

FDA Publishes Final Rule on Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption

November 17, 2015

Food & Drug

On November 13, 2015, the Food and Drug Administration (FDA) filed its final rule implementing the produce safety provisions of the Food Safety Modernization Act (FSMA) for public display.¹ The final rule establishes science-based minimum standards for the safe growing, harvesting, packing, and holding of fruits and vegetables grown for human consumption. This client alert highlights key aspects of the final rule.

Scope of the Produce Safety Final Rule

The final rule applies to both domestic and imported produce, with several exemptions and limitations. Certain specified produce commodities that are rarely consumed raw (e.g., asparagus, black beans, and collards) are not subject to the final rule. The final rule also does not apply to produce that is used for personal or on-farm consumption; produce that is not a “raw agricultural commodity,” a defined term that refers to any food in its raw or natural state; food grains; or farms with an average annual value of produce of \$25,000 or less over the previous three-year period.

FDA exempts produce from the rule if it receives commercial processing that “adequately reduces the presence of microorganisms of public health significance.” The final rule also provides a qualified exemption and modified requirements for eligible farms.

Key Requirements of the Produce Safety Final Rule

The final rule focuses on five major routes of contamination as determined in a qualitative assessment conducted by FDA of risks associated with the growing, harvesting, packing, and holding of produce. FDA has defined these major areas as the following:

¹ The produce safety final rule is currently available in its [pre-publication version](#) and is scheduled to be published in the *Federal Register* on November 27. This rule was first proposed on January 16, 2013 (78 Fed. Reg. 3504), with revisions announced in a supplemental proposed rule released last year (79 Fed. Reg. 58434 (Sept. 29, 2014)).

- **Agricultural water.** The final rule establishes two sets of criteria for microbial water quality, both of which are based on the presence of generic *E. coli*, which can indicate the presence of fecal contamination. Under the final rule, no detectable generic *E. coli* are allowed for certain uses of agricultural water in which it is reasonably likely that potentially dangerous microbes, if present, would be transferred to produce through direct or indirect contact (e.g., water used for washing hands during and after harvest). The second set of numerical criteria is for agricultural water that is used for growing produce other than sprouts.
- **Biological soil amendments.** FDA is conducting a risk assessment and extensive research on the number of days needed between the applications of raw manure as a soil amendment and harvesting to minimize the risk of contamination. At this time, FDA does not object to farmers complying with the U.S. Department of Agriculture's National Organic Program standards, which call for a 120-day interval between the application of raw manure for crops in contact with the soil and 90 days for crops not in contact with the soil. The final rule requires that untreated biological soil amendments of animal origin be applied in a manner that does not contact covered produce during application and minimizes the potential for contact with covered produce after application.
- **Domesticated and wild animals.** The final rule requires all covered farms, at a minimum, to visually examine the growing area and all covered produce to be harvested, regardless of the harvest method used. Under certain circumstances, the final rule also requires farms to conduct additional assessments during the growing season and to take measures reasonably necessary to assist later during harvest (e.g., placing flags outlining the affected area) if significant evidence of potential contamination by animals is found. FDA encourages farmers to voluntarily consider applying waiting periods between grazing and harvest as appropriate for the farm's commodities and practices.
- **Equipment, tools, and buildings.** The final rule establishes standards related to equipment, tools and buildings (e.g., greenhouses, germination chambers, and toilet and hand-washing facilities) to prevent these sources from contaminating produce. Required measures include appropriate storage, maintenance, and cleaning of equipment and tools.
- **Worker training and health and hygiene.** The final rule adopts requirements for health and hygiene, such as taking measures to prevent contamination of produce and food-contact surfaces by ill or infected persons and using hygienic practices when handling covered produce or food-contact surfaces. FDA also requires farm workers who handle covered produce and/or food-contact surfaces to be trained on certain topics and to have a combination of training, education, and experience necessary to perform their assigned responsibilities.

The final rule also includes new requirements to help prevent the contamination of sprouts, which have frequently been associated with foodborne illness outbreaks. Examples of these requirements specific to sprouts include taking measures to prevent the introduction of dangerous microbes into or onto seeds or beans used for sprouting, and testing spent sprout irrigation water from each production batch of sprouts, or in-process sprouts from each production batch, for certain pathogens.

Compliance Dates and Assistance to Industry

The final rule is effective 60 days after its date of publication in the *Federal Register*, which is expected to be November 27, 2015. All farms other than small and very small businesses must comply with the final rule's requirements for covered activities within two years of the final rule's effective date. The final rule also includes specific compliance dates for modified requirements for farms eligible for a qualified exemption and for covered activities involving sprouts after the rule's effective date. FDA is developing guidance documents relating to this final rule.

Michael Taylor, FDA's Deputy Commissioner for Foods and Veterinary Medicine, noted in a press call on November 13 discussing the agency's FSMA rules that successful implementation of the produce safety final rule will depend on an appropriation of \$109.5 million by Congress.

Covington & Burling LLP continues to monitor FDA's implementation of FSMA and to advise clients on relevant developments. If you have any questions concerning FSMA or other food regulatory matters, please contact any of the following attorneys in our Food & Drug Practice Group or visit our food and beverage practice website:

Miriam Guggenheim	+1 202 662 5235	mguggenheim@cov.com
Jeannie Perron	+1 202 662 5687	jperron@cov.com
Jessica O'Connell	+1 202 662 5180	jpoconnell@cov.com
MaryJoy Ballantyne	+1 202 662 5933	mballantyne@cov.com
Mingham Ji	+1 202 662 5621	mji@cov.com

This information is not intended as legal advice. Readers should seek specific legal advice before acting with regard to the subjects mentioned herein.

Covington & Burling LLP, an international law firm, provides corporate, litigation and regulatory expertise to enable clients to achieve their goals. This communication is intended to bring relevant developments to our clients and other interested colleagues. Please send an email to unsubscribe@cov.com if you do not wish to receive future emails or electronic alerts.