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FSMA TWO YEARS AFTER ENACTMENT: IT HAS NOT YET HAD ITS PREDICTED EFFECT ON INDUSTRY, BUT IT WILL

On January 4, 2011, the Food Safety Modernization Act ("FSMA") was signed into law with great fanfare. The Food and Drug Administration 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 important 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 are not yet in effect. But important changes are on the way. On January 4, 2013—the second anniversary of FSMA's enactment—the FDA proposed two major sets of rules. The first, "Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food," will apply to most manufacturers. The second, "Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption," will apply to most farms. Compliance with each set of rules will cost hundreds of millions of dollars every year.

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. Furthermore, although FSMA calls for greatly expanded oversight of imported foods, the FDA does not yet have the capacity to meet this goal.

Other activity from the FDA includes promulgating internal rules pertaining to the new enforcement tools. 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 coming, but are not yet here.

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 finalized many key regulations. Many of these anticipated new rules will not be in effect for years. However, two major sets of proposed ruled were issued on January 4, and companies that want an opportunity to shape the final regulations must examine the proposals and submit comments to the FDA within the next 120 days.

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's proposed rule, published on January 4, "is intended to build a food safety system for the future that makes modern science-, and risk-based preventive controls the norm across all sectors of the food system."

The hazard analysis rules will apply to every facility, unless exempted, that "manufactures, processes, packs, or holds food for sale in the United States." Most farms will be exempt from these rules. Farms performing low-risk manufacturing operations and very small businesses are exempt from most of the hazard analysis provisions. Facilities whose products are already subject to heightened regulations—facilities that produce seafood, juice, certain canned foods, and dietary supplements—are exempt, as are certain storage facilities and manufacturers of alcoholic beverages. All other businesses that must register their food facilities will be subject to the regulations if enacted as written.

The FDA estimates that the annual compliance costs for domestic facilities will be between $319 million and $475 million, depending on the scope of the exemption for "very small businesses." The FDA gave no estimate of the costs that will be borne by foreign producers, nor did the FDA provide any estimate of the benefits that would result from the new rules.

The proposed hazard analysis rules are modeled after the "HACCP" (Hazard Analysis and Critical Control Points) regulations that govern the production of seafood, juices, meats, and poultry products. In short, the regulations require manufacturers to create a food safety plan that identifies the hazards reasonably likely to occur in their operations. The manufacturers must then implement effective control measures to prevent these hazards. They must verify the efficacy of the controls, monitor them to ensure they are implemented and working, and re-evaluate the food safety plan every three years or as circumstances dictate. Manufacturers must plan how they will implement corrective action and recalls if the control measures do not work. Compliance with all these requirements must be carefully documented.

In addition, the FDA is taking the opportunity to modernize the existing cGMP (current Good Manufacturing Practice) regulations, which have not been formally revised since 1986. In part, the FDA is clarifying its terminology and making explicit certain requirements that the FDA has long been reading into the rules. For example, it is a point of emphasis that manufacturers should protect consumers who suffer from food allergies. The existing GMP regulations, as interpreted by the FDA and as clarified in the proposed new rules, require diligence in avoiding "cross-contact" between foods that contain allergens and other foods. The proposed rules would also abandon some non-mandatory "guidance" regulations; other guidance regulations would become mandatory. The proposed rules make dozens of other changes and heighten the record-keeping requirements.

These rules are not yet finalized, and the publication of final rules is not imminent. The FDA is soliciting comments from the public and will then need to analyze the comments and revise the regulations. The FDA will be accepting comments on the proposed rules until May 16, 2013.

While the rules will become "effective" 60 days after being published in final form, the FDA will not expect compliance at that time. Most businesses will be expected to comply one year after their publication. Small business will have two years, and very small businesses (which are in any event exempt from most provisions) will have three years.

Produce Safety Standards. In another January 4, 2013 announcement, the FDA published draft produce safety regulations. These extensive new regulations will govern farm operations. Such intensive oversight over farm operations is a departure from historic practice. Until now farms have been exempt from most (but not all) FDA regulations.

The compliance burden from the new regulations is considerable. According to FDA estimates, annual compliance costs will be about $460 million for domestic farms and $171 million for foreign operations, for a total of about $630 million per year. The estimated per-farm cost will range from $4,697 per year for very small farms to $30,566 for large farms. These totals, no doubt, do not include the cost of wading through the 72 pages of proposed new regulations.

Under the proposed rules, farm workers will be subject to requirements relating to training, health, and hygiene. All agricultural water must be of safe and sanitary quality. New controls will govern the use of biological fertilizers and other biological soil amendments. Other rules are intended to prevent contamination from animals (both domesticated and wild). Rules will mandate sanitary conditions for facilities and for the use of equipment and tools. Lastly, particularly stringent regulations will govern the production of sprouts. The produce safety rules focus entirely on microbiological hazards. Unlike the hazard analysis rules, the produce safety rules are not designed to prevent chemical, physical, or radiological hazards.

Most farms will need to comply with the new rules, although small farms are partially exempt, and very small farms are entirely exempt. The regulations do not apply to specified products that are seldom consumed raw, nor to produce that, in later processing, will be subject to a "kill step" that adequately reduces the presence of microorganisms.

Like the hazard analysis rules, the produce safety rules are not in final form. The FDA will be accepting comments on the proposed produce safety rules until May 16, 2013. After further analysis, the FDA will then publish the final rules.

The rules will become "effective" 60 days after published in final form, but as with the hazard analysis rules, the FDA will not expect compliance on the effective date. The compliance period begins two to four years after publication of the final rule (depending on the size of the farm). Compliance with the water quality rules will not be enforced until four to six years after publication of the final rule.

Other New Compliance Mandates. Still other new regulations are in the pipeline. These other regulations are not yet public, even in draft form. Rules establishing transport safety standards were said (in September) to be "close to completion within FDA." However, the FDA has not yet submitted these rules to the Office of Management and Budget ("OMB"), which in turn must review and approve the regulations before they are published. 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 years away, FSMA has already provided the FDA with more tools to combat violations of existing obligations. The FDA can now order the recall of food products. 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), and the FDA revoked the suspension order six weeks later. In 2011, the FDA announced the 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, and the FDA submitted the importer verification regulations to OMB more than a year ago. The regulations remain under review by OMB, 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 now 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. The compliance costs of the proposed rules issued on January 4 will likely exceed $1 billion per year. And more regulations are coming, including two other sets, now pending at OMB, that are classified as "economically significant."

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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