

# What We Know About New FDA Rules

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National Public Radio (NPR) reported in January that the FDA's own figures indicate that 42 percent of foodborne illness cases in 2010 were related to produce contamination. Since then, many high-profile produce outbreaks suggest the figure in more recent years could be even higher.

Recently, the FDA proposed new rules that would overhaul food safety for produce processors and packers, in addition to regulations that would impact the entire food manufacturing industry.

I spoke with Angela Spivey, a partner with the law firm McGuireWoods and a member of the firm's food and beverage industry team. Spivey says there's a good chance that large food processors will already be in compliance with the new rules being proposed, but that small and medium-sized processors could find the new requirements more challenging.

In addition to rules governing fruit and vegetable growers' hygiene practices — hand-washing, the use of sanitary wash water, etc. — the FDA has proposed rules that would implement stricter planning requirements across all food industry segments. Spivey says, "Having a simple HACCP plan is not enough," as the proposed Preventative Control Planning requirement mandates not only HACCP planning, but the implementation of Good Manufacturing Practices (GMPs), written Standard Operating Procedures (SOPs), specific hygiene programs, food defense plans and supplier verification protocol, among other practices.

The primary burden created by these requirements will be, for many manufacturers, merely a concern over adequate documentation. Large processors likely have GMPs, HACCP plans and the like in place and functioning. The trick could simply be ensuring that these plans are sufficiently documented according to regulatory

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standards.

But Spivey warns that industry-leading processors could face other concerns. Though large processors are likely up-to-speed with regard to food safety protocol, these processors could see the new documentation requirements lead to breaches of trade secret. Any audit documents turned over to food safety regulators will be open to Freedom of Information Act (FOIA) requests, and the information contained within them could become a matter of public record. For this reason, Spivey says she recommends “that policies and procedures likely subject to FOIA requests not contain proprietary information such as formulations or specific processes.”

For the most part, food processors support these new regulations, in part because they level the playing field. In the responses to the reader survey reported in this issue’s Food Safety Update (p. 28), several readers wrote that they support mandatory HACCP planning and the constant presence of USDA inspectors in meat and poultry facilities primarily because they do not believe risk-taking processors should get a leg up by sidestepping food safety protocol. In the wake of the new rules’ proposal, the Grocery Manufacturers Association (GMA) released a statement that read, in part:

*Consumers expect industry and government to work together to provide Americans and consumers around the world with the safest possible products. FSMA and its implementation effort can serve as a role model for what can be achieved when the private and public sectors work together to achieve a common goal.*

The GMA and other industry actors will no doubt be actively involved in the rulemaking process ahead. The public — including industry — will have 120 days to read and comment on the proposed rules. At that point, the FDA will take about a year to review public comments and write the final regulations. After that point, processors will have one to two years to become fully compliant.

But Spivey’s advice to her clients regarding updating and redacting proprietary information from documentation is sound. Despite the seemingly expansive timetable for compliance, she says: “Do it now. Don’t wait!”

*What’s your take? Please feel free to comment below or email [krystal.gabert@advantagemedia.com](mailto:krystal.gabert@advantagemedia.com) [1].*

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