Implementation of the Food Safety Modernization Act

Effective July 3, 2011, The FDA Has Increased Administrative Detention Authority

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ABSTRACT

As of July 3, the authority of the Food and Drug Administration (FDA) to use administrative detention as an enforcement tool will increase. For this reason, companies that manufacture, prepare, pack or hold food should ensure that their strong record-keeping practices are strong.

Under the current criteria of the Food, Drug, and Cosmetic Act, the FDA may order the detention of human or animal food if there is **credible evidence** or information indicating that an article of food presents a threat of serious adverse health consequences or death to humans or animals. As of July 3, the rule is amended under the Food Safety Modernization Act (FSMA), which provides greater authority to use detention as an enforcement method. The new rule allows the FDA to order detention if there is **reason to believe** that an article of food is adulterated or misbranded. Foods can be detained for 20 calendar days, with a possible 10 calendar day extension if needed.

INTRODUCTION

The goal of the administrative detention of foods is to protect public health and prevent potentially harmful products from being consumed or used. Detaining products where there is doubt concerning safety certainly can reduce risk. The decision-making skills of those implementing administrative detention, combined with the ability of companies to create and maintain good records, will determine whether detention will be used appropriately to protect health while avoiding unnecessary burdens, shipment delays and added costs.

The majority of FDA administrative detention decisions historically appear to have been appropriate. According to information published in the Federal Register, the FDA estimates that up to 48% of detained imported foods may have been detained because time was needed to determine the facts, and the product was later released as acceptable. This implies that 52% of detained imported food was not released after detention. In other words, investigation showed that 52% of the detentions were justified. For the public, this implies that a majority of the FDA administrative detentions rightly protected public health.

These estimates are based on imported product, because the FDA has not used administrative detention for domestic foods, for which other methods have been used, including voluntary recall, a seizure action, or referral of the matter to state authorities. The prior use of these other enforcement methods makes it difficult to predict how often the detention of domestic product may be used starting on July 3. If future FDA detentions of domestic products are based on decision-making skills similiar to those employed for imports, the same rate (48%) of potentially unnecessary detentions may be the result. It should be a shared goal between industry and government to reduce

that value to ensure that the vast majority of detention actions are necessary and that controls are effectively implemented.

The FDA indicates that it is more likely to use administrative detention where this is the most effective enforcement tool available and where use of or exposure to the product may cause temporary or reversible adverse health consequences. This would be similar to the situation involving a product potentially subject to a Class II recall. Detention decisions will be made on a case-by-case basis. The Federal Register indicates that each circumstance is "fact-specific." Recording, documenting and ensuring a solid audit trail of the facts accurately is essential to every eligible entity susceptible to such a detention. The time and resources the company has spent gathering the necessary information are factors in how well the required audit trail has been maintained in order that the product can be released, thus avoiding the headache and costs of being forced to keep the product from the market.

A concern for companies engaged in manufacturing or holding human or animal foods is that administrative detention actions no longer need to be justified by credible evidence. Rather, a "reason to believe" could cause potentially unnecessary product loss or shipment delays of wholesome, legal products. Where facts are missing or inappropriately recorded, FDA must act upon available information to form a reason to believe that the product is or is not safe. The old adage "when in doubt, throw it out" might be changed to "when in doubt, consider the use of enforcement tools." If sufficient doubt exists regarding a product or process, actions should be considered by the responsible company before the FDA might take action.

The FDA has no funds or means of reimbursement for a company facing product loss caused by an administrative hold of product that is later found to be wholesome. The solution to avoiding potentially unnecessary actions is to ensure that case-by-case decisions are based on well documented fact, not on belief.

A thoroughly documented food safety system with validated preventive controls (a HACCP plan) is the best means to avoid unnecessary detention. This can be achieved only with appropriate training, organized record-keeping systems and process management that ensures consistent enforcement of policies. Companies should review their food safety plans or have a third party do so, paying specific attention to record keeping, to ensure communication of accurate and complete data. Use of electronic quality management systems is highly encouraged, based on the potential for human error and the costs associated with managing a system of manual controls.

When reviewing a data system, consider the following:

- If an activity has an impact on food safety, it should be recorded. For example, lack of evidence of appropriate use of sanitizers, combined with the presence of a strong odor, could constitute a "reason to believe" that the product is adulterated.
- The frequency of recorded events should be related to food safety and process stability. Be prepared to consider the product or process from the time of an "out-of-limits" event back to the last acceptable check as unacceptable. For example, if a company checks temperature once per hour, all production for up to one hour could be suspect if the process is discovered to be out of limits. If the same checks are once per shift, up to eight hours of production would be suspect.
- Records are to be completed in ink or signified electronically (21 CFR part 11 compliant) at the time of the event and by the person conducting the activity.
- Each recorded activity should include either affirmative or negative results accompanied by the signature or initials of the person who completed the action. Don't record only noncompliance; record evidence of compliance or control as well. For example, a daily sanitation inspection should document acceptable conditions as well as any unacceptable ones.
- Following a corrective action, always document a return to control or appropriate conditions. For example, documentation of unacceptable sanitation should be followed by documentation of re-cleaning and re-inspection, including the results of that inspection.

These are some of the steps needed to ensure factual communication that will lead to appropriate decisions and decrease the risk and costs associated with production losses. A reason to believe that a product is adulterated could arise from an anonymous call to the FDA reportable food registry, a simple observation or even a customer complaint. Companies need to be prepared to share validated documentation of product status to remove doubt wherever possible.

Administrative detention of foods can be an effective tool beginning on July 3, 2011, if facts support the decisions made. Manufacturers and others who store, distribute, import, or produce food can ensure the effectiveness of this tool by using good record-keeping practices and by adopting quality systems and technologies that enable those practices to be enforced and embraced.

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