

Compliance for Food-Grade Product Manufacturing

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All materials that are part of the food supply chain, including food packaging and contact materials, can significantly influence food safety. Inadequate packaging can fail to protect food properly or allow for contamination or adulteration. Producing safe food demands food safety management and compliance from all who contribute to the final food packaging and contact materials—those supplying materials, making the packaging, manufacturing food contact materials, and distributing the final packaged products.

Setting the Standard

Under the Global Food Safety Initiative (GFSI) standards, major schemes (e.g., IFS PACsecure, the BRC Global Standard for Packaging, SQF Packaging, and FSSC 22000) provide guidance for the producers of packaging materials to ensure the safety and quality of food and non-food products.

The GFSI standards are described as different but equal. It is important that companies determine the best fit of the GFSI options for their own company requirements. All of the standards help manufacturers, packers/fillers, and retailers demonstrate that every reasonable measure has been taken to avoid a food safety incident. Qualified legal reviews have shown that these GFSI benchmarked standards also meet nearly all of the food safety requirements of FDA/FSMA.

The GFSI standards address the requirements to assure food safety by applying the Hazard Analysis and Critical Control Points (HACCP) and Good Manufacturing Practice (GMP) principles specific to food packaging risk and this sector of the food industry. The standards help manufacturers take responsibility by establishing a recognized Food Safety Management System (FSMS).

Each food packaging standard follows a defined documentation program for GFSI certification, and may fit specific packaging applications and food risk differently. As a general example, the FSSC 22000 certification scheme uses ISO 22000 and PAS 223 to identify the requirements for certification and to define a set of food safety requirements, as listed in sections 4-8 of the standard (see table below).

Preparing for Certification

Taking measures upfront to adhere to food safety standards helps assure that food packaging will meet in-use demands and regulatory requirements so that the food contents can be enjoyed safely. To prepare for certification, companies should:

- Identify regulatory requirements, which may include commissioning of plant and equipment to confirm compliance with food safety requirements

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- Set clear target dates for assessment and implementation
- Establish an informed and thorough materials evaluation process
- Identify and document food safety hazards and relevant control measures (HACCP/GMP)
- Identify applicable GMPs (e.g., pest control, equipment & building maintenance, housekeeping & cleaning)
- Establish a robust FSMS that aligns with existing management systems (i.e., quality, environmental, health & safety)
- Implement any needed structural improvements
- Institute ongoing material and packaging testing protocols, as well as strict handling and use requirements

Case Study: Food-Grade Paper Mill

Kestrel has been involved with a number of paper and packaging facilities considering expanding production operations to manufacture food-grade product that meets GFSI, FSSC 2200, GMP, HACCP, and customer requirements. The following provides an example of how a Kentucky-based paper mill commissioned its site to manufacture paper products to meet the needs of food customers nationwide.

Phase 1: HACCP/GMP Compliance Analysis

Due to the recent changes in regulatory and certification requirements, this paper mill needed to be confirmed or commissioned as food-material compliant to continue its food-grade materials manufacturing. Building on its existing management system documentation, originally designed and certified to ISO 9001, the mill determined that it would comply with FDA food contact paper requirements and sought alignment with the GFSI FSSC 22000 standard.

Kestrel conducted a preliminary GMP/HACCP certification analysis to provide a third-party audit report on the mill's compliance to regulatory and industry standards. The desktop, physical site, and process reviews included analysis of the following:

- Site HACCP program
- Risk analysis assessment
- GMP requirements under FDA
- Supplier program and receipt of goods
- Customer requirements and release of goods
- CAPA management
- Food safety objectives/policy

Based on this assessment, Kestrel established a project workplan and estimated timeline to develop and implement a food safety management program for both FDA and GFSI FSSC 22000 certification requirements.

Phase 2: GMP/HACCP FSMS

The mill proceeded with establishing the required programs for compliance to regulatory and industry standards for the manufacture of food-grade product meeting the processing requirements under GMP and HACCP. Specific project goals for this phase included:

- Designing and implementing a sustainable and compliant FSMS
- Developing a system that fully complies with all the FDA and industry (GFSI/HACCP) programs, procedures, and metrics
- Using a design and implementation process that draws from existing business/management systems and documentation
- Using a process that actively engages the workforce in the design/development, implementation, and ongoing improvement activities of the FSMS to create a participative food-safe packaging culture
- Using a scalable design and implementation process that is responsive to the company's resources

Kestrel began this phase of the project by focusing on foundational management system elements and working stepwise through the GMP and HACCP programs. Project tasks included:

- Completing food safe packaging compliance register
- Conducting physical review
- Developing HACCP/preventive controls plan
- Creating GMP requirements list
- Developing food safety plan policies/procedures
- Determining second level procedures and work instructions
- Developing/providing training modules
- Conducting internal audits
- Starting management reviews
- Commencing program integrity audits and status updates
- Integrating with current corrective actions and management processes
- Starting FSSC certification process (staged)

Kestrel's most recent review and assessment of the mill's management systems and approaches to food safety standards indicate that the overall business integrity and compliance is at the highest level in respect to food safety packaging standards. A legal review has confirmed that the process and developed programs also meet food safety legal requirements.

Benefits

The flexible packaging industry has experienced rapid growth. Ongoing innovation has led to more new materials being used, growth in packaging formats, extreme in-use conditions, and increasingly more stringent FDA regulations and food safety standards. Commissioning plants for food safety is vital to operating within the food industry.

A company's achievement as a reliable supplier is linked to its capability to provide safe products. In addition, adhering to food safety standards:

- Allows manufacturers to report on their status to key stakeholders (e.g.,

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- food retailers, customers)
- Covers areas of hygiene and product safety throughout the packaging industry
- Helps ensure that suppliers are also following good hygiene practices to complete the due diligence chain
- Ensures that a sustainable quality and product safety system is established and continually improved

Submitted by Bill Bremer, Principal, Food Safety Compliance of Kestrel Management. A seasoned practitioner, Bremer has worked in manufacturing and distribution operations for over 30 years.

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