

## 2 FSMA Final Rules Give Industry Food For Thought

*Law360, New York (November 24, 2015, 4:34 PM ET)* -- The wait is over! After four-and-a-half years, the Food and Drug Administration recently finalized the first two of seven major rules required under the Food Safety Modernization Act on Sept. 10, 2015. FSMA was originally enacted by Congress in 2010 and signed into law by President Obama in January 2011.[1] FSMA came about after the United States experienced a number of tainted food outbreaks between 2006 and 2010, some involving fatalities. The FDA hails FSMA as historic, calling for sweeping changes.[2] In fact, it's been more than 70 years since the United States overhauled the nation's food safety regime.[3]

The FDA expects FSMA to better protect public health, strengthen the food safety system and help prevent — versus react — to food safety problems.[4] FSMA's four key objectives include prevention, inspections compliance and response, enhanced partnerships and import safety.[5]

### Key Takeaways from the Rules for Preventative Controls for Human & Animal Food

FSMA's two new finalized rules for preventative controls are titled Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food & Animals. The rules for preventative controls are specifically designed to decrease the harm from foodborne illnesses. The rules compel the food industry to move from reaction (i.e., damage control), to prevention. Key takeaways include:

- *Hazards & Risk-Based Analysis* — Human and animal food facilities must first identify the potential hazards in their products.[6]
- *Plans for Preventative Controls* — Facilities must then develop and implement written food safety plans that carry out preventative measures to ensure the hazards are minimized or prevented.[7]
- *Monitoring and Verification* — Facilities must also monitor the plans and verify that they work.[8] This requires keeping extensive records of their plans for preventative controls.
- *Recall Plan* — Facilities that produce animal food with a hazard requiring a preventive control must have a recall plan.[9]
- *FDA Authority and Oversight* — For the first time, the FDA now has an inspection mandate and the authority to order a mandatory food recall. The FDA can assess the facilities' plans to better respond when food safety problems occur, and better protect the safety of manufactured food.[10]

- *Compliance* — Compliance dates for businesses range from one to four years.[11] Most businesses will need to comply with the rules for preventative controls for human and animal food by August and September 2016.

## **Industry Reactions**

Although newly finalized, the industry has already begun weighing in on the two rules for preventative controls for human and animal food. These initial reactions generally fall into three categories.

### ***Praise***

Many in the industry praise the new rules for preventative controls. The Food Marketing Institute Vice President of Food Safety Programs, Hilary Thesmar, commended the FDA “for its commitment to transparency, guidance and education throughout the rule making process.”[12] The Grocery Manufacturers Association and the American Frozen Food Institute are reported to be pleased with the issuance of the final rules.”[13] Pamela Bailey, GMA’s president and CEO released a statement that “FSMA ensures that prevention is the cornerstone of our nation’s food safety strategy, places new responsibilities on food and beverage manufacturers and provides the FDA with the authorities it needs to further strengthen our nation’s food safety net.”[14] GMA is the world’s largest trade association representing the food, beverage and consumer products industry.

### ***Neutral***

Taking a more neutral stance, some see limited impact or change from the new rules. Many believe that responsible food manufacturers are already doing the things required by the rules, such as contamination prevention and response mechanisms. Likewise, Michael Taylor, the FDA’s Deputy Commissioner for Foods stated, “current good manufacturing practices aren’t disrupted” by implementation of the rules for large manufacturers.[15] To the neutral group, FSMA’s impact does not appear as wide-sweeping and profound as the FDA forecasted. In other words, is FSMA the chicken or the egg? However, many do recognize that FSMA does expand the preventative practices into broader standards for the industry.[16]

