



Food Safety Modernization Act

The Food Safety Modernization Act (FSMA) regulations are in place with specific compliance requirements and defined implementation dates. (see 21 CFR Part 117 or ask for an annotated copy of the regulations.)

Help to comply with the FSMA regulations

The new Food Gas regulations generally follow the old regulations ... with the following new requirements:

- Hazard Analysis and Risk Prevention Controls (HARPC)
- Supply-Chain Program
- Allergen and Sanitation Training
- Etc.

We have developed the following resources to help develop a compliance program specific to your company's needs:

- Sample Written Operating Procedures
- Allergen/Sanitation Training
- Food/Bev Gas Current Good Manufacturing Practice Training
- HARPC's for
 - CO₂ cylinder filling
 - CO₂ Micro-bulk
 - Beer Gas and other high-pressure gases
- Monthly Food Gas Roundtables
- Self-Assessment Checklist Spreadsheet
- Registration Instructions

These resources are at no cost to GAWDA members to help establish a solid foundation for an effective Food/BevGas compliance program.

Quick Compliance Highlights

- **Registration** – All production, distribution and warehousing facilities must be registered with the FDA and appropriate state agencies where required.
- **Raw material qualification** – Annually obtain a certificate of conformance from each bulk food gas supplier as a part of your material controls. Additional details will follow from the FDA.
- **Lot Numbers** – A lot numbering system to track food/beverage gas cylinder or bulk shipments to your customer.
- **Housekeeping/Pest Control** – A documented housekeeping and pest control program to look for cleanliness and for evidence of pests (spider webs, rodent droppings, etc.).
- **CGMP/Allergen/Sanitation Training** – Documented personnel training in Food GMP's, allergen and sanitation requirements. Asterisk conducts free monthly Food Gas Roundtable to satisfy many of these needs.
- **Risk Assessments** – Conduct and document a Hazard Analysis and Risk Prevention Control analysis to insure that any risk of contamination to food grade products has been considered and mitigated. Asterisk can offer sample HARPC's for many products.
- **Product Testing** – Your risk assessment would determine whether or not your bulk product or full cylinders would require analysis over and above your supplier qualification.



Food & Beverage Gas Myths

- **Bulk Tank Annual Testing** – Cylinder and micro-bulk plants are not required by the FDA, CGA or ISBT to have their Food/BevGas bulk tank tested by an outside lab annually or any other time. You may decide to have your tank tested if it becomes contaminated or if your risk assessment/procedures require testing.
- **Bulk Tank Testing Upon Delivery** - Cylinder and micro-bulk plants are not required by the FDA, CGA or ISBT to test their Food/BevGas bulk tanks each time they are filled by the supplier, unless your risk assessment or procedures require testing. An annual letter of conformance from the supplier may be adequate.
- **Full Cylinder Testing** - Cylinder and micro-bulk plants are not required by the FDA, CGA or ISBT to test their finished product... unless your risk assessment/procedures require testing.
- **Consultants** - Cylinder and micro-bulk plants are not required to have a consultant implement their Food/BevGas compliance program or conduct periodic audits. Even the largest end users have provisions for you to develop your own program and conduct your own audits.
- **The FDA Requires Cylinder Inversion** – The truth is that the FDA does not explicitly require cylinder inversion or RPV valves. The new regulations require that you consider the food safety risks of your products. Both CGA and ISBT have published guidelines about inverting cylinders or using residual pressure valves. (See the sample written procedures or CGA/ISBT publications for additional details.) Due to historical safety and contamination issues, both CGA and ISBT have identified serious corrosion and safety risks with customers backing up water/syrup into your cylinders. Cylinder inversion/RPV valves are the recommended means to mitigate the risks. In short – the FDA requires you to consider the risk and CGA/ISBT provide the recommended solutions. We also recommend that you follow CGA guidelines.
- **Food Compliance Is Hard To Achieve** – There are certainly some specific new requirements (HARPC, Allergen Training, etc.). However, the resources you have available can make the compliance implementation process smooth.
- **USP Products used for Food Gas Applications** - A company cannot offer USP grade products in lieu of food grade for food applications. First, the customer would require the appropriate credentials to receive medical products, such as registration with FDA or a doctor's prescription. Second, the USP product may not have the appropriate controls as required by the FSMA or may not have been appropriately tested in accordance with the Food Chemical Codex or other food gas requirements.
- **Industrial Grade products for Food Gas applications** - A company cannot offer industrial grade products in lieu of food grade for food application. The industrial product may not have the appropriate controls as required by the FSMA or may not have been appropriately tested in accordance with the Food Chemical Codex or other food gas requirements.

Do you need more information?

Contact tom@asteriskllc.com if you need access to these free resources or if you would like hands-on assistance and further compliance program development/implementation.