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Protecting the Nation's Food Supply from Terrorist Attacks: FDA Proposes New Rule

In this Issue:

The Food & Drug Administration ("FDA"), in consultation with the Department of Homeland Security, has published its Proposed Rule on Protecting Food Against Intentional Adulteration. The proposed rule, published on December 24, 2013, is primarily focused on preventing terrorist attacks on the nation's food supply which are intended to cause large-scale public health harm. Protection from intentional adulteration is yet another step in the implementation of the Food Safety Modernization Act ("FSMA"), a legislative effort to create a comprehensive food safety system to protect both human and animal food.

This proposed rule against intentional adulteration has been long anticipated and may be most notable for what it ***does not*** address.

- First, the most common types of intentional adulteration are specifically excluded from this rule. Instead, the FDA has reversed its position and will now require facilities to consider some types of intentional adulteration when creating its hazard analysis plans pertaining to the safety of human and animal food. The hazard proposed analysis rules which were only issued in 2013 are going to be amended before becoming final.

- Second, the scope of the processes deemed to be vulnerable to attack is narrower than some expected, primarily only focusing on bulk liquids.

- Finally, the facilities and industries that are exempted from this rule are broad, including all manufacturing, processing, packing or holding of food for animals.

What Is Required

Every facility not exempted from this proposed rule must prepare and implement a Food Defense Plan. This written document is in addition to the written Food Safety Plan required by the FDA's proposed regulations on preventative controls for the safety of human and animal food. The Food Defense Plan must include the following:

1. **Analysis of Vulnerabilities**: As a threshold issue, facilities must determine whether they have certain processes within their systems that are likely vulnerable to an intentional adulteration attack ("actionable process steps"). While a food facility has the option to conduct its own vulnerability assessment, the FDA has identified what it believes to be the four most vulnerable processes:

   - 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); and
   - mixing and similar activities.

2. **Protection Efforts**: If a facility determines it has vulnerabilities, its Food Defense Plan must also include:

   a) mitigation strategies to significantly minimize or prevent the vulnerability to adulteration;

   b) the mitigation strategies must be monitored in a systematic basis;

   c) corrective actions must be initiated if the mitigation strategies are not properly implemented;

   d) verification activities must insure that monitoring is being conducted;

   e) corrective actions are being taken, including periodic reanalysis of the Food Defense Plan at least every three years or when appropriate;

   f) training of personnel and supervisors in food defense awareness and their responsibilities for implementing the mitigation strategies will be required; and

   g) recordkeeping relating to the entire process is specified.

As with other proposed rules under the FSMA, compliance dates will be staggered based upon the size of the business.

The FDA has identified three separate categories of acts of intentional adulteration. The first type of intentional adulteration is acts intended to cause massive public health harm, including acts of terrorism. Although acknowledged by the FDA to be the least likely type of act to occur, terrorism is deemed to be the most "high risk" because the intent of the act is to cause wide-spread, significant public health harm. Acts of terrorism are the primary focus of this proposed rule.

The other two categories of acts of intentional adulteration are economically motivated adulteration

intended to result in economic gain and acts of disgruntled employees, consumers or competitors intended to attack the reputation of a company. Although neither of these categories is primarily intended to cause public health harm, the FDA acknowledges that such harm to the public may occur. The FDA further acknowledges that these two categories of intentional adulteration have not only occurred in the past, but are more likely to occur in the future than terrorist attacks. Nevertheless, the FDA specifically excludes both acts of economically motivated adulteration and acts of disgruntled employees, consumers or competitors from the proposed rule.

In previous comments, the FDA had represented that all acts of intentional adulteration would be addressed in this rule. It even went so far as to advise in its rules for preventative controls for the safety of human food and animal food that facilities need not consider safety threats from intentional adulteration as that risk would be addressed here. Now, the FDA is proposing to go back and amend those preventative control rules to require the consideration of risk of economically motivated intentional adulteration. Additional public comment will be allowed following the new amendments to those previous rules. The FDA is also proposing to amend the current seafood and juice HACCP regulations and the dietary supplement current good manufacturing practice (CGMP) rule to require consideration of economically motivated adulteration that could result in serious adverse health consequences or death.

Exemptions

Finally, the facilities or operations which are excluded or exempt from this proposed rule to protect food against intentional adulteration are broad. The rule will not apply to:

- The manufacturing, processing, packing or holding of food for animals.
- Activities subject to Standards for Produce Safety.
- Certain alcoholic facilities.
- The packaging, re-packaging, labeling, or re-labeling of food where the container that directly contacts the food remains intact.
- The mere holding of food, except for the holding of food in liquid storage tanks.
- Activities that fall within the statutory definition of "farm."
- Transportation carriers, including the transportation of bulk liquids.
- Activities that occur on dairy farms – although fluid milk storage and loading has been identified as a significant vulnerability. The FDA is seeking comment from the public as to how to best address this risk.

A public meeting to discuss the proposed rule is scheduled for February 20, 2014. Public Comment will remain open until March 31, 2014.

For More Information

For questions about this proposed rule, how it fits within the overall framework of the FSMA and, more importantly, how it affects your business, please contact the author of this alert:

- Kathleen A. Hardee | *Practice Area Vice Chair* | 816.520.4903 | khardee@polsinelli.com

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