



# BREWERS' RESPONSIBILITIES AND OBLIGATIONS UNDER THE U.S. FOOD SAFETY MODERNIZATION ACT (FSMA)

## What is the Food Safety Modernization Act?

The U.S. Food and Drug Administration (FDA) Food Safety Modernization Act (FSMA) was signed into law on January 4, 2011. FSMA is one of the most sweeping reforms of our food safety laws in more than 70 years. It aims to ensure the safety of the U.S. food supply, and therefore public health, by requiring domestic and foreign processors (exporting product to the U.S.) to proactively manage food safety hazards associated with the manufacture and transport of FDA-regulated food products. Facilities that manufacture, process, pack, hold or transport FDA-regulated food products (including alcoholic beverages) produced for consumption by humans and animals need to comply with the final rules, though exemptions apply for specific types of businesses, including manufacturers of alcoholic beverages.

## Main elements of FSMA include:

- New responsibilities for food companies
- New controls over imported food
- New powers for FDA
- New fees on food companies and importers

## Which aspects of FSMA apply to breweries?

FSMA specifically defines alcoholic beverages as food, and for the first time brings breweries, wineries, cider producers and distilleries under direct FDA regulation, without affecting TTB authority. As per Code of Federal Regulations Title 21, Subpart A, Section 117.5 (21 CFR 117.5), these facilities are exempt from several portions of FSMA, but need to comply with some of the requirements **regardless of the size of their operation:**

Portions of FSMA that apply to breweries	Portions of FSMA that do NOT apply to breweries*
FDA Facility Registration (21 CFR 1.225)	21 CFR 117 Subpart C – Hazard Analysis and Risk-based Preventive Controls
Compliance with Definitions (21 CFR 117 Subpart A, includes staff competencies and training)	21 CFR 117 Subpart G – Supply Chain Management
Compliance with Good Manufacturing Practices (21 CFR 117 Subpart B)	21 CFR Parts 1 and 11 Sanitary Transport Rule
Compliance with proper management of human food byproducts sold/ donated for animal feed (21 CFR 117.95)	21 CFR Parts 11 and 121 Protecting Food Against Intentional Adulteration
Compliance with Record keeping requirements (21 CFR 117 Subpart F)	21 CFR Parts 1, 11, and 111 Foreign Supplier Verification Programs

\* As per 21 CFR 117.5(i)(1)

Businesses also producing non-alcoholic products may additionally need to develop a food safety plan following the hazard analysis and risk-based preventive controls methodology for the non-alcoholic products, unless the food is pre-packaged and does not constitute more than 5% of the facility’s overall sales (21 CFR 117.5 (i)(2)). Please refer to the FDA website for further information.

## Doesn't beer have physical properties that make it inherently safe?

Multiple hurdles, including the inherent antimicrobial properties of ingredients (such as hops in beer), pH, alcohol and the processing methods used in the manufacture of alcoholic beverages, create an environment that makes it difficult for human pathogens to survive. Food safety hazards in alcoholic beverages are not restricted to human pathogens, because chemical and physical hazards may be introduced through their supply chain (e.g., ingredients), environment, process, etc.

## Do I need to have staff trained on FSMA and food safety in my brewery?

Sites that only manufacture alcoholic beverages still need to ensure that staff meet competency requirements outlined in 21 CFR 117.3 (Qualified Individual). Staff involved in any aspect of the food production process must be qualified to do their jobs and be trained on the principles of food safety, including personal and facility hygiene. It is important to document such training in order to verify staff competencies.

Sites that need to develop formal food safety plans, which address additional controls over food safety hazards utilizing the Hazard Analysis and Risk-based Preventive Controls (HARPC) methodology (outlined in 21 CFR 117 Subpart C), need to have an individual that meets the definition of a Preventive Controls Qualified Individual. This qualification can either be expressed through experience (including documented self-study of the regulation) or through participating in the Food Safety Preventive Control Alliance’s (FSPCA) Preventive Controls for Human Foods training course.

## What if my brewery is very small?

Regardless of size, breweries are responsible for controlling food safety hazards that could enter their products. The FDA makes special provisions for small facilities and classifies them as Qualified Facilities. Sites meeting the Qualified Facility definition (21 CFR 117.3, 117.201) due to being a very small business, or a combination of being a small business and selling directly to the consumer in a retail setting, will need to submit an attestation to the FDA that they are complying with the applicable portions of FSMA, or are otherwise meeting food safety requirements, and hold all applicable permits and/or licenses.

## What if my facility is a brewpub?

Brewpubs are themselves exempted from this rule if they only sell directly to a customer, but they are required to comply with the FDA Food Code, which details food safety requirements within a food service environment. If a brewpub manufactures beer and sells the beer to other facilities, then they would need to comply with applicable FSMA rules. Depending on the size of their operation, brewpubs may fall into the Qualified Facility status.

## Final Rules

FSMA is supported by rules designed to help the industry shift their focus from reacting to foodborne hazards, to preventing them at key steps throughout the supply chain and production practices. The rules that apply to alcoholic beverage facilities are summarized below:

