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E-ALERT | Food & Drug

December 24, 2013

FDA RELEASES PROPOSED RULE TO PROTECT FOOD FROM INTENTIONAL ADULTERATION

Today, as part of its efforts to implement provisions in the Food Safety Modernization Act (FSMA),[1] FDA published its proposed rule for protecting food against intentional adulteration, which would become new 21 C.F.R. Part 121.[2] In general, the rule is intended to protect food against intentional adulteration caused by acts of terrorism, *i.e.*, acts intended to cause large-scale public harm. While the preamble to the proposed rule discusses economically motivated adulteration that does not result in large-scale public health harm, it does not currently propose any regulations addressing this issue.

The comment period is open until March 31, 2014, and FDA will hold a public meeting February 20, 2014, to explain the proposal and provide additional opportunity for input. Given the challenges in creating a practical and effective rule, FDA has urged stakeholders to submit comments to help refine the approach and scope of the rule. This client alert summarizes the highlights of the proposed rule and issues for industry comment.

BACKGROUND

In assessing the scope of the rule, FDA concluded that although intent to cause public harm via intentional adulteration of the food supply is unlikely, it could have catastrophic results if it did occur. FDA therefore concluded that the proposed rule should apply to intentional adulteration designed to cause large-scale public health harm, *i.e.*, acts of terrorism. Consequently, the rule in its current form would not apply to acts of intentional adulteration caused by disgruntled employees, consumers, or competitors.

In addition, although the proposed rule does not incorporate measures to protect against economically motivated adulteration, FDA proposes to address such adulteration in human food, animal food, and dietary supplements by revising the recently proposed rules for the preventive controls for human food and animal food and by amending existing HACCP regulations for seafood and juice and the dietary supplement good manufacturing practices regulations.

FDA's rule proposes an approach that targets certain processes within a facility that are most likely to be vulnerable to intentional adulteration, rather than targeting specific foods or hazards.

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[1] FSMA was signed into law on January 4, 2011. Click here for our client alert issued when FSMA was enacted that described its key provisions. Click here for our client alert summarizing FDA's proposed rule for hazard analysis and risk-based preventive controls and current good manufacturing practices for human food, here for our client alert on FDA's proposed rule on produce safety, and here for our client alert on foreign supplier verification.

[2] 78 Fed. Reg. 78014 (December 24, 2013), available here. The proposed rule would implement the intentional adulteration provisions in sections 418, 419, and 420 of the Food, Drug, and Cosmetic Act (FDCA). FDA also created it's a webpage for the proposed rule with a fact sheet and additional information, which can be found here.

FACILITIES TO WHOM THE RULE APPLIES; EXEMPTED FACILITIES

With a few exceptions, the rule would apply to both domestic and foreign facilities required to register under section 415 of the Food, Drug, and Cosmetic Act (FDCA). Generally, the rule would exempt the following:

- Very small businesses (that make < $10,000,000 in total annual sales of food, adjusted for inflation).
- The holding of food, except the holding of food in liquid storage tanks.
- The packing, re-packing, labeling, or re-labeling 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.[3]
- Alcoholic beverages under certain conditions.

Notably, activities exempt under the hazard analysis and risk-based preventive controls provisions in section 418 of the FDCA because such activities are subject to HACCP regulations (e.g., activities related to seafood, juice, dietary supplements, low-acid canned food (for certain microbiological hazards)) would be subject to the proposed rule, unless otherwise exempt.

SCOPE OF THE PROPOSED RULE

FDA's proposed rule would require the largest food businesses to: (1) conduct an assessment of vulnerable processes in their operations susceptible to acts that could cause large-scale public harm; (2) prepare and implement a written food defense plan; (3) conduct personnel training; and (4) prepare and keep written records.

Conduct a Vulnerabilities Assessment

The rule would require a company to assess, using one of two methods proposed in the rule, whether any process steps (manufacturing, processing, packing, or holding) are at high risk of intentional adulteration.

Under the first method, the company would assess whether it had one or more of the four key activities that FDA has determined are the most vulnerable to intentional adulteration:

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

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[3] FDA's proposed rule does not directly apply to animal food even though section 420 of the FDCA arguably encompasses intentional adulteration of animal food by requiring the regulations to apply "to food for which there is a high risk of intentional contamination . . . that could cause serious adverse health consequences or death to humans or *animals*" (emphasis added). Click here for our client alert summarizing FDA's proposed rule for hazard analysis and risk-based preventive controls and current good manufacturing practices for animal food.

Under the second method, the company would conduct its own facility-specific vulnerability assessments for each type of food manufactured, processed, packed, or held at the facility. It would identify and prioritize the points, steps, and procedures in food operation at risk for intentional adulteration that must be mitigated in order to prevent/eliminate/reduce vulnerability of the food to intentional adulteration ("actionable process steps").

