

More FDA Detention Slips For Food Cos.

Law360, New York (March 06, 2013, 11:37 AM ET) -- The U.S. Food and Drug Administration continues to roll out regulations and guidance implementing the 2011 Food Safety Modernization Act (FSMA).[1] On Jan. 4, 2013, the agency issued two proposed rules on preventive controls and produce,[2] and on Feb. 5, 2013, it finalized an interim rule spelling out when the agency will exercise administrative authority to detain food it believes poses a safety risk.[3]

With the rule on administrative detention finalized, the FDA has available an array of administrative tools it can use to compel compliance with new food safety requirements. These tools, which can be exercised quickly and without the involvement of the U.S. Department of Justice, complement the agency's well-established authority to direct civil and criminal enforcement actions for violations of the federal Food, Drug and Cosmetic Act.[4]

The FDA can now order the mandatory recall of a food article that is adulterated or misbranded and if "use of or exposure to such article will cause serious adverse health consequences or death." [5] The agency can also suspend the registration of food facilities — effectively forcing them to cease operations — if it determines that "food manufactured, processed, packed, received, or held by a facility ... has a reasonable probability of causing serious adverse health consequences or death." [6]

The standard the FDA must meet to order administrative detention of food, however, is far more relaxed than mandatory recall or suspension of registration require. To order the detention of any article of food, the FDA officers or qualified employees need only have "reason to believe that the article of food is adulterated or misbranded." [7]

In comments accompanying the final rule, the FDA expressly refused to narrow this exceedingly broad standard. For instance, the agency declined to clarify what evidence might support a "reason to believe," stating obliquely that detention decisions are made on a case-by-case basis.[8] It also declined to centralize authority to issue detention orders, expressing confidence that regional offices would apply consistent standards across the country.[9]

Thus, the final rule intentionally reserves the authority to the FDA district directors and other field officers to move quickly and aggressively against suspect food. As Michael Taylor, the FDA's deputy commissioner for foods, noted recently, "with FSMA's new preventive control requirements and administrative enforcement tools (such as product detention and facility suspension), [the FDA inspectors] will be able to assess whether facilities have in place the proper systems and controls to prevent problems, and take much more immediate corrective action to protect public health when facilities don't have these in place." [10]

The consequences of a detention to food manufacturers can be significant as the FDA may initiate and publicize an action, causing serious damage to a company's reputation, if the company is unable to quickly and convincingly demonstrate its products' compliance with safety standards.

Although there is a swift appeals process — appeals concerning perishable food items must be filed within two calendar days and may be resolved within 10 — even if successful, an appeal is unlikely to undo entirely the damage a detention might cause to a brand with retailers and customers.

The FDA has already demonstrated a willingness to use its expanded authority. Whereas the FDA never utilized its detention authority under the pre-FSMA standard, which required the agency to find “credible evidence or information indicating that [the] article present[ed] a threat of serious adverse health consequences or death to humans or animals,”^[11] in the six months after the interim rule first went into effect on July 3, 2011, the FDA twice exercised its authority to detain suspect food.

The first detention began on Sept. 2, 2011, just two months after the interim rule went into effect. During an inspection of a storage and processing facility in Washington state, the FDA claimed evidence of “active and widespread rodent and insect infestation, and bird activity in the food warehouse and processing area.”

It placed all articles of food that were not hermetically sealed under administrative detention for 30 days. Showing a willingness to use detention in conjunction with more traditional enforcement tools, the agency then initiated a seizure action against the detained items, asking a U.S. district court to issue a warrant of arrest for the products, which were ultimately seized by U.S. marshals prior to the end of the detention period.

The agency's second exercise of its administrative detention authority also stemmed from observations made during an inspection. The FDA was inspecting a food processing and storage company in Maine in December 2011 when inspectors found *Listeria* on processing equipment and elsewhere in the facility.

The agency responded by detaining the cold smoked salmon product at the facility. In that case, the company voluntarily agreed to destroy the detained salmon under FDA supervision and without further agency action.

Going forward, the FDA says it is “more likely to use administrative detention,” even in Class II-like recall situations, in which a product may cause temporary adverse health consequences, or when the possibility of serious adverse health consequences is remote. ^[12] According to Taylor, “FDA eagerly embraces change in its food safety program and is hard at work laying the foundation for a modern, prevention-oriented food safety system that works better for consumers and the food industry.”^[13] Thus, food manufacturers need to be prepared and take their food safety obligations seriously.

Nearly all food is subject to being detained, regardless of whether it enters interstate commerce, including dietary supplements. Furthermore, when the proposed rules on preventive controls and produce are finalized, they will greatly expand the circumstances under which the FDA can administratively detain food.

For instance, facilities subject to the preventive controls rule could have food detained if the owner or operator has not sufficiently analyzed the known and reasonably foreseeable hazards for each type of food at the facility, even if none of those potential hazards have been realized.

The agency is expected to release additional proposed rules shortly on imported food and preventive controls for animal food, which are likely to further expand the bases for the agency's administrative detention authority.

--By John Fuson and Michael L. Kuppersmith, Crowell & Moring LLP

John Fuson is a partner, and Michael Kuppersmith is an associate in the firm's Washington, D.C., office.

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[1] Pub. L. No. 111-353, 124 Stat. 3885 (2011).

[2] Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food, 78 Fed. Reg. 3646 (Jan. 16, 2013) (to be codified at 21 C.F.R. pts. 1, 16, 106, 110, 114, 117, 120, 123, 129, 179 & 211); Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption, 78 Fed. Reg. 3504 (Jan. 16, 2013) (to be codified at 21 C.F.R. pts. 16 & 112).

[3] Criteria Used To Order Administrative Detention of Food for Human or Animal Consumption, 78 Fed. Reg. 7994 (Feb. 5, 2013) (to be codified at 21 C.F.R. pt. 1).

[4] 21 U.S.C. § 301 et seq.

[5] 21 U.S.C. § 350l.

[6] 21 U.S.C. §350d(b)(1).

[7] Criteria Used To Order Administrative Detention of Food for Human or Animal Consumption, 76 Fed. Ref. 25,538 (interim final rule May 5, 2011) (to be codified at 21 C.F.R. pt. 1).

[8] Criteria Used To Order Administrative Detention, 78 Fed. Reg. at 7995.

[9] *Id.*

[10] Michael R. Taylor, Deputy Comm'r for Foods, U.S. Food & Drug Admin., Remarks at the 2012 the FDA Science Writers Symposium: Progress on FSMA, Changes within the the FDA Foods Program, and on Partnerships (Sept. 11, 2012) (available at <http://www.theFDA.gov/Food/FoodSafety/FSMA/ucm319053.htm>).

[11] Administrative Detention of Food for Human or Animal Consumption Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, 69 Fed. Reg. 31,660, 31,702 (June 4, 2004).

[12] Criteria Used To Order Administrative Detention, 76 Fed. Reg. at 25,540 (interim final rule).

[13] Taylor, *supra* note 10.

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