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NEW REGULATIONS EXPAND FDA'S POWER TO SEIZE FOOD; REQUIRE ADDITIONAL DISCLOSURES FROM FOOD IMPORTERS

INITIAL REGULATIONS IMPLEMENTING FOOD SAFETY MODERNIZATION ACT BECOME EFFECTIVE JULY 3

On January 4, 2011, President Obama signed into law the Food Safety Modernization Act ("FSMA"). A focus of this law is to strengthen the Food and Drug Administration's ability to detect and prevent potential outbreaks of food-borne diseases. The FDA has identified prevention of such outbreaks as a major priority. According to the FDA, "[e]ach year about 48 million people (1 in 6 Americans) are sickened, 128,000 are hospitalized, and 3,000 die from food borne diseases." The FDA views these illnesses as "largely preventable."[1]

To fulfill this expanded mandate, the FSMA calls upon the FDA to implement numerous new rules and policies. The first two rules enacted under authority of the FSMA become effective on July 3, 2011. One of the new rules greatly increases the FDA's ability to seize food without a court order. The other new rule requires food importers to declare, before arriving at a United States port, whether the food in question had been denied entry at a foreign port. The rules, although effective as of July 3, are classified as "interim final rules." The FDA has invited further comments upon the rules and may revise them.

The FDA touts these rules as "the latest accomplishment of FDA in implementing the new food safety law."[2] While the rules (particularly the seizure rule) could greatly alter the relationship between the FDA and the regulated community, it remains to be seen whether the FDA wishes (or has the resources) to create a dramatic break from past practices.

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1 Federal Register, Vol. 76, No. 87 at 25538 (May 5, 2011).

2 FDA News Release, "FDA issues first new rules under Food Safety Modernization Act" (May 4, 2011).

EXPANDED AUTHORITY TO SEIZE FOODS

For decades, the FDA has had the authority to bring a court action to seize any "adulterated or misbranded" food, drug, or cosmetic. FD&C Act § 304(a)(1). More recently, the FDA gained the power to order the "administrative" detention of food. This permits an FDA official, by unilateral decree, to seize food for a 20- to 30-day period to enable the FDA to bring a court proceeding. FD&C Act § 304(h)(1)(A), (h)(2). The regulations governing administrative detentions can be found in 21 C.F.R. §§ 1.377 *et seq.*

Before passage of the FSMA, the FDA's power to declare an administrative detention of food was limited, and unused. The FDA was required to possess "credible evidence or information" that the food in question "presents a threat of serious adverse health consequences or death." FD&C Act § 304(h)(1)(A) (as effective before January 4, 2011). The FDA claims that it has "never administratively detained an article of food."[3] This may be due to the fact that regulated firms commonly recall dangerous products on a voluntary basis. The lack of administrative detentions may also have been due to a lack of enforcement resources, a focus on other enforcement priorities, or the difficulties in gathering the necessary evidence.

The FSMA greatly expands the FDA's authority. A seizure need not be directed at dangerous articles of food. The FDA can now seize food that is in any respect "adulterated or misbranded." FSMA, § 207(a)(2). Furthermore, rather than needing "credible evidence or information" that the food is subject to detention, the FDA now merely needs "reason to believe." FSMA, § 207(a)(1).

The new rule implements this expansion of power. The rule rewrites the regulation that answers the question: "What criteria does FDA use to order a detention?" 21 C.F.R. § 1.378. The regulation now reads, echoing the wording of the FSMA:

> An officer or qualified employee of FDA may order the detention of any article of food … if the officer or qualified employee has reason to believe that the article of food is adulterated or misbranded.

Federal Register Vo. 76, No. 87 at 25541 (May 5, 2011) (revising 21 C.F.R. § 1.378).[4]

The FDA anticipates that as a result of its new mandate, it is "more likely to use administrative detention … in situations which include … where the use of … a violative product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote."[5] This signals that the FDA will be more aggressive than it has been in the recent past. By comparison, current regulations regarding product recalls state that the FDA will not even issue a *request* for a recall—a nonbinding communication that signals a readiness to seek a court-ordered seizure—except in "urgent situations." 21 C.F.R. § 7.40(b); accord FDA, *Regulatory Procedures Manual*, § 7-5-2.

With this new power comes the potential for abuse. Any number of regulatory violations may make a food "adulterated or misbranded"—and hence subject to administrative detention—without presenting any material danger to human health. Some instances of adulteration or misbranding can, of course, cause imminent and severe danger, such as when food is known to be contaminated by virulent pathogens. But the terms "adulterated and misbranded" also encompass less exigent circumstances, such as if ingredients are substituted, or if the product is an imitation of another food without so declaring, or if all the requisite nutritional information does not appear on the label. *See* FD&C Act §§ 402(b); 403(c), (q). The regulations governing how to label foods are legion. Applesauce is misbranded if its "soluble solids content" is less than 9 percent. 21 C.F.R. § 145.110(a). Peanut butter is misbranded if its fat content exceeds 55 percent, (21 C.F.R. § 164.150(a)), and "mixed nuts" are misbranded if fewer than four kinds of tree nuts are used, or if any one nut constitutes more than 50 percent of the mixture without appropriate disclaimers. 21 C.F.R. § 164.110(a), (d). A violation of these regulations perhaps gives the FDA legal authority to initiate a seizure, but such violations can surely be corrected without resort to *ex parte* emergency measures.

