JONES DAY

APRIL 2013

THE FDA IS MOVING FORWARD ON MAJOR NEW "FSMA" REGULATIONS

In January 2011, President Obama signed the **Food Safety Modernization Act**. This Act, known as FSMA, directs the FDA to make sweeping changes to how America's food supply is regulated. For the following two years, not much happened. Although inspections and enforcement actions are now more frequent, the most anticipated new regulations remained under wraps.

On January 4, 2013—the second anniversary of FSMA's enactment—the FDA published drafts of two of the most important new regulations: the **Produce Standards** rule and the **Preventive Controls** rule. These rules are not in their final form, and won't be enforced for several years—but when they are, they will have a big impact on the industry.

For at least the next month, affected businesses can voice their opinions on the proposed rules by submitting written comments. Our next *Commentary* will discuss how to take advantage of this important opportunity to shape the proposed regulations. The FDA also obtained reactions to the proposed rules by holding three public meetings at which participants were encouraged to provide informal, face-to-face feedback. A report of the first of these meetings can be found below.

THE FDA'S PERSPECTIVE ON FSMA AND THE TWO NEW RULES

The FDA views FSMA as the most important change to food regulation since the Food, Drug, and Cosmetic Act was passed in 1938. These changes will result in compliance costs to industry that the FDA estimates at well over $1 billion each year. Although the FDA is attempting to balance increased safety against the compliance costs, safety is its chief concern.

Accordingly, the FDA intends its new rules to be preventive, risk-based, and science-based. In English, this means, first, that the purpose of the additional

regulations is preventing food-borne illnesses, rather than merely reacting to outbreaks.

Second, the nature of a firm's responsibilities for preventing contamination will depend on the risks posed by that firm's operations. This is both good and bad. It is helpful that the FDA recognizes that one-size-fits-all solutions are cumbersome and often inappropriate. But the flexibility of this approach also makes it harder to determine exactly what must be done to comply.

Third, the regulations are supposed to reflect real-world risks, as proven by scientific evidence, and mandate efforts that are scientifically proven to be effective in reducing these risks.

THE PROPOSED PRODUCE STANDARDS RULE

At present, the FDA does not directly regulate farming methods. This will change when the FDA finalizes the Produce Standards rule, known formally as the "Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption." This proposed rule identifies five vectors that can lead to microbial food contamination on farms:

- Agricultural water,
- "Biological soil amendments" (essentially manure or wastewater used as fertilizer),
- Worker hygiene,
- Equipment, tools, and facilities, and
- Animals (both domesticated and wild).

The rule imposes requirements addressed to each of these possible vectors, as well as requiring worker training and the maintenance of specified records. The rule exempts produce that is seldom eaten raw and produce that will be shipped to a processor who employs a "kill step" to eliminate pathogens. Sprouts, which the FDA views as particularly high risk, are subject to additional controls.

Farms with less than $500,000 in annual sales are exempt from most provisions.

THE PROPOSED PREVENTIVE CONTROLS RULE

The second major rule announced in January updates current good manufacturing practice ("cGMP") requirements and establishes new "Hazard Analysis and Risk-Based Preventive Controls" requirements. The latter requirements reflect the more important changes from current regulations. In short, the Preventive Controls regulations require covered firms to create a food safety plan that identifies the hazards reasonably likely to occur in their operations. The firms must then implement, verify, monitor, and document effective control measures to prevent those hazards. Firms must also plan how they will implement corrective action and recalls if the control measures do not work, and must periodically reevaluate their plans.

The Preventive Controls requirements are less of a sea change than the Produce Standards. Unlike farms, registered facilities such as manufacturers and processors are already subject to cGMP requirements and should already have compliance programs in place. The new Preventive Controls requirements are modeled after the existing "HACCP" (Hazard Analysis and Critical Control Points) regulations. HACCP regulations are already mandatory for facilities that produce seafood, juices, meats, and poultry products, and voluntary compliance with HACCP standards is increasingly common among dairy firms and many of the largest food manufacturers of all descriptions.

The changes are nonetheless significant. Most firms currently do not follow HACCP guidelines, and they will need to retrain their personnel, and often will want to hire outside auditors to monitor compliance.

"Very small businesses" are exempt from many of the new requirements. The scope of this exception remains uncertain; at present, the FDA is considering whether this exception should be restricted to businesses that sell less than $250,000 of food per year, or whether firms with up to $1 million in annual sales can qualify.

THE PUBLIC MEETING IN WASHINGTON

The FDA held the first in a series of public meetings to discuss the Produce Standards and Preventive Controls rules on February 28 and March 1. Many senior officials attended. The Commissioner, Margaret Hamburg, gave the opening presentation, and the Deputy Commissioner for Foods and Veterinary Medicine, Michael Taylor, stayed for the entire two-day meeting.

The public comments were consistently supportive of the regulations, albeit with varying levels of enthusiasm. The first four speakers set the tone. These speakers—and no doubt this was not a coincidence—were a girl suffering long-term health issues as a result of eating a contaminated cantaloupe, a young woman who nearly died from tainted spinach, a mother who had fed her daughters a nearly lethal spinach salad, and a man whose father died from cantaloupe. While many speakers voiced concern over specific issues, no one attempted a head-on assault on the rules.

The most common concern voiced by industry representatives involved imported foods. The FDA is explicit that imported foods will be required to meet the same requirements as domestic foods. The FDA promises to publish soon a series of proposed rules and initiatives designed to implement this policy. The most important anticipated rule will require importers to verify that their suppliers complied with all FDA requirements. Despite the FDA's assurances, there remains an undercurrent of doubt as to whether foreign producers really will be forced to comply. As a result, many speakers complained that they could not meaningfully comment on the Produce Standards and Preventive Controls rules until after the FDA publishes the importer verification rule. An FDA spokeswoman later stated informally that the FDA "will adjust the comment periods to allow the opportunity for the public to comment as a package."

Other comments addressed the scope of the small business exemptions. The consumer advocates, and some industry representatives, argued for making the exemptions as narrow as possible. All operations, they asserted, pose the same risks of contamination. Some commentators, however, asked the FDA to keep in mind the burden that the new regulations would impose on smaller firms and farms.

Even two years after FSMA became law, its implementation process is just beginning. The FDA will be accepting comments on the two rules we have been discussing until May 16, and the comment period may be extended.

And more regulations are coming. *Many* more regulations are coming. Importers will likely be dramatically affected by the importer verification rule mentioned above. New pet food rules, perhaps comparable to the Preventive Controls rules, are also coming soon, along with rules designed to beef up foreign enforcement abilities by establishing a network of third-party inspectors. Other rules in the pipeline will address sanitary transportation of food, intentional adulteration, and increased record-keeping burdens for high-risk foods.

This Commentary *originally appeared in the* **Perishable Pundit** *on April 11, 2013.*

LAWYER CONTACTS

For further information, please contact your principal Firm representative or one of the lawyers listed below. General email messages may be sent using our "Contact Us" form, which can be found at www.jonesday.com.

Jonathan Berman
Washington
+1.202.879.3669
jberman@jonesday.com

June K. Ghezzi
Chicago
+1.312.269.4171
jkghezzi@jonesday.com

Harold K. Gordon
New York
+1.212.326.3740
hkgordon@jonesday.com