

Proposed Rule Summary

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

What is FDA doing?

The Food and Drug Administration (FDA) is issuing a proposed rule to establish science--based standards for growing, harvesting, packing and holding produce on domestic and foreign farms. The proposed rule is required by the FDA Food Safety Modernization Act (FSMA). FDA will be accepting comments on this proposal and make decisions on which suggestions to include in a final rule.

Is citrus covered?

Yes, citrus is proposed to be covered in the rule. However, the California Citrus Quality Council, California Citrus Mutual and Sunkist are exploring options to request an exemption or less stringent regulations for citrus because of the commodity's lower risk profile.

What would the proposed regulations cover?

They would focus on commonly identified routes of microbial contamination of produce, including¹:

(1) Agricultural Water (p. 3563)

- Water used during production (irrigation or foliar spraying) that contacts produce must meet federal recreational water standards for generic E. coli.
- Agricultural well water must be tested at the beginning of the growing season and every three (3) months during the growing season.
- Agricultural water from surface water sources subject to run off must be tested every seven (7) days during the growing season.
- Agricultural water from sources which are not subject to runoff such as reservoirs and ponds must be tested monthly during the growing season.
- Water that does not touch covered produce (citrus) is not considered agricultural water and is therefore exempt from testing.
- Water testing for very small businesses is delayed for six years; for small businesses it is delayed five years; for all other businesses it is delayed four years.

(2) Farm Worker Hygiene (p. 3557)

- Take necessary measures to prevent contamination from ill, injured or infected people

¹ The bullet points are substantive summary interpretations of the requirements, but are not verbatim regulatory language. For specific regulatory requirements please reference the source documents at <http://www.regulations.gov/#!documentDetail;D=FDA-2011-N-0921-0001>. Page numbers are provided for each relevant section in the regulation.

- Exclude sick people from operations
- Instruct employees to inform supervisors if ill or potentially infected
- Maintain adequate personal cleanliness; use outer garments as necessary
- Avoid contact with animals
- Maintain gloves in sanitary condition and replace when no longer able to do so
- Must wash hands: before work, before putting on gloves, return to work after any break, after touching animals or animal waste, any other time of potential contamination.
- Wash hands after touching animals
- Prevent visitors from contaminating produce
- Make toilet and hand washing available to visitors
- Test water quality of hand washing water. It must be free of E. coli in a 100 ml sample.

(3) Manure and Other Additions to the Soil (p. 3575)

- For crops that are likely to touch the soil, untreated manure can only be applied in a manner that does not contact covered produce during application *and* must be applied at least 9 months before harvest
- Untreated manure would be permitted for use with no minimum waiting period when the soil amendment is applied in a manner that does not contact covered produce *during or after application*
- Records must be kept to document the date of application of untreated manure and harvest to verify compliance

(4) Animals in Growing Areas (p. 3586)

- Measures should be taken to prevent contamination of covered produce by wild or domestic animals
- A minimum 9 month preharvest interval is required if animals graze in growing areas
- If there is a reasonable probability that animal intrusion will contaminate covered produce, growers must monitor for animal intrusion during the growing season and immediately before harvest
- If growers detect evidence of animal intrusion immediately prior to harvest there must be an evaluation of whether the crop can be harvested without contamination

(5) Equipment, Tools and Buildings (p. 3590)

- Tools intended to, or likely to contact covered produce must be of adequate design, construction and workmanship to enable them to be cleaned and properly maintained
- Equipment and tools must be of adequate design and construction to be adequately cleaned and maintained.
- Requires industry to inspect, maintain and clean and sanitize when necessary and appropriate *all food contact surfaces* of equipment and tools as frequently as necessary to prevent contamination of covered produce
- Requires industry to maintain and clean *all non-food contact surfaces* of equipment and tools during harvesting, packing and holding as frequently as reasonably necessary to prevent contamination of covered produce

Regulations for Growing, Harvesting and Holding Produce (p. 3588)

- Growers, packers and harvesters must keep covered produce separate from non-covered produce. (Some commodities such as potatoes that are not usually eaten raw are not covered by the rule.)
- Food contact surfaces that contact covered produce must be adequately cleaned and sanitary for the intended use
- Food packaging material must be adequate for the intended use and adequately clean and sanitary for the intended use
- Take all measures reasonably necessary to identify and not harvest contaminated produce, such as produce touched by animal excreta and bird droppings.
- Prohibits distribution of produce dropped to the ground except for produce that will be heat processed.
- Must convey, store and dispose of trash, litter and waste to minimize potential for attracting and harboring pests and to protect against contamination.

Regulations Regarding Employee Training (p.3554)

- All employees and their supervisors that handle covered produce must receive training that is appropriate to the person's duties (i) upon hiring, (ii) at the beginning of each growing season, if applicable, and (iii) periodically thereafter.
- Training should be easily understood by the personnel being trained
- Training must include (i) principles of food hygiene and food safety, (ii) the importance of health and personal hygiene and (iii) the standards as applicable to the employee's job responsibilities
- Harvesting employees must receive training in (i) recognizing covered produce that should not be harvested, (ii) inspecting harvest containers to ensure proper functioning, cleanliness and prevent contamination and (iii) correcting problems with harvest containers or equipment or reporting such problems to their supervisor.
- At least one supervisor or responsible party for a farm must successfully complete a food safety course recognized as adequate by the Food and Drug Administration.

When would the new requirements be effective?

The regulation is effective 60 days after the *final rule* is published in the Federal Register. Comments on the proposed rule are tentatively due on due May 16, 2013. However, a deadline extension is likely to be granted. FDA could take as much as one year to review comments and publish the final rule.

When must businesses comply with the regulations?

Very small businesses - defined as having an average annual value of food sold during the previous three years of no more than \$250,000, would have four years after the effective date to comply; for some water requirements, they would have six years.

Small businesses - defined as having an average annual value of food sold during the previous three years of no more than \$500,000, would have three years after the effective date to comply; for some of the water requirements, they would have five years.

All other businesses - would have to comply two years after the effective date. They would have four years to comply with some of the water requirements.

For additional information please consult the regulation at:

<http://www.regulations.gov/#!documentDetail;D=FDA-2011-N-0921-0001>

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