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Industry: Regulations

## Maple Syrup and the New U.S. Food Safety Rules

*Winton Pitcoff*

The final rules for the Food Safety Modernization Act (FSMA) have been issued, after several years of drafts and revisions, and concern about what the new regulations would mean for maple producers. Based on a read of the rules, and a discussion with Jenny Scott, Senior Advisor at the Office of Food Safety of the Food and Drug Administration's Center for Food Safety and Applied Nutrition, for most sugar-makers the impact will be minimal.

Briefly, sugarmakers who make nothing but pure maple products are likely to be exempt from most of the rules due to the size of their operations or because they only conduct low-risk activities on specified foods. Those who make certain value-added products, or who make other foods on their farm, may be subject to the rules. All sugar-makers still must register with the FDA and follow standards spelled out in the federal Good Food Manufacturing Practices (GMPs), as has been the law for many years.

Making maple syrup and other pure maple products is considered manufacturing or processing, which triggers the FDA requirement to register the business, so all sugaring operations are classified as farm mixed-type facilities, and are subject to the Preventive Controls for Human Food rule. The rule spells out requirements for establishing and implementing a food safety plan that includes an analysis of hazards and risk-based preventative controls – essentially highlighting all of the points within a production process where food

safety could be compromised, and documenting and implementing steps that will be taken to eliminate those potential problems. Plans for monitoring and verification are key components of the plan, including extensive recordkeeping requirements. The plans don't need to be filed or approved, but do need to be in writing and followed, and will be reviewed during inspections. In addition, at least one employee must undergo training or be qualified through job experience to oversee critical safety functions of the operation.

However, small and very small on-farm businesses that conduct only low risk activities on foods specified in the rule are exempt from having to complete such a plan. Small businesses are those with fewer than 500 full-time equivalent employees, including all affiliates and subsidiaries to the business, and very small businesses are those with a three-year average of less than \$1 million in sales of human food, including the value of human food held without sale. Making maple syrup, candy, cream and sugar are considered low-risk activity/food combinations, and so are exempt from the plan requirements if these are the only products manufactured on the farm.

But sugarmakers who are above these thresholds or who create value-added products that are not considered low-risk, whether as part of their maple business (dressings or barbeque sauce, for instance) or as another part of their farm operation (cheese or meat pro-

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cessing, for instance) must create a food safety plan that includes all manufacturing activities of the farm, including maple. The safety plan for the maple portion of the farm can be simple and straightforward, though, says Scott. Since making maple products is classified as a low-risk activity under FSMA, the plan can stress this fact, and can point out that any hazards are already controlled inherently through the production process.

For those operations that need to create a plan, the FDA will provide substantial guidance, says Scott. The Agency is developing a small entity compliance guide. There are many resources available online, at [www.fda.gov/fsma](http://www.fda.gov/fsma), and sugarmakers can also fill out a web form at that site to submit questions. Extension specialists in many states can answer questions and provide guidance as well.

Many items that raised concerns in earlier drafts of the FMSA rules were dropped or modified in the final version, thanks to feedback from farmers and others. The definition of farms as being contiguous properties is no longer in the regulation, for example, and farms are not restricted from aggregating agricultural products from other farms.

The full rulemaking process is not yet complete. A final rule on amending the definition of retail food establishments is still pending, but Scott says that this most likely won't have an impact on sugarmakers who sell products through farmstores, farmstands, CSAs, or farmers markets.

Even if a sugaring operation is exempt from the requirement to develop a plan, all operations are required to

register with the FDA and comply with the federal Good Food Manufacturing Practices (GMPs), as they have been for many years. While these regulations aren't new, many sugarmakers have looked more closely at these rules recently, as the FSMA rulemaking has been in process.

Anyone who manufactures food for sale must register with the FDA under the Public Health Security and Biodefense Preparedness and Response Act of 2002. This regulation has been in effect since December 12, 2003. Registration is done through an online form at <http://goo.gl/nXYxP>, and must subsequently be renewed between October 1 and December 31 of every even numbered year. Registration means that sugarhouses are subject to inspection. The law requires that these inspections happen no less than once every five years, and in most cases the FDA contracts with state agencies to carry out these inspections.

The requirements for recordkeeping that come with being a food manufacturer are also available online, at <https://goo.gl/dMLuhj>. For the purposes of traceability, sugarmakers must keep written records of all of their products, including date produced, quantity, and where items came from or went to. Records must be kept on hand for at least two years, and be made available if requested by an inspector.

The GMPs (<http://goo.gl/3QIfRZ>) outline basic standards and practices for every element of food manufacture, from equipment specifications to cleaning practices to sanitation, and are generally regarded as the minimum requirements for producing safe food. Many states have developed their own

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guidelines, some of them called Best Management Practices (BMPs), which are comparable to or more stringent than the GMPs, and set the standards for compliance in those states.

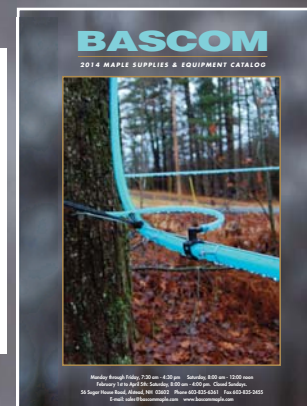
With growing concerns about food safety, these regulations have been put in place to protect public health. While pure maple products and the processes of making them may not pose the same potential hazards as other foods, they need to be held to the same standards of production and handling as other foods so that the public will trust our industry's commitment to safety.

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