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## What's Happening with Food Safety Modernization Act Rules

By William H. Kitchens

While the industry waits for the new rules under the Food Safety Modernization Act (FSMA), here's what I see the FDA is doing regarding these new rules.

The FDA recently announced that it expects to publish a proposed rule shortly that will require new safety standards for shippers, carriers, receivers and others involved in food transportation (implementing Section 111 of FSMA). Congress added this requirement after FDA failed to draft similar standards under the Food and Drug Administration Amendments Act of 2007.

Also, supposedly coming soon is an advance notice of proposed rulemaking that would begin the process of implementing FSMA's intentional adulteration provision (Section 106 of FSMA). FSMA had directed FDA by January 4, 2012 to write rules that spell out science-based mitigation strategies and measures to protect vulnerable points in the supply chain, but that deadline was not met. FDA officials have recently stated that the agency plans instead to issue a notice and collect more information from industry before writing the rules. Some industry sources say this provision could end up costly for companies, depending on how it's implemented.

Besides working on what the FDA calls these "deliverables," the agency has been spending a lot of time looking at how it needs to change its approach to match FSMA's requirement that the agency and industry move toward a preventive system for food safety. The FDA's emphasis has been on making observations during inspections, finding violations and collecting evidence to build enforcement cases. However, the FDA will now shift the focus to assess the systems companies are operating. It plans to assess whether companies are using prevention controls correctly and, if not, push for corrective actions to protect public health, instead of relying on the number of enforcement actions brought against the regulated community.

As the old saying goes, "the wheels of the Gods grind slow but exceeding fine."

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# Legal Insights

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A close-up photograph of a fountain pen nib resting on a document with legal text. The text is slightly blurred but includes words like 'with', 'law', '1 The', 'ernment', 'agreements', 'the law', and 'Observe'.

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