FDA at a Glance

FDA FOOD SAFETY MODERNIZATION ACT

Key Revisions: Proposed Rule on Produce Safety

Based on FDA's outreach efforts and public comments, the FDA is proposing revisions to its proposed rule on produce safety that are more flexible and less burdensome in key areas. The agency is accepting comments for 75 days after the publication date. The FDA published the original proposed rule on Jan. 16, 2013, and the comment period closed on Nov. 22, 2013; no additional comments are being accepted on the original proposed rule. The FDA will accept comments on the revised provisions while continuing to review comments already received on the original proposed rule. Here is a summary of the key revisions.

1. **Water quality standard and testing more flexible**
   - The FDA is proposing various revisions to the microbial standard for water that is directly applied during the growing of produce (other than sprouts). The agency is updating the microbial quality standard to reflect data that supports the 2012 Environmental Protection Agency recreational water quality criteria.
   - Farmers with agricultural water that does not initially meet the proposed microbial standard would have additional means by which they could meet the standard and then be able to use the water. These options include establishing a sufficient interval of days between last irrigation and harvest to allow time for potentially dangerous microbes to die off. They could also apply 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. And there is an option to calculate and apply appropriate pathogen removal rates for activities such as commercial washing.
     - A number of commenters felt that the FDA should allow for microbial die-off that occurs naturally in the field before the crop is harvested. This provision provides that flexibility. However, any of these options would have to provide the same level of public health protection and not increase the likelihood that the covered produce will be adulterated.
   - Recognizing that water sources have different levels of contamination risk, the FDA is proposing a tiered and more targeted approach to testing each source of untreated water that will be less burdensome on farmers while still protective of public health. The revisions reduce how often the water is tested, with the frequency depending on the water source (i.e. surface or ground water) and on the results of prior tests.

2. **Manure strategy to be further studied**
   - The FDA is removing the nine-month proposed minimum-time interval between the application of untreated biological soil amendments of animal origin (including raw manure) and crop harvesting. The agency is deferring its decision on an appropriate time interval until it pursues certain actions. These include conducting a risk assessment and extensive research to strengthen scientific support for any future proposal, working with the U.S. Department of Agriculture and other stakeholders.
   - At this time, the FDA does not intend to take exception to farmers complying with the USDA'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 FDA is proposing to eliminate the previously proposed 45-day minimum application interval for compost (also known as humus), including composted manures. Properly treated and handled compost is safer than raw manure from a public health standpoint and this change to the proposal would help facilitate its use while still providing an appropriate level of public health protection.

3. Covered farms better defined
- The FDA is proposing that farms or farm mixed-type facilities with an average annual monetary value of produce sales of $25,000 or less will not be covered. The original proposed rule defined that monetary threshold in terms of all food sales. The FDA is also proposing corresponding changes to the definitions of "very small business" and "small business" to base those monetary thresholds on produce sales rather than food sales. The monetary threshold for the qualified exemption with modified requirements, however, would not change because that exemption is defined by statute.
- The definition of "farm" would be revised; a farm would no longer be required to register as a food facility merely because it packs or holds raw agricultural commodities grown on another farm under a different ownership. The FDA is proposing that such activities would be subject to the produce safety rule rather than the preventive controls rule for human food.

4. Withdrawal of qualified exemptions process further clarified
- The proposed revisions would establish procedures to guide the FDA in withdrawing an exemption for a farm for food safety reasons as specified in the proposed regulation:
  - The FDA may consider one or more other actions to protect public health prior to withdrawal, such as a warning letter, recall, administrative detention, or seizure and injunction.
  - The FDA must notify the farm of the circumstances that jeopardize the exemption, provide an opportunity for the farm to respond, and consider actions taken by the farm to address the issues raised by the agency.
- The revisions also provide procedures for reinstating a withdrawn exemption.

5. Clarifying provisions on wild animals
- The FDA states in the proposed revisions that the proposed 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. There were concerns expressed that growers would interpret the original proposed rule in ways that would harm wildlife, including taking measures to exclude animals from outdoor growing areas or destroying animal habitats. This clarification is intended to relieve those concerns.

Compliance Dates
- Very small businesses, those with more than $25,000 but no more than $250,000 in annual produce sales, would have four years after the rule's effective date to comply with most provisions.
- Small businesses, those with more than $250,000 but no more than $500,000 in produce sales, would have three years after the rule's effective date to comply with most provisions.
- All other farms would have two years after the effective date to comply with most provisions.
- The compliance dates for water quality standards, and related testing and recordkeeping provisions would be an additional two years beyond the compliance dates for the rest of the final rule.

More Information
- Visit http://www.regulations.gov/
- FDA's Food Safety Modernization Act page at www.fda.gov/FSMA