### ***Skepticism***

Funding concerns foster skepticism of the FDA’s ability to implement the new rules. The FDA will need significant funding from Congress to provide the oversight, monitoring and industry assistance that FSMA’s rules for preventative controls now permit. When the rules for preventative controls for human and animal foods were finalized, FDA Commissioner Taylor stated that the president’s fiscal year 2016 budget request asks for an increase of \$109.5 million for the FDA, which is “essential to maintaining momentum toward timely, effective and efficient implementation of FSMA.”[17] Industry leaders echo this sentiment. Sandra Eskin, the Food Safety Project Director at the Pew Charitable Trusts commented after the rules’ release last month that “the funding context for these rules is critical and if the agency doesn’t receive enough funding, the FDA is going to have to make some hard choices when it comes to implementing.”[18] The president of GMA commented that “it is essential that the FDA be appropriately resourced to effectively implement and enforce all of the food safety mandates set forth in the law.”[19] Both the industry and the FDA agree that without the needed funds, the actual reach of FDA’s oversight power granted by FSMA will likely fall short.

### ***Criticism***

As expected, some are critical of the rules. For example, the Manager of Federal Policy for the California Farm Bureau Federation, Josh Rolph, recently stated that the FDA overreaches with the new rules with a “sizable regulatory burden that outweighs any benefits.”[20] Critics point to the immense size of the regulations, which are difficult — and will be difficult — for those in the industry to comprehend. Also critical of the FDA’s exemptions, some organizations, such as the Center for Science in the Public Interest commented that “CSPI is disappointed, however, that the FDA exempted thousands of companies that Congress intended to be covered by the new requirements.”[21] As businesses and industry groups begin navigating and complying with the new rules, additional criticisms will likely emerge.

### **What’s Next?**

The remaining five FSMA rules will be finalized by 2016.[22] These included the long-awaited produce safety rules and foreign supplier verification rules. Under these rules, importers will be required to verify that the food products they are bringing into the U.S. meet the same safety standards as domestic food products.[23] The final produce safety rules will create require certain actions to minimize contamination for farms and growers.

—By Brent L. Reichert, Robins Kaplan LLP



*Brent Reichert is a partner in Robins Kaplan's Minneapolis office.*

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[1] Pub. L. No. 111-353, 124 Stat. 3885 (2011) (codified in sections of 21 U.S.C.S. § 301 et seq.).

[2] U.S. Food and Drug Administration, The FDA Food Safety Modernization Act: Putting Ideas into Action (Jan. 27, 2011).

[3] Id.

[4] U.S. Food and Drug Administration, Background on the FDA Food Safety Modernization Act (FSMA) (July 12, 2011).

[5] U.S. Food and Drug Administration, Public Meeting Tr. on the Food Safety Modernization Act: Focus on Preventative Controls for Facilities (Apr. 20, 2011),

[6] U.S. Food and Drug Administration, The FDA takes important steps in modernizing the food safety system (Sept. 10, 2015).

[7] U.S. Food and Drug Administration, FSMA Final Rule for Preventative Controls for Human Food.

[8] Id.

[9] U.S. Food and Drug Administration, FSMA Final Rule for Preventive Controls for Animal Food.

[10] FDA, *supra* note 6.

[11] Final Rule for Human Food, *supra* note 7; Final Rule for Animal Food, *supra* note 9.

[12] Supermarket News, Industry praises FDA's finalization of two FSMA rules (Sept. 10, 2015).

[13] Id.

[14] GMA Newsroom, GMA Welcomes FDA Release of Final FSMA Regulations (Sept. 10, 2015).

[15] Law360, FDA Cements Rules To Prevent Food Contamination (Sept. 10, 2015).

[16] Id.

[17] Food Safety News, FDA Finalizes Preventative Controls Rules For Human, Animal Foods, (Sept. 10, 2015).

[18] Inside Health Reform, FDA Releases Food Safety Preventative Controls Rules, Funding Concerns Remain, Sept. 16, 2015.

[19] Supermarket News, *supra* note 12.

[20] AgAlert, Commentary: FDA overreaches with new food-safety regulations (Sept. 15, 2015).

[21] Center for Science in the Public Interest, FDA Issues New Preventive Control Rules Required by Food Safety Law, Statement of CSPI Senior Food Safety Attorney David Plunkett (Sept. 10, 2015).

[22] FDA, *supra* note 6.

[23] David Elder Interview on FSMA Import Provisions (Aug. 15, 2011).

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