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3 Federal Register, Vol. 76, No. 87 at 25540 (May 5, 2011).

4 The FDA is also making conforming changes to 21 C.F.R. § 1.393, which describes the format of a detention order. *See id.*

The FDA also wields broad discretion by virtue of the low burden of proof necessary to justify an administration detention. It is unclear exactly how the new "reason to believe" standard differs from the previous "credible evidence or information" standard. Arguably the new standard is less exacting, although it is hard to see how the FDA could have "reason to believe" that an article is subject to detention without being in possession of "credible … information."

Moreover, the authority to declare an administrative detention is not confined to a small number of officers. Such a restriction could have provided a check against seizures that are not sufficiently important to command high-level attention. Instead, a seizure can be ordered by an FDA District Director. FD&C Act § 304(h)(1)(B); 21 C.F.R. § 1.391. Thus, at least in theory, an FDA District Office can order a seizure without the input of headquarters.

Hopefully, the FDA will act with focus and restraint. The FDA takes seriously its mission to protect the public, and it well knows that it would be a waste of scarce enforcement resources to initiate seizures based upon dubious evidence, or to punish minor transgressions.

In the end, the impact of the new rule may be more subtle. One of the FDA's core strategies, which it shows no signs of abandoning, is to encourage the regulated community to voluntarily recall adulterated or misbranded products. *See* 21 C.F.R. § 7.40(a). This strategy is on the whole effective in securing compliance with regulatory requirements while minimizing the effort the FDA is forced to expend to remedy any particular problem. Given the current budgetary climate, the FDA may find that its new authority is too costly to exercise outside of urgent situations; the FDA simply does not have the manpower to fight too many unnecessary battles.

Firms initiate recalls for a variety of reasons, including to protect their customers, to protect their reputations, and to forestall harsh enforcement actions. The FDA's new authority may give it increased leverage over firms that would otherwise decline to recall their products but do not want to endure the costs and publicity of a government seizure. Thus, the new power to seize food may result in more recalls, even if seizures, whether administrative or court-ordered, remain uncommon.

ADDITIONAL DISCLOSURES FOR IMPORTED FOODS

The second of the new FDA regulations requires a food importer to disclose whether an article of food was previously refused entry by foreign countries.

Under current law, food importers must provide "prior notice" of their shipments. That is, before imported food arrives in the United States, the importer must file a form with the FDA disclosing a variety of information about the shipment. *See* FD&C § 801(m)(1); 21 C.F.R. § 1.276 *et seq*. The list of required disclosures is set out at 21 C.F.R. § 1.281.

A failure to provide the "prior notice" will result in the food being refused admission into the United States. FD&C § 801(m)(1). Imported food will also be refused admission, among other reasons, if it is adulterated, if it is misbranded, or if it was produced or held under unsanitary conditions. FD&C § 801(a).

Under Section 304(a) of the FSMA, the "prior notice" must also list "any country to which the article has been refused entry." The implementing rule becomes effective July 3, and it adds the new disclosure requirement to the applicable regulation.[6]

An article of food that has been refused entry elsewhere will not be automatically refused admission to the United States. Rather, "[r]equiring notice of prior refusals allows FDA to better identify imported food shipments that may pose safety and security risks to U.S. consumers."[7]

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5 Federal Register, Vol. 76, No. 87 at 25540 (May 5, 2011).

6 Federal Register, Vol. 76, No. 87 at 25542, 25545 (May 5, 2011) (amending 21 C.F.R. § 1.281).

7 Federal Register, Vol. 76, No. 87 at 25543 (May 5, 2011).

The practical effect of this new regulation is uncertain. The new regulation may, as the FDA states, "improve[] [the FDA's] ability to detect accidental and deliberate contamination of food and ... deter deliberate contamination."[8] However, the FDA's analysis of the need for (and expected benefits from) the new regulation contains no evidence that any substantial quantity of food arrives at U.S. ports after being rejected elsewhere.

CONCLUSION

When fully implemented, the FSMA is likely to have a significant effect on how food is regulated, and upon the burdens faced by the regulated community. The two new rules that go into effect on July 3 provide the FDA with additional weapons. The importance of these weapons will, in the first instance, depend on how the FDA chooses to wield them.

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8 Federal Register, Vol. 76, No. 87 at 25544 (May 5, 2011).