Prepare and Implement a Written Food Defense Plan

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

- Written identification of actionable process steps identified in the vulnerability assessment;
- Written focused mitigation strategies;
- Written procedures for monitoring;
- Written corrective action procedures; and
- Written verification procedures.

As part of the written food defense plan, the rule would require companies with identified vulnerabilities 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 facility will not be adulterated. In addition, the rule would require companies to monitor the focused mitigation strategies and to include in the written food defense plan the frequency with which such monitoring is to be performed. The rule would require companies to use corrective actions if focused mitigation strategies are not properly implemented and to verify that monitoring is being conducted and appropriate decisions about corrective actions are being made.

In addition, the rule would require companies to conduct periodic reanalyses of the food defense plan every three years or under certain specified conditions.

Conduct Personnel Training

The rule would require companies to train personnel and supervisors assigned to the actionable process steps in food defense awareness and in their responsibilities for implementing focused mitigation strategies.

Prepare and Keep Records

Finally, the proposed rule would require companies to establish and maintain certain records, including: the written food defense plan; records documenting monitoring, verification activities, and corrective actions; and documentation related to training of personnel. Records would be required to be retained at the facility for at least two years after the date they were prepared, except for the food defense plan, which must be retained for at least two years after its use is discontinued.

COMPLIANCE AND COMPLIANCE DATES

Non-compliance with the proposed rule would be a prohibited act under sections 301(uu) and 301(ww) of the FDCA. The rule proposes tiered compliance dates, depending on the size of the business, and would provide small and very small businesses additional time to comply. FDA proposes the following compliance time frames:

- Very Small Businesses: businesses with less than $10,000,000 in total annual sales of food would have to comply within three years after the publication of the final rule.
- Small Businesses: businesses employing fewer than 500 persons would have to comply two years after the publication of the final rule.
- Other Businesses: business that are not small or very small and do not qualify for exemptions would have to comply one year after the publication of the final rule.

FDA SEEKS INPUT FROM STAKEHOLDERS

Throughout the preamble to the proposed rule and in the December 20, 2013 teleconference with stakeholders announcing the proposed rule, FDA repeatedly requested that stakeholders provide FDA with comments to help narrow and refine the scope of the rule. In addition, FDA has requested comments on the following specific issues:

- Whether the exemptions are appropriate and whether additional exemptions are warranted.
- FDA's proposal to address economically motivated adulteration by revising the proposed rules for the preventive controls for human food and animal food and by amending existing HACCP regulations for seafood and juice and the dietary supplement good manufacturing practices regulations.
- FDA's tentative conclusion that the proposed rule should be applicable to intrastate activities because the statutory intentional adulteration provisions do not include a limitation to interstate commerce.
- FDA's tentative conclusion not to propose additional requirements for protection of food against intentional adulteration caused by acts of disgruntled employees, consumers, or competitors.
- Which entities would derive the greatest benefit (i.e., the greatest protection of public health) from implementing measures to protect against intentional adulteration, and how could the proposed regulation be modified to better target such entities.
- Whether it would be feasible to require measures to protect against intentional adulteration only in the event of a credible threat. If so, would such an approach be consistent with the intentional adulteration provisions of FSMA? How would such requirements be communicated to industry in a timely and actionable manner?
- What is an appropriate level of public health protection with respect to intentional adulteration.
- FDA's suggestions of other ways to further focus the scope of the rule using information such as a food's shelf life, turnover in the marketplace, batch size, serving size and serving per batch, distribution and consumption patterns, and intended consumer.
- How to address activities that occur on dairy farms that are vulnerable and therefore considered "high risk," such as fluid milk storage and loading.

Finally, FDA has also requested stakeholder input on its Appendix 4 to its Draft Qualitative Risk Assessment: Risk of Activity/Food Combinations for Activities (Outside the Farm Definition) Conducted in a Facility Co-Located on a Farm.[4]

[4] FDA requested comment on a draft qualitative risk assessment when it announced the proposed rule for preventive controls for human food. The draft qualitative risk assessment is designed to provide a science-based risk analysis of those on-farm activity/food combinations that would be considered not reasonably likely to introduce unintentional hazards that are reasonably likely to cause serious adverse health consequences.

NEXT STEPS

In light of FDA's repeated urging that stakeholders comment to help narrow and refine the proposed rule, affected stakeholders should consider submitting individual or joint comments to FDA and developing strategies to address the many implications that might arise when this proposed rule is finalized.

Covington & Burling LLP offers unparalleled expertise in food regulatory law, and we are available to assist in the development of comments and contingency planning regarding these important developments.

If you have any questions concerning the material discussed in this client alert, please contact the following members of our food & drug practice group:

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