

Food Safety Modernization Act - Final Rule

On Thursday, 9/17/2015, the FDA published in the Federal Register the “Final Rule” to the Food Safety Modernization Act: “Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food”. The new rules are fairly detailed, however, most GAWDA members will not find them to be demanding. And.... we have plenty of time to comply. We are developing templates for the FSMA provisions.

(Download the entire 262 pages by clicking: <http://federalregister.gov/a/2015-21920>)

This new rule amends the regulations for Current Good Manufacturing Practice In Manufacturing, Packing, or Holding Human Food by modernizing requirements, adding requirements including registration, and clarifying the scope for exemptions to registration requirements.

- Some of the previously nonbinding provisions, such as education and training, are now binding.
 - Management is required to ensure that all employees who manufacture, process, pack or hold food are qualified to perform their assigned duties.
 - Such employees must have the necessary combination of education, training, and/or experience necessary to manufacture, process, pack, or hold clean and safe food. Individuals must receive training in the principles of food hygiene and food safety, including the importance of employee health and hygiene.
 - Note that there are similar requirements related to preventive controls.
 - We conduct free CGMP training for GAWDA members as a part of the monthly Food Gas Roundtable.
- The FDA’s longstanding position that CGMPs address allergen cross-contact is now explicit in the regulatory text. This is not a difficult provision for most GAWDA members and we have the template you can use to provide the allergen training.

One of the new requirements applicable to those establishments that must register as a “food facility” is to implement:

- A written Food Safety Plan;
- Hazard Analysis and Risk-Based Preventive Controls (HARPC), the new Part 117. This would replace the use of Hazard Analysis and Critical Control Points (HAACP) which was developed by the agency to address issues related to seafood, juice and certain other targeted food industries. HARPC is a risk-based evaluation of our operations to prevent food-borne illnesses which would have the establishment institute preventive controls for the mitigation of those identified (*or reasonably foreseeable*) hazards, unless an exemption applies. As a result of the hazard analysis, certain elements will be established:
 - Preventive controls;
 - Monitoring;
 - Corrective actions and corrections;
 - Verification;
 - Recall plan; and
 - Associated records.

- A newly established 21 CFR 110 Subpart G Supply-Chain Program requires a supplier verification (approval) program.

The final rule also establishes a preventative controls “Qualified Individual” who develops and applies on behalf of the owner, operator, or agent in charge, the Food Safety Plan and oversees the HARPC process. Qualification is established by successfully completing certain training in the development and application of risk-based preventive controls or is otherwise qualified through job experience to develop and apply a food safety system. GAWDA training programs for the qualified individuals are in the works. A qualified individual may be, but is not required to be, an employee of the establishment.

Who or what is exempt from the requirements for hazard analysis and risk-based preventive controls?

The following “Qualified Facilities” as defined by FSMA can be exempt from HARPC requirements:

- Business with average annual sales of <\$500,000 and at least half the sales to consumers or local retailers or restaurants (within the same state or within 275 miles); or
- Very small business, which the rule defines as a business (including any subsidiaries and affiliates) averaging less than \$1,000,000, adjusted for inflation, per year, during the 3-year period preceding the applicable calendar year in sales of human food plus the market value of human food manufactured, processed, packed, or held without sale (e.g., held for a fee).

We expect that many GAWDA members could be considered a Qualified Facility.

Note as a “Qualified Facility”, modified requirements apply—i.e., a qualified facility is required to:

- Notify FDA about its status; and
- Either:
 - Notify FDA that it is addressing hazards through preventive controls and monitoring; or
 - Notify FDA that it complies with applicable non-Federal food safety regulations, and notify consumers of the name and complete business address of the facility where the food was manufactured or processed.
- The notification is in the form of an attestation, and must be submitted every two years, during the same timeframe as the facility is required to update its facility registration.

A facility solely engaged in the storage of packaged food that is not exposed to the environment (i.e. a Distributor that does not otherwise fill food gases), can also be exempt from HARPC.

Keep in mind that your customer, especially major beverage companies or restaurant chains may still require a HARPC in order to be qualified as an approved supplier.

Templates are being developed for these HARPC’s in the CGA Food Gas Committee. The ASU template is nearly complete and then the cylinder filling template will be developed. When completed, these templates will make compliance with HARPC a LOT easier and more consistent. Even if not required, it can be considered a best practice.

Implementation Schedule... this is the good news... we have plenty of time to implement the HARPC and related provisions.

See: http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm334115.htm?source=govdelivery&utm_medium=email&utm_source=govdelivery#Compliance_Dates

For non-HARPC FSMA provisions:

- "Very small businesses" - If your sales of food gases are under a million dollars per year (likely most GAWDA members), you will have three years to be in compliance.
- "Small businesses" - If you have fewer than 500 employees, you will have two years to be in compliance.
- "Large businesses" - You will have one year to be in compliance.

For the new Supply Chain Program (AKA supplier qualification):

- Depending on the size of your food business, you will have six to 24 months to develop your Supply Chain Program
- We are developing standard industry supplier qualification procedures that will make this rule simple to accomplish.

We cover the compliance details and new interpretations of these rules in the free GAWDA Monthly Food Gas Roundtables. These teleconferences occur at 2 PM ET on the last Friday of most months. We also discuss practical compliance with the regulations in the GAWDA Professional Compliance Seminar, October 20-22, 2015, Aurora, IL.

If you need information about either of these training opportunities, contact tom@asteriskllc.com.