FDA FOOD SAFETY MODERNIZATION ACT

THE FOOD SAFETY LAW AND THE RULEMAKING PROCESS: PUTTING FSMA TO WORK

The FDA Food Safety Modernization Act (FSMA), which became law when President Obama signed it January 4, 2011, will be fully implemented over time, and the public, including companies affected by the new law, will have many opportunities to participate in the implementation process.

FSMA is the most sweeping reform of FDA's food safety authority in more than 70 years, and a law of this scope and complexity often comes with direction from Congress for the federal agency responsible for implementing it to go through a process called rulemaking.

The new food safety law calls for a number of rules (also called regulations) and guidances. This will not happen overnight and will not happen in a vacuum.

Putting FSMA to Work

Under the new food safety law, FDA will be issuing a number of rules including a preventive controls rule in food facilities, a foreign supplier verification rule, and a produce safety rule. In some instances, FDA holds public meetings to give all interested parties an opportunity to participate and provide comments even before proposing a rule. During these public meetings, FDA officials involved in the development of the rule often make presentations.

Every rule is developed under slightly different circumstances, but this is an overview of the process FDA follows when it issues rules under "notice and comment rulemaking." This process is set out in another federal law, the Administrative Procedure Act. Final rules issued by FDA under this process have the force of law.

Step 1: FDA Proposes a Rule and Requests Comments

FDA issues a proposed rule, also known as a Notice of Proposed Rulemaking (NPRM). This proposal is published in the Federal Register (FR) so that members of the public can review it and send their comments to us. The public is given a period of time to submit their comments – this typically ranges from 30 - 90 days. The proposed rule and supporting documents are also filed in FDA's official docket on Regulations.gov.

As implementing rules for FSMA are drafted that have the potential to impact international trade, FDA will send notice to the World Trade Organization so that international stakeholders are aware of developments such as proposed rules.

If FDA determines that it does not have enough information to issue a proposed rule, the agency may seek more information by issuing an Advance Notice of Proposed Rulemaking.

Step 2: FDA Considers Your Comments and Issues a Final Rule

FDA considers the comments received during the comment period on the proposed rule. We then consider revising the rule based on our review of the comments and issue a final rule. In the preamble to the final rule, we discuss the significant comments received on the proposed rule. This final rule is also published in the FR and FDA's official docket on Regulations.gov.

Step 3: Companies Comply with the Rule Based on the "Effective Date"

Even when a final rule is published, it may have an effective or compliance date in the future; sometimes this has been established in the law. The amount of time before a rule goes into effect can vary; it may be six months from publication of the final rule, or it may be a year from publication, for instance. In addition, sometimes a final rule provides accommodations for small businesses.

Additional Tool: FDA Issues Guidance Documents to Assist Industry

An FDA rule may not address every specific issue faced by a regulated industry. So, FDA often issues "guidance" for regulated industry.

Guidance documents represent FDA's current thinking on a topic. They do not create or confer any legally enforceable rights or responsibilities and do not legally bind FDA or the public. You can use an approach other than the one set forth in a guidance document if the approach satisfies the requirements of the applicable statutes and rules.

Guidance documents describe FDA's interpretation of or policy on a regulatory issue (21 CFR 10.115(b)(1)). These documents often discuss issues that relate to the design, production, labeling, promotion, manufacturing, and testing of regulated products. Guidance documents may also relate to the processing, content, and evaluation or approval of submissions as well as to inspection and enforcement policies.