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FSMA TWO YEARS AFTER ENACTMENT: WAITING FOR THE OTHER SHOE TO DROP

On January 4, 2011, the Food Safety Modernization Act ("FSMA") was signed into law with great fanfare. The Food and Drug Administration ("FDA") pronounced FSMA to be "the most sweeping reform of our food safety laws in more than 70 years." FSMA provided the FDA with new enforcement tools and a mandate to step up the pace of inspections. Among many other provisions, FSMA also instructed the FDA to promulgate regulations—on an aggressive timetable—that would impose new compliance obligations and that would force importers to ensure the compliance of foreign suppliers.

Two years later, the effect of FSMA on the regulated community has been modest. This is not because FSMA was overhyped. Rather, it is because the most significant regulations—and some of these regulations will have a major impact—have not yet been written. Furthermore, although FSMA calls for greatly expanded oversight of imported foods, the FDA does not yet have the capacity to meet this goal.

The parts of FSMA that are currently in effect have a more incremental effect. For example, the FDA seldom uses its new enforcement tools, continuing its historic practice of securing "voluntary" compliance through informal pressure.

The FDA has not been inactive. The regulations pertaining to the new enforcement tools are largely in place. The FDA has issued new guidance documents and reports, revamped the registration portal, issued grants, and launched various pilot programs. But from the perspective of industry's ongoing compliance requirements, the most important changes are yet to come.

FSMA'S NEW COMPLIANCE REQUIREMENTS

FSMA called for the FDA to promulgate numerous major regulations on an expedited schedule,

including seven proposed or final rules within 18 months. The agency's response, according to the testimony of the Deputy Commissioner for Foods and Veterinary Medicine, was to "quickly determine[]" that meeting the statutory deadlines "would not be feasible." Accordingly, the FDA has not yet published many key regulations, even in draft form. These anticipated new rules might not be in effect for years.

Hazard Analysis and Preventive Control Systems. Perhaps FSMA's most radical mandate is to require manufacturers to install hazard analysis and preventive control systems. The FDA considers the regulations implementing this mandate to be among the FDA's "first wave" priorities. Over a year ago, the FDA submitted two sets of draft regulations (one set for human food, the other for animal food) to the Office of Management and Budget ("OMB"). But we still do not know the details regarding how FDA intends to implement the hazard analysis mandate. OMB has not finished reviewing the regulations, and no draft will be made public until OMB does so.

What we do know is that the new regulations are ambitious in scope, and likely to be burdensome. In addition to implementing FSMA's hazard control provisions, the FDA is using this rulemaking proceeding to modernize its cGMP (current Good Manufacturing Practices) regulations, which have not been updated since 1986. The FDA plans to more explicitly address issues such as environmental pathogens, food allergens, mandatory employee training, and sanitation of food contact surfaces. The FDA forecasts that compliance will cause the industry to bear significant one-time and recurring costs involving adopting new plans, training employees, implementing allergen controls, purchasing new tools and equipment, auditing and monitoring suppliers, and keeping additional documentation.

However, even if OMB acts immediately, implementation of the new rules remains a long way off. The FDA must still publish the draft regulations, obtain and analyze comments from the public, and publish a final regulation. Following publication of the final regulation, there will be a grace period before the regulation goes into effect; the FDA has stated that it will not enforce any hazard analysis requirements until a date to be announced with the publication of the final regulations.

Other New Compliance Mandates. Regulations establishing other important aspects of FSMA are also still in process. Although the FDA views establishing "minimum standards for the safe production and harvesting" of fruits and vegetables to be a "first wave" priority, the FDA has not yet released a draft of the implementing regulations. Along with the other "first wave" regulations, the produce safety regulations have been under review at OMB for more than a year, inaccessible to the public.

Still other new regulations are even farther away from being effective. Rules establishing transport safety standards were said (in September 2012) to be "close to completion within FDA," but the FDA has not yet submitted these rules to OMB. The FDA will not begin drafting regulations preventing intentional adulteration until after it receives public comments in response to an Advanced Notice of Proposed Rulemaking (which is not yet drafted). The FDA has provided no information on the status of still other expected rules, including those requiring additional record-keeping for high-risk foods and requiring grocery stores to notify customers who may have purchased "reportable food."

NEW ENFORCEMENT TOOLS

Even though many new compliance obligations remain months or years away, FSMA has already provided the FDA with more tools to combat violations of existing obligations. The FDA can suspend a facility's registration, which would prevent the facility from lawfully shipping any products. FSMA also strengthened the FDA's ability to order the administrative detention of adulterated foods, and FSMA broadened the FDA's authority to demand the inspection of records that may be related to contaminated foods.

Even so, the FDA has continued its policy of being sparing in its use of formal enforcement proceedings. For example, the FDA has suspended the registration of only one facility (the facility that the FDA blames for the recent incidence of salmonella-contaminated peanut butter). In 2011, the FDA announced that it had used its administrative detention power for the first time—a power that (in a slightly weaker form) predated FSMA by a decade. To date, the FDA has announced a total of four such seizures of conventional

foods. At least as presented by the FDA, none of these was a close call. Three were in response to severe pest infestations, and one was due to Listeria contamination. It should be no surprise that the FDA reacts strongly when it finds "live and dead rodents in and around food products."

