FDA at a Glance

FDA FOOD SAFETY MODERNIZATION ACT

Key Revisions: Proposed Rule on Preventive Controls for Animal Food

Based on FDA outreach efforts and public comments, the FDA is proposing a number of revisions to its proposed rule on preventive controls for animal food that are more flexible and less burdensome in key areas. The FDA is accepting comments for 75 days after the publication date. The FDA published the original rule on October 29, 2013 and the comment period closed on March 31, 2014; 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. **Current good manufacturing practice regulations made more applicable to animal food**
   - The FDA is now proposing CGMPs that are more applicable to the animal food industry, provide flexibility for a wide diversity in the types of animal food facilities, and establish standards for producing safe animal food.
   - Human food processors already complying with FDA human food safety requirements, such as brewers, would not need to implement additional preventive controls or Current Good Manufacturing Practice regulations when supplying a by-product (e.g., wet spent grains, fruit or vegetable peels, liquid whey) for animal food, except for proposed CGMPs to prevent physical and chemical contamination when holding and distributing the by-product (e.g., ensuring the by-product isn't co-mingled with garbage). However, further processing a by-product for use as animal food (e.g., drying, pelleting, heat treatment) would require compliance with the Preventive Controls for Animal Food rule.

2. **Definition of very small business proposed at less than $2.5 million in sales**
   - A "very small business" would be defined as having less than $2.5 million in total annual sales of animal food, adjusted for inflation.
   - Previously, three options were proposed: annual sales of $500,000; $1,000,000; or $2,500,000.
     - The new proposed definition of a $2.5 million threshold would exempt from the proposed rule less than 2 percent of the dollar value of all animal food produced in the United States. FDA estimates that 4,325 facilities would be covered by the proposed rule, compared to 6,603 under the $500,000 scenario and 6,124 under the $1,000,000 scenario.

3. **Withdrawal of qualified exemptions process further developed**
   - 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 animal or human 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. Potential regulatory language for product testing, environmental monitoring, supplier controls offered for public comment

- While these potential provisions were referenced in the preamble of the proposed rule, they were not in the regulatory text. The FDA is now providing an opportunity for input on specific proposed language and seeking comment on whether to include it in the final rule. The FDA is seeking comment on whether the preventive controls for animal food rule 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.
  - Conduct environmental monitoring to verify implementation and effectiveness of preventive controls if contamination of finished animal food with an environmental pathogen is a significant hazard.

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.

6. Feed mills associated with farms

- The FDA specifically requests comment on whether feed mills associated with fully vertically integrated farming operations (i.e., farms where the feed mill, animals, land, and establishment are all owned by the same entity) should be required to register as a food facility under section 415 of the FD&C Act and thus be subject to the proposed rule.

Compliance Dates

- **Small business**—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 business**—a business having less than $2.5 million in total annual sales of animal food, adjusted for inflation, would have three years after publication of the final rule to comply. As "qualified facilities," they would be subject to modified requirements for preventive controls.
- **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