FSMA—Enforcement by Another Means: Litigation

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This is the third article in a three-part series that examines developments in and the future of the FDA Food Safety Modernization Act. If you missed the first article "Outbreaks Persist as FSMA Implementation Lags", go here . To read last week's piece, "FSMA: Minimizing Risks of Foodborne Illness and Identifying Hazards", go here .

By Marc Sanchez, Esq.

The FDA Food Safety Modernization Act (FSMA) is taking shape. Three of the rules at the heart of the first change in food-safety enforcement since the 1930s were released in January, nearly a year late. Much of the buzz centers on what the new rules will require of food facilities and farms. The scope and depth of the rules is dizzying, even for those accustomed to reading the Food Drug and Cosmetic Act. Although many in the industry are asking what the rules mean, a growing number are asking why they should bother complying with them when the U.S. Food and Drug Administration (FDA) may never inspect their facility.

The best answer I provide clients is that FSMA relies on enforcement by another means: namely through plaintiff's lawyers and a tidal wave of litigation they will bring. It is no secret, even before FSMA was enacted, that FDA lacked enough boots on the ground to review a majority of facilities. The broader mandate of FSMA brought a push for more agents, but only a trickle in increased funding. Yet the legislation doesn't need more FDA agents to be enforced. The legislation points to a new enforcer of food safety.

It starts with mandatory standards. Standards in the proposed produce-safety rule and preventative controls rule are replacing outdated, voluntary guidance documents, and in some cases, filling a void. Mandatory standards will make food litigation easier. For example, plaintiff's lawyers litigating an outbreak case often must point to what a facility did wrong in regards to food processing, preparation, storage or handling.

Before FSMA, "wrong" would be defined by broad statutory definitions, like adulteration, and using recommendations from guidance documents. This approach easily allows room to build defenses, especially when an entire industry failed to follow a cited recommendation. Once the proposed rules are finalized, this will no longer be the case. More rules are coming, including standards on how food is shipped. In the end, the balance will be permanently shifted from guidance documents and broad definitions to a mountain of mandatory standards and recordkeeping.

Mandatory standards will be a ticket into court. Regardless of whether the FDA takes enforcement action, a plaintiff may entertain questions in the pursuit of damages, such as "why wasn't section 112.31 of the produce safety rule followed?" It opens the possibility for plaintiffs with small damages from less severe bouts of food poisoning to aggregate their claims in a class action. A model is already set for this type of class action in states like California where food-labeling lawsuits with nominal damages are successful. It may not stop at food poisoning. The potential for creative claims remains unexplored.

Mandatory standards are made more potent by new record-keeping requirements. FSMA generally expands the scope of records a facility must keep and make accessible to the FDA. It also adds record-keeping requirements in nearly every section where it introduces a new standard, exemption, or exception. When finalized, facilities will not only need to comply with the standards, but strictly demonstrate how and when. Plaintiff's lawyers will make quick use of the new records or their conspicuous absence. A common practice already exists for plaintiff's lawyers to rely heavily on U.S. Centers for Disease Control and Prevention (CDC) and FDA records. This practice will only expand under FSMA.

Added pressure to comply will come from manufacturers seeking to mitigate their risk exposure. FSMA provides more fluidity for the FDA to regulate up and down the supply chain. The preventative controls rule, for example, suggests a facility should audit and verify its suppliers. Looking at any recent outbreak case, one will find a string of defendants from farm to grocery store. Plaintiffs are in search of parties who can cover damages, and FSMA provides a new tool to aid in that effort.

Facilities aren't defenseless but must take a new approach to compliance. Compliance will no longer be a rote checklist. There is now a strategy to it. For example, the preventative controls rule requires facilities to implement a food-safety plan. The food-safety plan is an enhanced HACCP-style hazard analysis. If not drafted correctly, it can be a roadmap for regulators and plaintiff's lawyers. The rules are full of other examples where a defensive compliance strategy must be built-in.

The goal remains the same under FSMA: protect the consumers to protect the brand. It's the means FSMA changes. New standards require a new look at how a facility operates and complies with regulations. It also means if a facility fails to take a fresh look, it may not be the FDA that enforces non-compliance, but plaintiffs during litigation.

Marc Sanchez represents FDA-regulated companies in the food, dietary supplement, beverage, cosmetic, medical device and drug industries. With a focus on international trade, he advises clients on the regulatory requirements and strategic corporate considerations that affect the importation, distribution and exportation of FDA regulated products. Marc is a frequent national speaker on FDA compliance issues and is considered a leading voice in understanding the Food Safety Modernization Act, which has fundamentally changed food law in the U.S., with interviews and contributions in the Washington Post and Huffington Post.