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Food Safety Modernization Act Legislative Update

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January 4, 2012, marked the 1-year anniversary of the Food Safety Modernization Act (FSMA). In its "FSMA One-Year Progress Report," the U.S. Food and Drug Administration (FDA) reported that it had made certain strides toward implementing FSMA, including the following:

- Conducting outreach to domestic and international participants in the food industry to receive input in developing proposed rules
- Issuing final interim rules on criteria for administrative detention and on prior notice of imported food
- Establishing the Produce Safety and Food Safety Preventive Control Alliances
- Satisfying FSMA's mandate for foreign food safety inspections

January 4 also marked the date by which FDA was to publish for comment the following proposed food safety regulations implementing important sections of FSMA:

- Hazard Analysis and Risk-Based Preventive Controls (Section 103)
- Current Good Manufacturing Practice and Hazard Analysis and Risk-Benefit Preventive Controls for Food for Animals (Section 103)
- Produce Safety Regulations (Section 105)
- Foreign Supplier Verification Program (Section 301)

Those regulations are more than 3 months late. Each remains within the Office of Management and Budget (OMB), which is charged with assessing economic and other impacts of regulations. OMB ensures that agency regulations are consistent with the U.S. Administration's policies and budget.

How will this delay impact the date on which FSMA is fully implemented? FSMA specifies July 2012 as the deadline by which preventive controls, such as those reflected in the proposed regulations, are to take effect. At this juncture, FDA is unlikely to fully meet that deadline. The proposed regulations could significantly affect the economic interests of food companies, in particular smaller companies. Thus, OMB's review may take some time.

But even were the OMB to complete its analysis soon, an important step in the rule making process remains for completion before final versions of the four regulations may issue and take effect. Critically, that rulemaking step directly involves the food industry. That is, as with all regulations, the four proposed

regulations must be published for public comment. Typically, the comment period is at least 60–90 days, although a shorter period is possible. Following completion of the public comment period, FDA must consider and address public comments in whatever final regulations issue.

It is important for food companies to review, analyze and comment on proposed FSMA regulations, and others, that will govern the food industry. In that way, food companies can help shape the very rules that will control their operations, impact their success and, perhaps, affect their viability.

To that end, an important comment opportunity presently exists. On February 23, 2012, FDA published for public comment an interim final rule, and a draft guidance to the food industry, regarding FDA's authority to access and copy records. FSMA expands FDA's authority. Under the proposed interim rule and guidance, FDA can have access to a company's records regarding the specific suspect food product that FDA reasonably believes could cause adverse health consequences or that could be adulterated as well as to the records relating to the company's manufacture of any other food product (i) that the FDA reasonably believes is likely to be affected in a similar manner or (ii) for which the FDA believes there is a reasonable probability that use of or exposure to the food product will cause serious adverse health consequences. In other words, FSMA and, as written, the interim final rule significantly expand the scope or records FDA may access as part of an investigation.

In promulgating the final rule regarding records access, FDA must consider and comment on industry remarks to the interim rule and draft guidance that the FDA receives on or before May 23, 2012. The interim rules, the draft guidance and the instructions for submitting comments can be found on FDA's website, www.fda.gov, and at www.regulations.gov. Food companies should closely review, prepare for and, where appropriate, comment on the interim records access rules and guidance. For the unprepared, the new records rule, as with the other forthcoming FSMA regulations, could significantly impact your company.

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