Final Rule	Summary*
Preventive Controls for Human Food (21 CFR 117) Subpart A	Applies to facilities manufacturing and holding alcoholic beverages for human consumption.  Training of individuals who manufacture, process, pack or hold food.  Ensure staff are qualified to do their jobs and are knowledgeable about the principles of food hygiene and food safety, including employee health and personal hygiene.
Subpart B (21 CFR 117.10)	Implement current Good Manufacturing Practices (cGMPs). cGMPs address requirements and practices required to manufacture products in a sanitary environment to prevent the adulteration of foods. Specific sections of cGMPs include: <ul style="list-style-type: none"> <li>• Personnel</li> <li>• Plant and grounds</li> <li>• Sanitary operations</li> <li>• Sanitary facilities and controls</li> <li>• Defect action levels</li> <li>• Holding and distribution of human food byproducts</li> <li>• Equipment and utensils</li> <li>• Processes and controls</li> <li>• Warehousing and distribution</li> </ul>
Subpart D (Qualified Facility Status, 21 CFR 117.201)	Documented annual attestation to the FDA supporting qualified facility status.
Subpart F (Records)	Details documentation required for proof of training (21 CFR 117.9) and addresses basic requirements for records: genuine and accurate, contain actual data, and sufficient information to identify the facility and the product.
Preventive Controls for Animal Food (21 CFR 507)	Applies to domestic and foreign facilities that manufacture, process, pack or hold animal food, including those who manufacture materials destined for animal feed (directly or for further processing). These businesses make animal food “on purpose.”  Requires facilities manufacturing animal food to implement modified cGMPs and undertake a thorough Hazard Analysis to identify and control potential food safety hazards in their product and process. Steps identified as preventive controls must be scientifically valid and have critical limits (as appropriate), be monitored, have corrective action, be verified and supported by records.

\* Brief summaries are addressed above.

Please refer to the full text of FSMA and rules on the FDA website: [fda.gov/Food/GuidanceRegulation/FSMA/default.htm](http://fda.gov/Food/GuidanceRegulation/FSMA/default.htm)

## When does compliance start?

For breweries with 500 or more full time equivalent employees (FTEs, counting staff at the brewery and at other breweries that are part of the same corporation) compliance started in September of 2016. Breweries with less than 500 FTEs are categorized as “small businesses” and compliance started on September 18, 2017. Breweries with average annual sales of less than \$1 million fall into the “very small business” category . These businesses need to be in compliance by September 17, 2018.

All of the final rules went into effect 60 days following their publication as Final Rules. Compliance for most affected businesses begins one year after the publications of the Final Rules, with an additional year for very small businesses to comply. FDA enforcement mirrors compliance.

## Is compliance with cGMPs enough to protect my customers?

A brewery is responsible for controlling the food safety hazards which may be introduced into their products. Basic (and legally required) control measures are specified as current Good Manufacturing Practices (cGMPs). A brewery can take additional steps and develop a food safety plan that addresses risk-based controls and allocation of resources to prove those controls are in place. This can be done through the traditional HACCP approach or the new HARPC approach.

## What is the Difference between Hazard Analysis and Critical Control Points (HACCP) and Hazard Analysis and Risk-Based Preventive Controls (HARPC) Approach?

The hazard analysis and risk-based preventive controls approach (HARPC) aligns with HACCP in the design, development, implementation and verification of the food safety plan required. The primary difference lies in the designation of the preventive controls. Under HACCP, these controls would typically be restricted to steps in the process identified as critical control points (CCPs). Under the HARPC approach there is no such restriction. Thus, preventive controls will likely include process controls (i.e., CCPs), allergen controls, sanitation controls, supply chain controls or other types of controls, many of which are typically managed by sites outside the scope of a traditional HACCP plan, but are detailed in their prerequisite programs or cGMPs. The HARPC approach should encourage facilities to review their entire operation in a more holistic manner by managing all of the controls, regardless of how they are classified, and should allow facilities to better create food safety controls which reflect hazards within their operations.

## What about spent grain and other brewery byproducts sold/donated as animal feed?

Sites producing byproducts of human food as animal food (or an ingredient for animal food) who comply with human food cGMPs (21 CFR 117.110) do not need to comply with animal food cGMPs (21 CFR 507) or undertake a hazard analysis for the byproduct as long as the byproduct is not further processed, its identity is properly communicated and it is held and transported in a way that minimizes potential food safety hazards to animals (21 CFR 117.95). If materials are further processed in-house, the site must follow human or animal cGMPs for the materials, undertake a hazard analysis, and implement controls accordingly. Examples of further processing include drying, pelleting, and heat-treatment of spent grain.

## Where can I get additional information, support and resources?

- > Brewers Association – Provides checklists which follow a typical FDA inspection format and food safety plan and hazard analysis templates – [Good Manufacturing Practices for Craft Brewers](#), [Food Safety Plan for Craft Brewers](#). [BrewersAssociation.org](http://BrewersAssociation.org)
- > Master Brewers Association of the Americas – MBAA [Food Safety Committee](#) has developed resources addressing GMPs, aka [good brewing practices](#), and HACCP programs for breweries. [mbaa.com](http://mbaa.com)
- > Food Safety Preventive Controls Alliance - provides access to training manuals and courses on FSMA for those businesses who wish to learn more about the law, including the Preventive Controls for Human Foods training course. [ifsh.iit.edu/fspca](http://ifsh.iit.edu/fspca)
- > Food and Drug Administration FSMA page [fda.gov/Food/GuidanceRegulation/FSMA/default.htm](http://fda.gov/Food/GuidanceRegulation/FSMA/default.htm)
- > Preventive Control for Human Foods Rule [regulations.gov/document?D=FDA-2011-N-0920-1979](http://regulations.gov/document?D=FDA-2011-N-0920-1979)
- > FDA Guidance on human food byproducts such as spent grain [fda.gov/Food/GuidanceRegulation/FSMA/ucm366510.htm](http://fda.gov/Food/GuidanceRegulation/FSMA/ucm366510.htm)
- > FDA Facility Registration Information [fda.gov/Food/GuidanceRegulation/FoodFacilityRegistration/default.htm](http://fda.gov/Food/GuidanceRegulation/FoodFacilityRegistration/default.htm)
- > FDA Guidance for Qualified Facility Attestation [fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm496264.htm](http://fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm496264.htm)

