

FSMA Compliance Checklist



Use this FSMA compliance checklist to help your team conduct internal audits and ensure you're maintaining compliance!

Scope and Personnel

- Assigned as a Qualified Individual under FSMA, skilled FSMA Auditor, and proficient Sanitation Manager.
- Defined roles for qualified individuals and allocated responsibilities for every aspect of the safety plan's implementation, verification, validation, and correction.
- Trained qualified individuals in applying risk-based preventive controls.
- Evaluated the applicability of FSMA regulations to the facility.

Hazard Analysis

- Are hazards assessed based on their significance?
- Is there a likelihood of hazards occurring despite preventive measures?
- Do the identified hazards pose a serious threat to consumer safety?
- Are allergens assessed for potential cross-contamination points?

Labeling

- Do individuals accurately label raw ingredients containing allergens?

Storage

- Are storage areas arranged to reduce the risk of allergen contamination due to spills?
- Can storage areas be adequately cleaned after an allergen spill?
- Are bulk storage containers and silos certified as allergen-free?

Staging

- Do allergen and allergen-free areas share staging areas?
- Are staging areas configured for efficient cleaning between production shifts?



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Utensils

- Are separate tools used for preparing allergen-free products?
- Are tools for allergen-free food preparation distinctly marked?
- Do tools share storage or cleaning spaces?

Personnel

- Can personnel move between allergen and allergen-free preparation areas?
- Do employees use personal protective equipment and follow sanitation protocols to avoid cross-contamination?
- Please define these protocols.

Biological

Equipment

- Is the processing equipment designed to be easily sanitized?
- Are processing surfaces devoid of cracks that could harbor bacteria?

Transportation

- Are transportation containers regularly sterilized?
- Are ingredients transported at appropriate temperatures?
- Are containers designed to effectively block environmental contaminants?

Sanitation

- Are there sanitation measures to prevent cross-contamination by employees?
- Please define these measures.
- Are processing areas configured for regular sanitation?



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Raw Materials

- Are raw ingredients inspected for spoilage and contamination before processing?

Facility

Grounds

- Are pests, dirt, and other potential contaminants detected on facility grounds?

Structure

- Do roofs and walls effectively prevent environmental contaminants?

Non-contact surfaces

- Are facility floors and fixtures free from cracks that could harbor bacteria or other contaminants?

Plumbing and HVAC

- Can drains and vents be sanitized effectively?

Non-food chemicals

- Are hazardous chemicals clearly labeled and properly stored?
- Does routine maintenance involve the introduction of non-food chemicals into the processing area?

Supply Chain

- Are suppliers of potentially hazardous ingredients regularly audited?
- Have the preventive controls of suppliers been documented and evaluated?
- Does your Food Safety Plan mandate actions if a supplier does not meet standards?



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Intentional Adulteration

- Could a malicious employee or intruder deliberately contaminate products?
- What measures are implemented to prevent and detect intentional contamination?

Preventive Controls

Monitoring

- Does your food safety plan pinpoint Critical Control Points to prevent contamination at its source, such as handwashing stations and pasteurization baths?
- What oversight measures ensure adherence to the Safety Plan at these critical points?
- Does your food safety plan define critical limits, like temperature or cooking time, that must not be exceeded?
- Is product testing to confirm the effectiveness of controls scheduled regularly?
- Is the processing environment continually monitored to prevent conditions that could lead to contamination?

Validation

- Are verification activities conducted according to a set schedule?
- Is verification carried out by a designated Qualified Individual?
- Are implementation records routinely reviewed for compliance?
- Is testing equipment regularly calibrated to ensure accuracy?
- If a critical limit is surpassed, what new testing protocols are implemented to confirm the efficacy of new controls?



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Re-analysis

- Has your Food Safety Plan been reevaluated within the last three years?
- Is there a new procedure for revising the plan to address new hazards?
- Does the plan incorporate the latest food safety research?

Recalls

- Is there a structured plan in place for recall events?
- Has a recall team been established? Are their roles well-defined?
- Can at least 98% of the affected product be removed from the supply chain?
- Can all affected products be identified and located within four hours?
- Can the supply chain be traced to pinpoint the source of contamination?
- Are notification protocols in place to inform distributors in the event of a recall?
- Are disposal processes adhered to for the safe removal of contaminated products and ingredients?



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