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Food Safety Rules: Rushed Deadlines Will Lead to Disaster

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Food Safety Rules: Rushed Deadlines Will Lead to Disaster. In 2011, President Barack Obama signed the Food Safety Modernization Act (FSMA) into law,[1] giving the Food and Drug Administration (FDA) unprecedented power to regulate the country's food supply.[2]

This new power includes the first time that the FDA has the authority to establish standards for the production and harvesting of produce and to identify preventive controls for food facilities. The FDA will also be able to place much greater restrictions on imported goods, establish programs for food testing, and conduct inspections of both domestic and foreign food facilities. These regulations will have a major impact across the food system, and the potential to drive up food costs and place unnecessary and intrusive restrictions on safe and proven practices.[3]

Unrealistic Deadlines. By setting up artificial and unrealistic deadlines in FSMA, Congress has effectively ensured that the regulations will be rushed and poorly considered. According to the FDA, it is required to "prepare more than 50 rules, guidance documents, reports and studies within strict timeframes."[4] Some of the rules had to be finalized in as little as 18 months, which was not enough time given the complex issues involved.

As should have been expected, the FDA was unable to meet several deadlines. In August 2012, two activist groups sued the FDA in the United States District Court of the Northern District of California to compel the agency to issue seven rules that were past deadline.[5] In April 2013, the court agreed that the FDA should issue the seven rules promptly.[6] On August 13, 2013, the court rejected another FDA attempt to delay two of the seven rules.[7] As of now, four proposed rules have been published with comment periods ending in November 2013.[8]

The Effect of Unrealistic Deadlines. Even the biggest FSMA proponents should want regulations that are carefully crafted and are based on sound science. By creating "aggressive" time lines, as the FDA describes them, for extremely complicated rules, Congress made informed rulemaking impossible.[9]

The FDA itself has explained the problems with implementing FSMA rules under a rushed regulatory process. According to the district court:

> The FDA asserts that it has responded to FMSA by making its implementation a top priority, but still has not been able to complete rules of such magnitude and complexity within the statute's timeframes.... The FDA agrees that these regulations are important to public health and safety, but argues that is just as important that any regulations that are promulgated be carefully developed, given the scope and magnitude of what is called for by the statute.[10]

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The FSMA rules are particularly complicated and time-consuming because Congress delegated an extensive amount of power to the FDA, allowing it, and requiring it, to fill in numerous gaps required to implement the law. This is just one more example of excessive congressional delegation of power.

The rules are further complicated because they are interrelated with each other. Developing one rule, in isolation, is pointless because of the impact on the other rules. This is precisely why the FDA gave the public more time to comment on two of the original proposed rules: "to allow interested persons the opportunity to consider the interrelationships between these two proposals [the first two rules], which were published on January 16, 2013, and the two new proposed rules."[11]

The public is the biggest loser when Congress sets these unrealistically short rulemaking periods. Affected industries, farmers, and the general public have little time to review the complicated rules and the underlying documents forming the basis of the rules. They are not able to give the FDA the necessary feedback that the agency needs because the FDA does not have the insight or expertise that the public can bring to an issue. The final rules will not represent sound policy but rushed regulations that do not properly consider the regulatory impact. They also could be more prone to legal challenges if they are not justified by sound science and data.

Extreme Implications. Most, if not all of the rules are being rushed through the process. However, the most extreme example is the intentional adulteration rule. The FDA argued before the California federal district court that it could not publish this proposed rule, a rule addressing the intentional adulteration of food, by the court-set date of November 30, 2013. The FDA claimed that it needed far more time, until the second half of 2015.[12]

According to the FDA, it has never regulated in this area and needs feedback from industry to learn "about how vulnerability is currently assessed and what measures are currently in place to guard against intentional adulteration."[13] The court rejected the FDA's request for more time. In an area as important as intentional food adulteration, the FDA is being forced to propose rules at least 18 months *before* it believes it would be ready to issue such rules.

Now What? Congress should seek feedback from the public and the FDA before any of the seven rules is finalized. This feedback should address what constitutes a reasonable time line to implement the regulations and what unintended consequences have been identified by regulated parties and the FDA. More detailed risk and economic analyses should

1. U.S. Food and Drug Administration, "FDA Food Safety Modernization Act (FSMA)," U.S. Department of Health and Human Services, http://www.fda.gov/Food/GuidanceRegulation/FSMA/default.htm (accessed August 19, 2013).
2. Diane Katz, "New FDA Powers: The Wrong Remedy for a Phony Crisis," Heritage Foundation *WebMemo* No. 3063, November 17, 2010, http://www.heritage.org/research/reports/2010/11/new-fda-powers-the-wrong-remedy-for-a-phony-crisis.
3. U.S. Food and Drug Administration, "Background on the FCA Food Safety Modernization Act (FSMA)," U.S. Department of Health and Human Services, http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm239907.htm (accessed August 19, 2013).
4. U.S. Food and Drug Administration, "Implementation of FSMA," U.S. Department of Health and Human Services, http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm247556.htm (accessed August 19, 2013).
5. *Center for Food Safety v. Hamburg*, No. C 12-4529 PJH, (N.D. Cal.), Complaint for Declaratory and Injunctive Relief, August 29, 2012, http://www.centerforfoodsafety.org/files/2012-08-29-fsma-complaint-filed_78450.pdf (accessed August 19, 2013).
6. *Center for Food Safety v. Hamburg*, No. C 12-4529 PJH, (N.D. Cal.), Order RE Cross-Motions for Summary Judgment, April 22, 2013, http://www.centerforfoodsafety.org/files/57-sj-decision_78315.pdf (accessed August 19, 2013).
7. *Center for Food Safety v. Hamburg*, No. C 12-4529 PJH, (N.D. Cal.), Order, August 13, 2013, http://www.centerforfoodsafety.org/files/69--order--granting-in-part-denying-in-part-mot-recons_34619.pdf (accessed August 19, 2013).
8. Center for Food Safety and Applied Nutrition, "FDA Extends Public Comment Period 60 Days for Proposed Rules on Preventative Controls for Human Food, Produce Safety," U.S. Food and Drug Administration, August 8, 2013, http://www.fda.gov/Food/NewsEvents/ConstituentUpdates/ucm364189.htm (accessed August 19, 2013).
9. *Center for Food Safety v. Hamburg*, Order RE Cross-Motions for Summary Judgment.
10. Ibid.
11. Center for Food Safety and Applied Nutrition, "FDA extends Public Comment Period."
12. *Center for Food Safety v. Hamburg*, Order, August 13, 2013.
13. Ibid.

also be considered, giving the FDA a better foundation for any rules it develops.

Many politicians correctly point out that Congress should hold agencies accountable for their regulations. When it comes to these seven FSMA rules, *based on deadlines alone,* Congress is the primary culprit for what will be flawed regulations. Congress should address these rules before it is too late.

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