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food industry lawflash

January 3, 2014

FDA Proposes Food Defense Rule to Protect Against Intentional Adulteration

New mandate would apply to major U.S. and international food processors and handlers.

On December 24, the U.S. Food and Drug Administration (FDA or the Agency) issued a proposed rule, Focused Mitigation Strategies to Protect Food Against Intentional Adulteration (Rule), establishing requirements for major U.S. and international food facilities to prevent acts on the food supply intended to cause large-scale public harm.[1] The Rule, which is mandated by the FDA Food Safety Modernization Act (FSMA), would require the largest food facilities to have a written food defense plan that addresses significant vulnerabilities in a food operation.

By pursuing a risk-based approach to this issue, the Rule contemplates the need for preventive control requirements targeting what the Agency considers to be the most vulnerable elements of the food processing and handling chain rather than specific food product categories. FDA's underlying goal is to protect food against intentional adulteration caused by acts of terrorism. Accordingly, the facility types contemplated under the Rule are those engaged in activities within the food system that are vulnerable to such intentional adulteration and, generally, those larger facilities at which intentional adulteration could have an impact on a sizeable portion of the United States' food supply.

Background

In its guidance on the Rule, the Agency notes that adulteration of the food supply with intent to cause public health harm is "unlikely to occur." However, the Rule seeks to address the potentially catastrophic results of intentional adulteration of food, including human illness and death, loss of public confidence in the safety of food, and significant adverse economic impacts, such as trade disruption—all of which can lead to widespread public fear.

FDA acknowledges that efforts to protect against intentional adulteration require a shift in perspective from what is considered adequate for traditional food safety. Accordingly, the Agency is proposing an approach that targets certain processes within a facility that are most likely to be vulnerable, rather than targeting specific foods or hazards.

The Agency has identified four "key activities" within the food system that are most vulnerable to forms of intentional adulteration. They include the following:

- Bulk liquid receiving and loading
- Liquid storage and handling
- Secondary ingredient handling (the step where ingredients other than the primary ingredient of the food are handled before being combined with the primary ingredient)
- Mixing and similar activities

1. Focused Mitigation Strategies to Protect Food Against Intentional Adulteration, 78 Fed. Reg. 78,014 (proposed Dec. 24, 2013) (to be codified at 21 C.F.R. pts. 16 and 121), *available at* http://www.gpo.gov/fdsys/pkg/FR-2013-12-24/pdf/2013-30373.pdf.

Under the Rule, all nonexempt facilities would be required to review their production systems to determine if they engage in any of these activity types or to complete their own vulnerability assessments. Once that is completed, the facilities would need to identify actionable process steps, i.e., the points, steps, or procedures in a food process that will require focused mitigation strategies to reduce the risk of intentional adulteration. Facilities would also be required to complete written food defense plans. Once in place, the Rule would establish measures that a food facility would be required to implement to protect against the intentional adulteration of food.

Requirements

Each facility covered by the Rule would be required to prepare and implement a written food defense plan, which would include the following:

- **Actionable process steps:** Facilities would need to identify any actionable process steps, using one of two procedures. FDA has determined that the presence of one or more of the key activity types (described above) at a process step indicates a significant vulnerability to intentional adulteration aimed at large-scale public harm. Facilities may identify actionable process steps using the FDA-identified key activity types or conduct their own facility-specific vulnerability assessments.
- **Focused mitigation strategies:** Facilities would be required to identify and implement focused mitigation strategies at each actionable process step to provide assurances that the significant vulnerability at each step will be significantly minimized or prevented and that food manufactured, processed, packed, or held by the facilities will not be adulterated.
- **Monitoring:** Facilities would need to establish and implement procedures, including the frequency with which they are to be performed, for monitoring the focused mitigation strategies.
- **Corrective actions:** Facilities would use corrective actions if focused mitigation strategies are not properly implemented.
- **Verification:** Verification activities would ensure that monitoring is being conducted and appropriate decisions about corrective actions are being made. They would also help ensure that the focused mitigation strategies are consistently implemented and are effectively and significantly minimizing or preventing any significant vulnerabilities. In addition, the Rule includes requirements for periodic reanalysis of the food defense plan every three years or under certain conditions.
- **Training:** Personnel and supervisors assigned to the actionable process steps would be trained in food defense awareness and in their responsibilities for implementing focused mitigation strategies.
- **Recordkeeping:** Facilities would be required to establish and maintain certain records, including the written food defense plans; records documenting monitoring, verification activities, and corrective actions; and documentation related to training of personnel.

Covered Entities; Exemptions

Generally, the Rule would apply to both U.S. and international facilities that manufacture, process, pack, or hold food and are required to register as food facilities under section 415 of the Federal Food, Drug, and Cosmetic Act (FD&C Act). The Rule would not apply to farms or other food facilities that are not required to register under section 415 of the FD&C Act. The following types of facilities or operations would be exempted from the Rule's requirements:

- A "qualified facility," meaning
  - a very small business (a business that has less than $10 million in total annual sales of food, adjusted for inflation), but such a facility may be required to provide to FDA documentation relied on to demonstrate that the business is very small, **or**
  - a facility whose average annual monetary value of food sold directly to qualified end users during the preceding three years exceeds that sold to all other purchasers **and** whose average annual value of all food sold during that three-year period is less than $500,000.
- The holding of food, except the holding of food in liquid storage tanks
- The packing, repacking, labeling, or relabeling of food, where the container that directly contacts the food remains intact

- Activities that fall within the definition of "farm"
- Manufacturing, processing, packing, or holding of food for animals
- Alcoholic beverages under certain conditions

Compliance Dates

The Rule contains the following staggered compliance dates, based on business size:

- **Very Small Businesses:** A business that has less than $10 million in total annual sales of food would have to comply within three years after the publication of the Rule.
- **Small Businesses:** A business employing fewer than 500 persons would have to comply two years after the publication of the Rule.
- **Other Businesses:** A business that is not small or very small and does not qualify for exemptions would have to comply one year after the publication of the Rule.

Comments on the Rule; Public Meeting

Interested parties are encouraged to submit comments on the Rule, identified by Docket No. FDA–2013–N–1425 and/or Regulatory Information Number (RIN) 0910–AG63, by March 31, 2014. Additionally, the Agency will hold a public meeting on the Rule on February 20, 2014.[2]

Contacts

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*In association with Mohammed Buhashem Advocates & Legal Consultants

2. For more information on the public meeting, visit http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm377956.htm.