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Food, Drug & Device Law Alert - FDA Issues Revisions To Proposed Food Safety Rules, Reopens Comment Period For Revisions Only

September 22, 2014 | Atlanta | Chicago | Columbus | Delaware | Elkhart | Fort Wayne | Grand Rapids | Indianapolis | Los Angeles | Minneapolis | South Bend

On Sept. 19, the FDA issued proposed revisions to four of the major proposed rules to implement the Food Safety Modernization Act (FSMA): Preventive Controls for Human Food, Foreign Supplier Verification Program, Preventive Controls for Animal Food and Produce Safety. FDA states that the revisions are based on extensive public comments on the original versions of the proposed rules.

For the rule on preventive controls for human food, the proposed revisions fall into five categories as follows:

1. Farms that pack or hold food from other farms are not subject to the preventive controls rule

- A farm would not have to register as a food facility merely because it packs or holds raw agricultural commodities grown on another farm under a different ownership.
- On-farm packing and holding of produce would be subject to the proposed produce safety rule, not the human food preventive controls rule.
- 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

- A “very small business” would be defined as a firm having less than $1 million in total annual sales of human food, adjusted for inflation.

3. Withdrawal of qualified exemptions process further clarified

- FDA proposes procedures to guide it 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 The revisions also include procedures for re-instating a withdrawn exemption.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

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withdrawn to comply with the full requirements for hazard analysis and risk-based preventive controls.

4. Product testing, environmental monitoring, supplier controls proposed

- FDA is seeking comment on whether the preventive controls for human food should require:
    - A facility to conduct product testing to verify implementation and effectiveness of preventive controls, as appropriate to the facility, the food, and the nature of the preventive control.
    - A facility 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, as appropriate to the facility, the food, and the nature of the preventive control.
- FDA is proposing supplier controls 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 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

- The 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

The FDA's proposed revisions to the Foreign Supplier Verification Program fall into three categories:

1. Hazard Analysis

The revisions propose a more comprehensive evaluation of food and supplier risks by combining (1) the proposed requirement that an importer conduct a compliance status review of each food to be imported and each foreign supplier being considered with (2) the proposed requirement than an importer analyze the hazards in each food.

This broader evaluation of risks would require importers to consider such factors as:

- the nature of hazards in food

- the entity that will be applying hazard controls, such as the foreign supplier or the foreign supplier's ingredient supplier
- the foreign supplier's procedures, processes, and practices related to food safety
- applicable U.S. food safety regulations and information regarding the foreign supplier's compliance with those regulations, and
- the foreign supplier's food-safety performance history.

FDA is also asking for input on whether importers should be required to consider hazards that may be intentionally introduced for purposes of economic gain as part of its hazard analysis.

2. Supplier Verification

The FDA is proposing a provision for required supplier verification activities that is a hybrid of the two options presented in the originally proposed rule. The new approach would provide importers the flexibility to determine appropriate verification measures based on food and supplier risks, while acknowledging the greater risk to public health posed by the most serious hazards in foods.

When there is reason to believe that a hazard will cause serious injuries or deaths, a clear, rigorous verification standard is required in the form of annual on-site auditing of the supplier. Importers would be allowed to use a different approach (possibly including less frequent auditing) only if they can establish that it will provide adequate assurance that the hazard is controlled.

3. Consistency with Other Proposed FSMA Rules

To make the proposed FSVP rule consistent with the revisions to the proposed rules on preventive controls for human food and animal food, the revisions include:

- changing the definitions of "very small importer" and "very small foreign supplier" to a firm having no more than $1 million in annual food sales rather than the previously proposed limit of $500,000 in annual food sales, and
- deeming that importers who operate food facilities in compliance with any potential supplier verification provisions that may be included in the preventive controls rules are in compliance with any parallel FSVP requirements to avoid duplicative regulations.

The Produce Safety rule revisions relate to water quality standards; manure strategy; the definition of covered farms; procedures for withdrawing qualified exemptions; and, clarifying the provisions on wild animals.

There are six categories of proposed revisions to the rule on preventive controls for animal food: making CGMPs more applicable to animal food; pegging the definition of very small business at less than $2.5 million in annual sales; procedures for withdrawing qualified exemptions; product testing, environmental monitoring, and supplier controls; economically motivated adulteration; and, possible registration of feed mills associated with farms.

FDA is accepting comments on the proposed revisions only (not the original rules) until Dec. 15.

Copies of the proposed revisions are available here: Animal Food, Foreign Supplier Verification, Human Food and Produce Safety.

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