Bloomberg BNA

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Food Safety

As promised, FDA's long-awaited proposed rules implementing the 2011 Food Safety Modernization Act (FSMA) are sweeping, author Jonathan Berman of Jones Day writes.

Now is the time, he says, for food manufacturers, processors, and farmers to thoroughly familiarize themselves with the proposed regime—and submit comments to FDA spelling out the problems (and strengths) of FDA's approach.

FDA-Proposed Food Safety Rules Cover Most Manufacturers, Processors, Farms

BY JONATHAN BERMAN

The Food Safety Modernization Act (FSMA), enacted in 2011, provided the Food and Drug Administration with new tools to enforce food regulations, and new authority to promulgate regulations. The FDA views its mandate expansively. According to the FDA, FSMA is a ''sweeping reform of our food safety laws,'' aiming to ''ensure the U.S. food supply is safe by shifting the focus from responding to contamination to preventing it.''[1]

On Jan. 4, 2013—the second anniversary of FSMA's enactment—the FDA proposed major rules that would require the food sector to do more to prevent foodborne hazards. The first set of rules, ''Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food,'' will apply to most manufacturers and processors. 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.

[1] http://www.fda.gov/Food/FoodSafety/FSMA/default.htm.

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The Proposed GMP and Hazard Analysis Rules

Manufacturers and processors will be required to install hazard analysis and preventative control systems. The FDA's proposed rule ''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

 ISSN 0148-8155

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.

Hazard Analysis Rules TRACK HACCP. 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 reevaluate 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.

FDA is clarifying terminology, and making explicit certain requirements it has long been reading into the cGMP (current Good Manufacturing Practice) regulations.

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 it 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 recordkeeping 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 (who are in any event exempt from most provisions) will have three years.

Produce Safety Standards

The other draft regulations that the FDA published Jan. 4 concern produce safety regulations. These extensive new regulations will govern farm operations, and will ''set forth procedures, processes, and practices that minimize the risk of . . . biological hazards.'' 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.

FDA will be accepting comments on both proposed rules until May 16.

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.

Conclusion

Within a few years, FSMA will have a significant impact on the regulated community. Compliance costs of the proposed rules issued Jan. 4 will likely exceed $1 billion per year. And more regulations are coming. Major regulations implementing a ''foreign supplier verification program'' are expected to be unveiled very soon. These regulations are likely to require importers to

  DER ISSN 0148-8155

verify that their suppliers comply with U.S. standards regarding adulteration, Good Manufacturing Practices, and allergen labeling. Additional compliance requirements will eventually include transport safety standards, prevention of intentional adulteration, and further recordkeeping for high risk foods.

Companies that want to lessen the blow from the new regulations should submit comments to the FDA within 120 days. All companies would be well advised to continue to monitor developments, and prepare for a more highly regulated future.