

Requirements for Sugarmakers Under the New U.S. Food Safety Regulations

Signed into law in 2011, the final rules of the federal Food Safety Modernization Act (FSMA) took several more years to complete. Now that they have been issued, there are new requirements that may apply to many sugarmakers. However, there are also a number of exemptions based on size and type of operation. (The information presented in a *Maple Digest* article from December 2015 remains accurate, but with the enactment of the final rule the information offered here is more complete.) In summary, sugarmakers who sell most of their product directly to consumers have no new responsibilities under the Act, since they qualify as a “retail food establishment” and are not subject to registration. Those that do not qualify for the registration exemption as a retail food establishment but have less than \$1 million in annual sales of human food are subject to modified requirements as “qualified facilities.” The details, of course, are more complex.

Registration

Registration requirements fall under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002. The Act requires that any facility that manufactures, processes, packs or holds food for consumption in the U.S. must register with the FDA. Registrations can be submitted electronically at <http://www.access.fda.gov/>, and must subsequently be renewed between October 1 and December 31 of every even numbered year. There is no charge for registration. There are a number of exemptions to the require-

ments to register, including farms and retail food establishments.

Compliance

For compliance purposes, sugaring falls under the Current Good Manufacturing Practice (CGMP) and 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 recordkeeping requirements (goo.gl/W7DsNR) to demonstrate that the plan is being followed. 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. There are a number of exemptions with respect to the requirements for hazard analysis and risk-based preventive controls (discussed below). Most facilities that are exempt from those requirements still must comply with the current Good Manufacturing Practice requirements of the rule, which existed prior to FSMA.

Inspections

As for inspections, once a sugarhouse is registered, as above, the operation is

subject to inspection. The law requires that these inspections are made no less than once every three years for “high risk” foods and once every five years for other foods (which would include facilities that only make maple syrup and many other maple products), and in many cases the FDA contracts with state agencies to carry out these inspections. Even if the inspection is only able to occur off-season, inspectors can and will still look for clean, well-maintained facilities, with equipment and supplies being stored in a safe manner that prevents contamination. If a sugarmaker feels that an inspector’s findings are inaccurate or unfair, they may ask to speak to a supervisor or other person in the FDA District Office.

Exemptions

First, it should be noted that these rules are not intended for backyard sugarmakers and hobbyists who make a few gallons for their families and friends. They are intended for those who sell syrup to the general public.

For those that do sell to the public, the Act provides for many exemptions, based on type of operation and size. While farms are exempt from registration (and thus the requirements for hazard analysis and preventive controls), maple syrup production is classified as food manufacturing, so sugarmakers cannot benefit from this exemption. However, those who tap trees, collect sap, and sell it to another operation for syrup production would meet the definition of a farm and qualify for the exemption. Even purchasing bulk syrup in drums, reheating and filtering and bottling it counts as manufacturing.

However, since many sugarmakers sell much of their product directly to consumers, the Retail Food Estab-

lishments exemption may apply. If at least half of the monetary value of your sales of human foods comes from foods sold directly to consumers, rather than to others (for example, sold bulk or wholesale), you meet the definition of a retail food establishment and are exempt from registration (and the requirements for hazard analysis and preventive controls). Sales at farmers

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FSMA FAQs for Sugarmakers

Do I have to register?

If more than half of the annual monetary value of your human food sales are in bulk or wholesale, rather than direct to consumers, you must register your facility with the FDA.

Do I have to create a food safety plan?

You must create a food safety plan if you are required to register, as above, and:

- your sales of human food exceed \$1 million a year, and
- you are manufacturing products that are not on the list of low-risk activity food combinations.

Will I be inspected?

If you are required to register, as above, you are subject to an inspection at least every five years if you are producing only maple products, and more frequently if you also produce foods classified as high-risk or if your state requires it.

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markets, farm stands, and through CSAs count as direct sales, as do sales of non-maple food products produced on your farm and maple and other food products you purchase wholesale and re-sell in your store. Direct sales also include on-site retail sales of ready-to-eat items directly to consumers, such as cotton candy, ice cream, or breakfasts served in a restaurant. If you qualify for the Retail Food Establishment exemption, you do not need to register your operation under FSMA or comply with the Preventive Controls rule, and no new inspections will be required.

Note that even if you do qualify for an exemption, some wholesale purchasers are requiring that their vendors comply with FSMA, regardless of FDA exemptions.

If you do not sell product direct to consumers, or if less than half of your food sales are directly to consumers, and you must register, you may still be eligible as a very small business for the Qualified Facility exemption to the requirements for hazard analysis and preventive controls, as long as you have less than \$1 million in annual sales of human food (adjusted for inflation and averaged over 3 years, <https://>



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goo.gl/4QEztT). Under this exemption you must still register your operation, but you are not subject to the hazard analysis or preventive control plans required by FSMA. However, there are some modified requirements (<https://goo.gl/syXB7t>) that mean having to attest to the aspects of your operation that qualify you for the exemption and to the fact that you have identified hazards and implemented preventive controls or that you are in compliance with a non-Federal food safety law. You are still subject to inspections, and your operation will be expected to be compliant with the federal Current Good Manufacturing Practices (CGMPs) (<https://goo.gl/NaV26H>). These 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 guidelines, some of them called Best Management Practices (BMPs), which are comparable to or more stringent than the CGMPs, and set the standards for compliance in those states.

If you qualify as a small or very small business and your products are solely maple products produced on your farm you can still be exempt from many of FSMA's requirements due to maple syrup, candy, and cream being classified as 'low risk' activity/food combinations. You still have to register and be inspected, but do not have to follow requirements of sub-part C (Hazard Analysis and Risk-Based Preventive Controls) or G (Supply-Chain Program). This only applies if your manufacturing involves only maple syrup or other items on the low-risk list (<https://goo.gl/b6L3CX>). If you are adding other ingredients to make products

that are not on the low-risk activity/food list, such as barbecue sauce or salad dressing, you are not eligible for this exemption. Note that if your overall operation produces products that are not exempt, all products – including maple – would be subject to the Preventive Controls requirements and inspections targeted to those requirements.

The FDA has not developed guidance for their inspectors or for sugarmakers that is specific to maple syrup. The agency's priority right now is to focus on general guidance and on guidance for high risk products. There are many resources available online at www.fda.gov/fsma, including "Draft Guidance for Industry: Hazard Analysis and Risk-Based Preventive Controls for Human Food," 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.

Finally, it is very important to note that all of these regulations are federal, and that your state or municipality may have other requirements that you should be familiar with and adhere to.

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. Even those sugarmakers who are exempt from some or all of the new regulations should be familiar with them, and should strive to employ practices that eliminate opportunities for contamination or other safety hazards.