

FDA Food Safety Modernization Act (FSMA) – Developing a Food Safety Plan

Overview:

Beer distributors are increasingly covered by FDA regulation for their non-alcohol beverage portfolio. Beyond facility registration requirements passed after the September 11 terrorist attacks, Congress has passed the Food Safety Modernization Act (FSMA) to shift the focus from responding to foodborne illness to preventing it.¹ The FDA finalized seven key rules to further the safety of food and beverages.² These rules are intended to make clear and specific procedures that must be applied at each of those places to avoid contamination.³ The Agency has expressed a willingness to train and educate facility managers. The FDA can shut down a facility's operations if problems arise that put the public at risk.⁴

Requirements:

Each facility involved in the manufacturing, holding, or transporting of food and beverages must implement recognized systems in which the company and its employees are tasked with ensuring food safety.⁵

All distributors that are required to register with section 415 of the Food, Drug & Cosmetic Act⁶ **must produce a written food safety plan**, which includes an analysis of hazards and risk-based preventive controls, in compliance with FSMA and the modernized Current Good Manufacturing Practices (CGMPs).⁷

Key Elements:

Updates to the Current Good Manufacturing Practices (CGMPs)^{8,9}

¹ Center for Food Safety and Applied Nutrition. "FDA Food Safety Modernization Act (FSMA)." *U S Food and Drug Administration*, Center for Drug Evaluation and Research, 15 Nov. 2018, www.fda.gov/Food/GuidanceRegulation/FSMA/default.htm.

² *Id.*

³ *Id.*

⁴ Armstrong, Steve. "The Food Safety Modernization Act, After One Year: Advancing and Building Food Safety Systems for the 21st Century." *Update: Food and Drug Law Institute, Food Issue*, 2018, p. 7.

⁵ *Id.*

⁶ 21 U.S.C. § 350d (2017)

⁷ Center for Food Safety and Applied Nutrition. "Food Safety Modernization Act (FSMA) - FSMA Final Rule for Preventive Controls for Human Food." *U S Food and Drug Administration*, Center for Drug Evaluation and Research, 14 Nov. 2018, www.fda.gov/food/guidanceregulation/fsma/ucm334115.htm.

⁸ 21 C.F.R. § 210 (2018)

⁹ Center for Food Safety and Applied Nutrition. "Food Safety Modernization Act (FSMA) - FSMA Final Rule for Preventive Controls for Human Food." *U S Food and Drug Administration*, Center for Drug Evaluation and Research, 14 Nov. 2018, www.fda.gov/food/guidanceregulation/fsma/ucm334115.htm.

- It is essential management ensures that all employees are fit to accomplish their assigned duties (those that manufacture, process, pack or hold food), meaning that workers must have the basic education, training and experience to do so. This includes training in food hygiene and food safety, as well as employee health and hygiene.
- Much of the regulations deal with preparing food. Beer distributors invariably deal with prepackaged beverages and thus limit much of the concerns the FDA regulations seek to address.

Food Safety Plan must include:¹⁰

- *Hazard analysis* (identification): Distributors will need to consider any known or possible biological, chemical, and physical hazards, if they could have an influence on the safety of food.
- *Preventive controls*: If the hazards identified can be averted, the facility must produce written “preventive controls” for those hazards. These controls can be flexible in that they address the exact products you handle.
 - *Process controls*: Ensure your preventive controls are met (e.g. refrigerating).
 - *Sanitation controls*: practices and procedures that safeguard sanitary conditions within the facility (e.g. beverage handling).
 - *Other controls* not explicitly specified that will prevent hazards.
- *Oversight and management* of your preventive controls:
 - *Monitoring procedures*: It is **mandatory** that monitoring be documented (i.e. monitoring of a heat process to kill pathogens, and recording those temperature values¹¹)
 - *Timely Correction* of any minor problems that risk food safety.
 - *Corrective actions*: Actions that are taken in identifying the issue affecting a preventive control; actions that would decrease the possibility of a reoccurrence, examination of any products that might have been affected, then preventing them from entering the market if you cannot ensure the products’ safety. It is **mandatory** that corrective actions be recorded.
 - *Verification*: Verify that your preventive controls are steadily effective in reducing hazards; includes checking that appliances and tools are working properly. It is **mandatory** that these verification activities be documented.
- *Supply chain program*: Required for manufacturers, although a distributor can conduct supplier verification activities.
- *Recall Plan*: Your facility must have a written recall plan if you have identified hazards and preventive controls. The plan must contain methods to inform consignees, the public, perform effectiveness checks, and proper disposal of the product.

¹⁰ *Id.*

¹¹ *Id.*

Training, Educational & Technical Assistance, and additional info

Qualified facilities that are exempt from registering under section 415 of the Federal Food, Drug, and Cosmetic Act include:¹²

- “Very small businesses – a business averaging less than \$1,000,000 per year, during the 3-year period preceding the applicable calendar year in sales of human food plus the market value of the food manufactured, processed, packed, or held without sale.”¹³
- “A facility in which the average annual monetary value of food is sold directly to qualified end-users exceeded the average annual monetary value of the food sold by such facility to all other purchasers, and facilities in which the average annual monetary value of all food sold during the 30 year period preceding the applicable calendar year was less than \$500,000, adjusted for inflation.”¹⁴

Your food safety plans must be reanalyzed at least once every three years or when preventive controls are found to be ineffective.¹⁵

Every facility must have a written food plan, even if they produce the exact same product within the same company.¹⁶

Unless you are exempt from registering under section 415 of the Federal Food, Drug, and Cosmetic Act, you are required to have a **Preventive Controls Qualified Individual (PCQI)** to develop and implement your facility’s food safety plan.¹⁷ The employee charged with implementing the food safety plan does not need any specific certifications, although it should be noted that PCQI training is provided through the Food Safety Preventive Controls Alliance, but this is not mandatory – FDA will review adequacy of the safety plan rather than the individual that implemented it.¹⁸

Food Safety Plan Builder: The FDA developed a Food Safety Plan Builder, a free downloadable software application that guides businesses, step-by-step, through the creation of a food safety plan. Go to www.accessdata.fda.gov/scripts/foodSafetyPlanBuilder/ to start your download. Training materials for this tool can be found at www.fda.gov/Food/GuidanceRegulation/FSMA/ucm539791.htm.

Distributors are encouraged to create a food safety plan and have it ready for any FDA inspection.

¹² 21 C.F.R. § 117.5 (2016)

¹³ 21 C.F.R. § 117.3 (2018)

¹⁴ *Id.*

¹⁵ *Id.*, at p. 5.

¹⁶ *Id.*

¹⁷ *Id.*, at p. 6.

¹⁸ *Id.*