$250,000, but no more than \$500,000, will have three years to comply with most requirements. Very small businesses, which

are farms where the average annual monetary value of produce sold during the previous 3-year period is no more than \$250,000, will have four years to comply with most requirements. Businesses of all sizes will have an additional two years to comply with certain agricultural water requirements.

The following table outlines the various compliance dates for different parts of the rule:

Size of covered farm	Covered activities involving sprouts covered under subpart M (i.e., subject to all requirements of part 112)	Covered activities involving all other covered produce (i.e., subject to part 112, except subpart M)		Farms eligible for a qualified exemption (if applicable)		
		Compliance date for certain specified agricultural water requirements	Compliance date for all other requirements	Compliance date for retention of records supporting eligibility in § 112.7(b)	Compliance date for modified requirement in § 112.6(b)(1)	Compliance date for all other requirements in §§ 112.6 and 112.7
Time periods starting from the effective date of rule (60 days after final rule is published)						
Very small business ≤\$250,000*	3 years	6 years	4 years	Effective date of rule	January 1, 2020	4 years
Small business ≤\$500,000	2 years	5 years	3 years			3 years
All other businesses	1 year	4 years	2 years			N/A

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We will continue to closely monitor all developments related to FDA’s implementation of FSMA. If you have any questions regarding the proposed rule, please do not hesitate to contact us.