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Food Safety Modernization Act: The Case for Complementary Public Regulation and Private Standards

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PRESIDENT OBAMA signed into law the Food and Drug Administration (FDA) *Food Safety Modernization Act of 2010* (FSMA) in January 2011. FSMA is a set of regulations that modifies U.S. food safety laws and extends their scope. FSMA is considered to be the first major reform of U.S. food safety laws since 1938. FSMA specifically targets products that are under the jurisdiction of FDA and thus impacts products such as produce, dairy, seafood, fresh eggs and eggs used as ingredients. The stated objective of FSMA is to shift the focus from response to food contamination to prevention.

Since the adoption of the law, the FDA has been preparing rules for the execution of FSMA. The implementation of FSMA is done through seven rules: (1) standards for produce safety; (2) preventive controls for human food; (3) preventive controls for food for animals; (4) a foreign supplier verification program; (5) accreditation of third-party auditors; (6) sanitary transportation of human and animal food; and (7) food protection against intentional adulteration. We focus in this short piece on the rulemaking process for **produce safety** when FSMA rules overlap with existing private industry standards.

The Leafy-Greens Marketing Agreements (LGMA) in California

and Arizona provide an example of an industry initiative to develop private standards to control food safety hazards in produce. In response to the 2006 *E.coli* outbreak that prompted a nationwide recall of all fresh spinach, the California and Arizona leafy green products handler marketing associations adopted LGMA in 2007. LGMA covers 14 produce commodities and includes provisions regarding the environment, water, soil amendments, worker practices, and field sanitation. LGMA members handle, process, ship or distribute leafy green, although they do not necessarily produce leafy green themselves. However, LGMA handlers agreed to purchase leafy greens only from growers who meet the standards defined by LGMA. The stated objective of the agreement is to protect public health by reducing the risk of foodborne illnesses and outbreaks linked to leafy greens by implementing food safety practices during production and harvesting.

The produce safety rules under FSMA of course overlap with LGMA standards. However, the rulemaking process in the U.S. makes it possible to limit the burden of FSMA on producers that are already complying with equivalent or stricter LGMA standards. FDA first issued proposed rules for produce safety on January 16, 2013 and then sought input from stakeholders through public meetings



Scientists at the ARS Produce Quality and Safety Laboratory in Beltsville, Maryland, are focusing on ways to keep packaged fresh-cut lettuce and leafy greens safe. (Photo by Keith Weller.)

and other outreach activities. FDA also accepted comments on the proposed rules until November 22, 2013. FDA received more than 37,000 comments on the proposed produce safety rule. In response to the comments, FDA released supplemental proposed rule on September 29, 2014. Comments on the supplemental rule are due on December 15, 2014. (Note: The proposed rule and the supplemental proposed rule are posted under the [FDA's](#)

Table 1. Proposed FDA Microbial Water Testing (generic E. coli) Rule

LGMA	FSMA proposed rule	FSMA supplemental proposed rule
<ul style="list-style-type: none"> • Test all water source prior use if more than 60 days since last test of the water source • Test must be collected monthly during use • For wells and municipal water if generic <i>E.coli</i> are below detection limits for five consecutive samples sampling frequency may decrease to once every 180 days • Water can be used for irrigation only if test show less than 126 CFU/100ml over a rolling geometric mean of 5 samples or less than 235 CFU/100ml on a single sample 	<ul style="list-style-type: none"> • Test untreated surface water every 7 days • Test untreated ground water every 3 months • Geometric mean not to exceed 126 CFU/100ml • Upper limit on a single water sample of 235 CFU/100ml 	<ul style="list-style-type: none"> • For untreated surface water, baseline survey of a minimum of 20 samples during growing season. The baseline determines if water meets the microbial quality standard. If baseline shows that water is of good quality, then a minimum of five samples per year are required • For untreated ground water, at least four tests during a growing season. Then if water meets the quality standard, testing can be done once annually • Geometric mean not to exceed 126 CFU/100ml and a statistical threshold value not to exceed 410 CFU/100ml • If water does not meet quality standard, irrigation is allowed provided a die-off rate of 0.5 log per day between the last irrigation and harvest

same docket. Comments and other documents on the proposed rule and the supplemental proposed rule for produce safety are available at www.regulations.gov/#!docketDetail;D=FDA-2011-N-0921.)

There are many factors that may vary among producers in terms of location, the product category, the production method (e.g., organic vs. conventional) and scale of operation. The challenge for FSMA is to maintain the science-based design of the rule-making, yet support alignment with industry guidance in implementation. As the table above shows, there were extensive changes made to the water testing provisions for produce safety in response to comments to the proposed rule. This

is also true for other provisions. If the modifications to the rule are not done at the expense of weaker standards, they are then likely to improve the economics of the rulemaking process.

The success of either the publicly mandated rules or private standards depends on whether the required practice is effective at reducing the foodborne hazard. Furthermore, the success also depends on whether adopting the practice is cost effective relative to other methods and practices. These questions are very challenging to address in the natural environment of produce production. The data requirements are extensive for a controlled experiment to the extent that FDA has little information on the cost impact of specific produce rules. The

information gap is even greater when it comes to evaluating the benefits of the food safety interventions through a reduction in foodborne illnesses. A recent study by Jensen et al. (2013) shows how one might use data available from field studies and available cost information to assess the cost effectiveness of water testing. This is a first stage to developing multiple comparisons of effectiveness of all interventions relative to cost in initiatives such as FSMA and LGMA. A more systematic evaluation of the costs and benefit of farm-level regulation in produce can help to identify the best strategies for implementing food safety legislation.

Reference

Jensen, H.H., S. Pouliot, T. Wang, and M.T. Jay-Russell. 2014. "Development of a Cost Effectiveness Analysis of Leafy Green Marketing Agreement Irrigation Water Provisions." *Journal of Food Protection* 77: 1038–1042. ■

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