FSMA Proposed Rule for Produce Safety: Information on Specific Provisions

<< Proposed Rule for Produce Safety (/Food/GuidanceRegulation/FSMA/ucm334114.htm)

The following provides additional information to specific provisions of the Proposed Rule for Produce Safety.

Exemptions

Withdrawal of Qualified Exemption

- The original proposed rule established that the FDA could withdraw a qualified exemption if a farm is directly linked to an active investigation of foodborne illness outbreak, or if FDA determines that it is necessary to protect the public health and prevent or mitigate a foodborne illness outbreak based on conduct or conditions associated with the farm that are material to the safety of the food.
  - The original proposed rule would make a farm eligible for a qualified exemption and modified requirements if:
    - The average annual value of all food sold during the three preceding years was less than $500,000 (adjusted for inflation), and
    - The average annual value of food sold to “qualified end users” during that time exceeded the average annual value of food sold to all other buyers. A qualified end user is either a consumer, or a restaurant or retail food establishment in the same state as the farm or not more than 275 miles away from the farm.
- Commenters called for intermediate steps that would allow a farm to take corrective actions before losing its exempt status.
- The proposed revisions would establish that before FDA issues an order to withdraw a qualified exemption, the agency:
  - May consider one or more other actions to protect public health, including a warning letter, recall, administrative detention, refusal of food offered for import, seizure and injunction.
  - Must notify the farm of the circumstances that jeopardize the exemption, provide an opportunity for response, and consider actions taken by the farm to address the issues raised by the agency.

Reinstatement of Exemption

- The original proposed rule did not include provisions for re-instatement of a qualified exemption once it is

withdrawn.

- The proposed revisions provide procedures by which an exemption can be reinstated if:
  - It has been established that the problems with conduct or conditions material to the safety of the food produced or harvested at the farm have been adequately resolved, and
  - Continued withdrawal of the exemption is not necessary to protect public health or prevent or mitigate an outbreak of foodborne illness.

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Water Quality

The FDA is amending its previously proposed microbial standards for the use of water applied directly to produce (other than sprouts) during growing to be consistent with the data supporting the updated 2012 Environmental Protection Agency (EPA) criteria for recreational water quality.

- The updated standard takes into account the latest research correlating contaminated recreational contact water and illness.
- Commenters had questioned the scientific basis for the previously proposed microbial quality standard, saying there is a lack of adequate data to provide a complete understanding of produce contamination resulting from irrigation water.
- The revised microbial standard no longer has an upper limit for a single water sample of 235 colony forming units (CFU) of generic E.coli per 100 mL of water.
- Under the revised standard, the geometric mean of samples is not to exceed 126 CFU of generic E.coli per 100 mL of water and the statistical threshold value (STV) of samples is not to exceed 410 CFU of generic E.coli in 100 mL of water. (The STV approximates the 90th percentile of the water quality distribution and is intended to be a value that should not be exceeded by more than 10 percent of the samples taken.)
- If water does not meet the microbial quality standard, farmers would have additional means to achieve it. Alternate options are provided that allow time for microbial die-off or reduction.
  - Applying an interval of days between last irrigation and harvest, using a microbial die-off rate of 0.5 log (logarithmic dilution) per day.
  - Applying an interval of days between harvest and the end of storage using appropriate microbial die-off or removal rates, provided there is adequate supporting data.
  - Applying appropriate microbial removal rates during such activities as commercial washing, provided there is adequate supporting data.
- The previously proposed options for water that does not meet the microbial standard would also still be available. They include using the water in an application that does not result in direct contact during growing (such as furrow irrigation of fruit trees), using an alternative microbial standard with adequate scientific support that would provide the same level of public health protection, or treating the water.
- The FDA intends to issue guidance documents to assist with education and training when the rule is finalized. The agency intends to make tools available to assist with implementation, including an online tool that farmers can use to calculate the geometric mean and statistical threshold value of their water data.

Water Testing

- The revisions to the water testing provisions reduce how often farmers would have to test agricultural water, and the frequency of testing would vary depending on the water source.
- Commenters felt that testing strategies should be risk-based, with the original proposal failing to consider the wide range of sources of agricultural water, which includes rural rain water catchment.
- Under the proposed tiered approach, for untreated surface water—considered the most vulnerable to contamination—the FDA would require farms to do a baseline survey of the quality of agricultural water directly applied to produce (other than sprouts) during growing, using a minimum of 20 samples, collected during a time

period(s) as close as practical to harvest over the course of two years. The baseline findings would be used to determine if the water meets the microbial quality standard.
    - After the baseline has been established, an annual survey of a minimum of five samples per year would be required to verify the water quality profile and confirm that the water is still used appropriately. If the annual survey does not support the current water quality profile, a new water quality profile would be required. Water use would need to be modified as soon as practical and no later than the following year.
    - If there is reason to believe that the water-quality profile no longer represents the quality of the water because of a significant water event, such as changes in adjacent land use, erosion or other impacts to the water that are outside the farmer's control, a new water quality profile must be developed. Water use would need to be modified as soon as practical and no later than the following year.
    - For untreated surface water used for other purposes for which the proposed rule prescribes a microbial standard (e.g., hand washing), the FDA is proposing to require testing with an adequate frequency to provide reasonable assurances that the water meets the required microbial standard, with adequate documentation supporting the testing frequency.
- For untreated ground water used for any purpose for which the proposed rule prescribes a microbial standard, water must be tested at least four times over a growing season or over a period of one year, using a minimum of four samples collected during a time period(s) as close as practical to harvest.
    - If the samples meet the applicable quality standard, the testing can be done once annually thereafter, using a minimum of one sample collected.
    - Testing must resume at least four times per growing season or year if any annual test fails to meet the applicable microbial standard.
- For both untreated surface water and untreated ground water, farms would be required to test the quality of each agricultural water source.
- In addition, the FDA is proposing to permit data sharing among farms, and for farms to rely on testing data from third parties, under certain circumstances. For example, farms that share a water source may share testing data from that water source to meet the proposed testing requirements if there is no reasonably identifiable source of likely microbiological contamination between the sampling sites and the farms involved.