The broader impact of the new enforcement tools is likely to be more subtle than a flood of formal proceedings. Even before FSMA, companies facing informal requests to cure compliance issues were very likely to comply. The pressure for "voluntary" compliance may be marginally more effective now in light of the FDA's new weapons. Indeed, FSMA may even result in a lower number of formal enforcement proceedings, both because of this deterrent effect and because the FDA is shifting resources to inspections.

INCREASED INSPECTIONS

FSMA directs the FDA to "increase the frequency of inspection of all facilities." All domestic "high-risk" facilities must be inspected within five years of FSMA's enactment and every three years thereafter. Other domestic facilities are to be inspected within seven years and then every five years thereafter. FDA data indicates that food-related inspections are in fact increasing. In 2011, inspections were up about 20 percent from 2010, and the 2010 numbers themselves represented a 30 percent increase over 2009. But even the current pace falls well short of the frequencies demanded by FSMA, and meeting FSMA's schedules will require increased resources in an era of tight budgets.

IMPORTED FOOD

It has long been the law—on the books, if not always in practice—that imported food must meet the same standards as food from domestic facilities. Even before FSMA, both foreign and domestic establishments were required to register, subject to inspection and subject to the GMP (Good Manufacturing Practices) regulations. FSMA contains numerous provisions designed to enforce these existing requirements. But the full impact of these provisions has not yet been felt.

Even more than with domestic facilities, FSMA calls for dramatic increases in the inspections of foreign facilities. The FDA was required to conduct only 600 foreign inspections in 2011, but FSMA calls for inspections to at least double every year for five years. To meet that goal, the FDA now has 13 foreign offices, and it has renewed an agreement with China to cooperate on food safety issues. FSMA put teeth into the requirement that foreign facilities be subject to inspection. If the FDA is denied entrance to a facility, whether by the facility's owner or by a foreign government, food from that facility cannot be imported into the United States. Still, with only about 50 total employees staffing the FDA's foreign offices—and with more than 254,000 foreign establishments to inspect—the FDA is not likely to ever inspect the vast majority of foreign food establishments.

To fill the hole, FSMA calls for importers to police themselves and for the FDA to accredit foreign governments and other third parties to perform inspections on the FDA's behalf. But here again, the implementing regulations will not be in effect for some time. For example, the draft regulation allowing for accreditation of third-party inspectors was not submitted to OMB until November 2012.

Importers of foods will be required to verify that the food conforms to a variety of regulatory requirements, including adulteration and GMP requirements. The FDA views this set of regulations as a "first wave" priority. Like the other "first wave" regulations, the FDA submitted the importer verification regulations to OMB more than a year ago. And like the other "first wave" regulations, this set has also been pending at OMB ever since, inaccessible to the public. The FDA has indicated informally that it will not enforce the new verification requirements until sometime after it finalizes the implementing regulations. In the end, however, these rules will likely create a significant burden on importers. Mandated verification activity might include monitoring records for shipments, lot-by-lot certifications of compliance, annual on-site inspections, checking the hazard analysis and risk-based preventive control plans of foreign suppliers, and periodically testing and sampling shipments.

For foods that pose an elevated risk, or for food that originates in a country with particular safety risks or lax food

regulation, the FDA can promulgate regulations requiring certifications that the food complies with U.S. standards. The FDA will also establish a voluntary certification program. In exchange for obtaining certification that a facility operates in compliance with U.S. standards, an importer will receive "expedited review and importation" of its goods. These rules are farther back in the queue, and the FDA has not announced a timetable for their completion.

IMPLEMENTED PROVISIONS

FSMA is a complex bill, and many of its provisions are now in effect. As noted above, the new enforcement tools are in place. Compliance requirements currently in effect include re-registering facilities every two years. After a rocky start (which caused the FDA to extend the registration deadline to January 31, 2013), the registration portal is now open for this purpose. Whistleblower protection for employees who report or refuse to commit regulatory violations were effective immediately. The Reportable Food Registry has been tweaked to gather more information from each report. FSMA and finalized implementing regulations make modest steps toward identifying foods that have been denied entry to other countries or that have been smuggled into the United States. The FDA claims its progress includes publishing three final rules, nine draft and final guidance documents, an anti-smuggling policy, and various notices; providing Congress with five reports; carrying out a product tracing pilot study; and signing a Memorandum of Understanding with the Department of Agriculture regarding a grant program.

CONCLUSION

FSMA will, in time, have a significant impact on the regulated community. Four of the five regulations pending at OMB are classified as "economically significant." Although the regulations remain unpublished, the public summaries report that the compliance costs will be substantial. And more regulations are coming.

The regulated community should closely monitor the rule-making process, intervene where draft regulations threaten to impose unreasonable burdens, and prepare for a more highly regulated future.

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