FDA at a Glance

FDA FOOD SAFETY MODERNIZATION ACT

Key Revisions:
Proposed Rule on Preventive Controls for Human Food

Based on FDA's outreach efforts and public comments, the FDA is proposing revisions to its proposed rule on preventive controls for human food 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 rule closed on Nov. 22, 2013; no additional comments are being accepted on the originally 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. **Farms that pack or hold food from other farms are not subject to the preventive controls rule**
   - 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. FDA proposes to define such packing and holding as a traditional farming activity.
   - In general, on-farm packing and holding of produce is subject to the proposed produce safety rule, not the human food preventive controls.
   - Farms that conduct additional processing or manufacturing may be subject to preventive controls rule for those activities.

2. **Definition of a very small business proposed at less than $1 million in sales**
   - The A "very small business" would be defined as firms having less than $1 million in total annual sales of human food, adjusted for inflation. Previously, three options were proposed: annual sales of $250,000, $500,000, and $1 million. The new proposed definition would exempt less than 1 percent of the dollar value of food produced in the United States.

3. **Withdrawal of qualified exemptions process further clarified**
   - The proposed revisions would establish procedures to guide the FDA in withdrawing an exemption for a qualified facility for food safety reasons as specified in the proposed regulation:
     - The FDA first may consider alternatives to protect public health and would provide advance notification to the facility and an opportunity for the facility to respond. The revisions also provide procedures for re-instating a withdrawn exemption.
     - The FDA must provide an additional 60 days (for a total of 120 days) after the receipt of the order for a facility whose exemption is withdrawn to comply with the full requirements for hazard analysis and risk-based preventive controls.

4. **Product testing, environmental monitoring, supplier controls proposed**
   - While these potential provisions were referenced in the preamble of the proposed rule, they were not included in the regulatory text. The FDA is now providing an opportunity for input on specific language and seeking comment on whether to

include it in the final rule. FDA is seeking comment on whether the preventive controls for human food should require:

- A facility, as appropriate to the facility, the food, and the nature of the preventive control, to conduct product testing to verify implementation and effectiveness of preventive controls.
- A facility, as appropriate to the facility, the food, and the nature of the preventive control, to conduct environmental monitoring to verify implementation and effectiveness of preventive controls if contamination of a ready-to-eat food with an environmental pathogen is a significant hazard.

- Supplier controls are proposed when the receiving facility's hazard analysis identifies a significant hazard for a raw material or ingredient, and that hazard is controlled before the facility receives the raw material or ingredient from a supplier.
  If these provisions were to be included, the facility would have flexibility to determine the appropriate verification activity (such as onsite audit, sampling and testing) unless there is reasonable probability that exposure to the hazard will result in serious adverse health consequences or death to humans.
  - In that instance, an annual onsite audit of the supplier would be required unless the facility can show that other verification activities and/or less frequent onsite auditing of the supplier provide adequate assurance that the hazards are controlled.

5. **Economically motivated adulteration language proposed**
   - FDA is asking for input on whether a facility should be required to address hazards that may be intentionally introduced for purposes of economic gain as part of its hazard analysis.

Compliance Dates

- **Small businesses**—a business that employs fewer than 500 persons and that does not qualify for an exemption would have to comply two years after publication of the final rule.
- **Very Small Businesses**—defined as having less than $1 million in total annual sales of human food, adjusted for inflation, would have three years after publication of the final rule to comply. Considered "qualified facilities," they would be subject to modified preventive control requirements.
- **Other Businesses**—a business that is not small or very small and does not qualify for an exemption would have to comply one year after publication of the final rule.

More Information

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