See Agricultural Water – Proposed Microbial Standards (/downloads/Food/GuidanceRegulation/FSMA/UCM415227.pdf) (PDF: 117KB) for additional information.

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Manure

- The FDA is removing the originally proposed nine-month minimum-time interval between the application of untreated biological soil amendments of animal origin (including raw manure) and the harvesting of the crop, and deferring its decision on an appropriate time interval until the agency pursues certain specific actions:
- The FDA's decision to remove this interval for the use of raw manure was based on strong concerns expressed by stakeholders, FDA's ongoing efforts to build the scientific knowledge in this area, and the agency's commitment to adopt practical and effective produce-safety strategies.
- The FDA's risk assessment on the safe use of raw manure in produce fields may consider such variables as:
    - Source and type of manure
    - Method of application
    - Climactic conditions
    - Type of commodity
    - Soil characteristics
- After extensive research to strengthen scientific support for a decision on the safe use of raw manure and completing the risk assessment, the FDA will consider the new data in developing tentative scientific conclusions in advance of any future proposal.

- At this time, the FDA does not intend to take exception with farmers complying with the standards established under USDA's National Organic Program, which calls for a 120-day interval between the application of manure and harvest for crops in contact with the soil and 90 days for crops not in contact with the soil.

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Compost

- The proposed revisions eliminate the 45-day minimum application interval for composted biological soil amendments of animal origin (including composted manures) that meet these standards:
  - It is processed to meet a microbial standard specified in the Produce Safety rule.
  - It is applied in a manner that minimizes the potential for contact with produce during and after application.
- The FDA, along with multiple other federal, state and private entities, believes that properly composted manure is safer than raw manure from a public health standpoint and is more environmentally sustainable.

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Covered Farms

Farm Size

- The FDA believes that applying the $25,000 threshold for farms covered by the rule to produce sales rather than all food sales, as originally proposed, would address concerns expressed by commenters while still protecting public health.
- Commenters expressed that covering farms based on their total food sales would make it difficult for mid-size farms to diversify.
- This new proposed basis for calculating monetary thresholds would also be applied to the definitions of "very small business" and "small business:"
  - A farm that sells more than $25,000 but no more than $250,000 in produce each year would be defined as a "very small business."
  - A farm that sells more than $250,000 but no more than $500,000 in produce each year would be defined as a "small business."
  - These amended definitions would not affect coverage under the Produce Safety rule, but would qualify more farms for the extended compliance periods proposed for small and very small businesses.

Definition of 'Farm'

- The original proposed rule included a definition of "farm" that was mostly the same as the definition that already exists in FDA regulations for food facility registration and recordkeeping.
- Commenters expressed concern that, under the proposed definition, routine packing or holding activities involving produce grown on a farm under a different ownership would render the farm a "mixed-type facility" that would also be subject to the proposed rule for preventive controls for human food. They stated that
  - it is a common practice for farms to buy and re-sell produce from other farms or to pack or hold produce for a neighboring farm, and
  - the activities of packing or holding would present similar food safety risks regardless of who owns the farm on which the produce is grown.
- The FDA tentatively concurs that hazards associated with on-farm produce packing or holding activities would best be addressed through the produce safety rule regardless of the ownership of the farm on which the produce was grown.
- The FDA is now proposing a revised definition of "farm" for the produce safety rule (and for other rules, including the proposed rules for preventive controls for human and animal Food, and existing regulations).

- Under the revised definition, a farm that packs or holds produce raw agricultural commodities that are grown on a farm under a different ownership would not necessarily be considered a “farm mixed-type facility” potentially subject to the requirements of the proposed preventive controls for human food.
- Instead, farms that pack or hold produce raw agricultural commodities that are grown or harvested on a farm under different ownership would be subject to the provisions of the produce safety rule, unless an exception or limitation on coverage applies.

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Animals

- The original proposed rule includes standards directed at minimizing the potential for contamination of produce with biological hazards from domesticated animals (e.g., livestock, working animals, pets) and wild animals (e.g., deer, wild swine).
- Commenters expressed concern that the proposed rule, if finalized, would adversely affect wildlife, including threatened or endangered species.
  - Concerns were expressed that growers would interpret the proposed Produce Safety rule to mean that more fencing or less animal habitat in the farm environment is a necessary management strategy.
  - Comments acknowledged the FDA’s statements in the preamble to the proposed rule supporting co-management of both food safety and wildlife conservation, and urged the agency to provide similar language in the regulation itself.
- The FDA is stating in the proposed revisions that the produce regulation does not authorize or require farms to take actions that would constitute the “taking” of a threatened or endangered species in violation of the Endangered Species Act.
- The proposed revisions also state that farms are not required to take measures to exclude animals from outdoor growing areas, destroy animal habitat, or otherwise clear farm borders around outdoor growing areas or drainages.
- The final produce safety rule will be accompanied by an Environmental Impact Statement that evaluates the potential environmental effects of the rule, including those resulting from the provisions related to domesticated and wild animals.
- The FDA encourages the co-management of food safety, conservation and environmental protection.

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