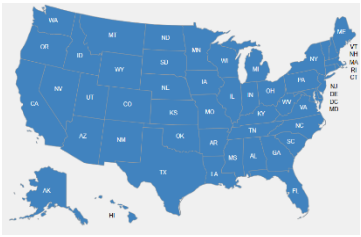
Food Safety Requirements to Consider When Starting Your Business

When starting up a new cheesemaking business, having proper food safety plans in place not only protects your future customers and your business, but it may be a legal requirement by local, state and/or federal agencies depending on the size of your business and if you manufacture or ship cheese to multiple locations, across state lines, or into retailers.



Knowing these requirements before you purchase equipment and make or sell cheese is important. Be sure to contact your local health department and/or state regulatory agency to find out what types of registrations, licenses and certifications are necessary for your location. A **map** of resources for locating individuals at your state dairy regulatory group or local extension agency by geography is provided.

Regardless of regulatory requirements, there are many steps you should take right now to grow your cheese business safely. Please see the Food Safety Program requirements listed below. Wishing you much future success to you and your business.

Food Safety Plan

The facility must maintain a written Food Safety Plan that is signed by leadership, prepared or overseen by a Preventive Controls Qualified Individual (PCQI), and re-analyzed at least every three years. Additional reanalysis is required whenever new hazards, new information, unexpected issues, or ineffective controls arise, and all such reviews must also be performed or overseen by a PCQI.

Section 1 Food Safety Plan - 21 CFR 117.126

The facility's Food Safety Plan is documented in writing.

- □ The facility's Food Safety Plan is prepared, or its preparation is overseen by one (1) or more Preventive Control Qualified Individuals (PCQI).
- □ The owner, operator, or person in charge of the facility has signed and dated the Food Safety Plan upon initial completion and upon any modifications.
- □ Reanalysis of the facility's entire Food Safety Plan is conducted at least once every three (3) years.
- □ Reanalysis of the applicable portion of the facility's Food Safety Plan is conducted due to a change in a hazard; new information about a hazard: an unanticipated food safety problem; or ineffective preventive control(s). - 21 CFR 117.170
- □ Any reanalysis of the facility's Food Safety Plan has been performed or overseen by a PCQI.

What's in a Food Safety Plan?

The facility's Food Safety Plan must include written programs covering recalls, hazard analyses, preventive controls, supply-chain controls, monitoring, corrective actions, and verification activities. Each element must be documented for every identified hazard and aligned with the specific foods the facility manufactures, processes, packs, or holds.

Section 2 Food Safety Plan Required Elements

- □ Facility has a written Recall Plan. (Section 3)
- □ Facility has a written hazard analysis for each type of food manufactured, processed, packed, or held at the facility. (Section 4)
- □ Facility has written Preventive Controls, as appropriate, for each identified hazard. (Section 5)
- □ Facility has a written Supply-Chain Program for each identified hazard. (Section 6)

- □ Facility has written Procedures for Monitoring the implementation of the preventive control(s), as appropriate, for each identified hazard. (Section 7).
  Facility has written Corrective Action Procedures appropriate to the nature of the hazard(s) and the preventive control(s). (Section 8)
- □ Facility has written Verification Procedures appropriate to the nature of the preventive control(s). (Section 9)

Recall Plan

The facility's Food Safety Plan must include written programs for recalls, hazard analyses, preventive controls, supply-chain controls, monitoring, corrective actions, and verification. Each component must be documented for every identified hazard associated with the foods the facility handles.

Section 3 Recall Plan - 21 CFR 117.139

- □ Written procedures include how to directly notify the direct consignee of the food products being recalled, including how to return or dispose of the affected food products and assign responsible for taking those steps.
- □ Written procedures include how to notify the public about any hazard presented by the food products.
- □ Written procedures include how to conduct effectiveness checks to verify that the recall is carried out.
- □ Written procedures include how to appropriately dispose of product.

Hazard Analysis

A facility must analyze all known or *reasonably foreseeable* biological, chemical (including radiological and allergen), and physical hazards for each product or process. It must also consider hazards that occur naturally, are unintentionally introduced, or are intentionally introduced for economic gain.

Section 4 Hazard Analysis - 21 CFR 117.130

(Similar products or similar types of production methods may be grouped together if the hazards and procedures are essentially identical.

- □ Facility has identified known or reasonably foreseeable hazards that include Biological, Chemical (including radiological and allergens) and Physical hazards.
- □ Facility has identified other known or reasonably foreseeable hazards, (i.e., Occurs Naturally, Unintentionally Introduced or Intentionally Introduced for purposes of economic gain).

Preventive Controls

Preventive controls must be documented at critical control points for each identified hazard. They must also include any additional written controls necessary to ensure food safety beyond those designated as CCPs.

Section 5 Preventive Controls - 21 CFR 117.135

- □ Includes written preventive control(s) at critical control point(s) (CCP) for the identified hazard(s). **
- □ Includes written preventive controls, other than those at CCPs that are also appropriate for food safety.

Supply Chain Program

A facility's supply-chain program must document that each ingredient supplier has an effective, written food safety program that includes allergen controls. It must also include approved-supplier lists, verification procedures, receiving protocols, and records of corrective actions taken when a supplier fails to control a hazard.

Section 6 Supply Chain Program 21 CFR 117 Subpart G

- □ Documented that a supplier of the ingredients has a functional and written food safety program that addresses hazards to include food allergen management.
- □ Written program includes documentation of approved suppliers; supplier verification activities to include frequency; conducting and documenting supplier verification activities before using raw materials and other ingredients; written procedures for receiving raw materials and other ingredients; and documentation that those procedures are being followed.
- □ Facility has taken and documented prompt action when a determination has been made that the supplier is not controlling the hazard.

Monitoring

Monitoring procedures must be written, implemented, and performed at specified frequencies to ensure preventive controls are functioning as intended. All monitoring records must be reviewed, dated, and signed or initialed by a PCQI or their designee within seven working days of creation.

Section 7 Monitoring - 21 CFR 117.145

- □ Written monitoring procedures including the frequency with which they are to be performed, are established, implemented, and consistently performed for monitoring the preventive control(s) for the identified hazard(s).
- □ Monitoring records are being reviewed, dated, and signed or initialed by or under the oversight of a PCQI within seven (7) working days after the records are created.

Corrective Actions

Corrective action procedures must be written, established, and implemented to address pathogens or indicator organisms found through product testing, environmental monitoring, or failures in preventive controls. All corrective action records must be reviewed, dated, and signed or initialed by a PCQI or their designee within seven working days.

Section 8 Corrective Actions - 21 CFR 117.150

- □ Established and implemented written corrective action procedures that shall be taken to address the presence of a pathogen or appropriate indicator organism detected because of product testing, as appropriate.
- □ Established and implemented written corrective action procedures that shall be taken to address the presence of a pathogen or appropriate indicator organism detected through environmental monitoring, as appropriate.
- □ Established and implemented written corrective action procedures that shall be taken if preventive controls are not properly implemented for the identified hazard(s).
- □ Corrective action records are being reviewed, dated, and signed or initialed by or under the oversight of a PCQI within seven (7) working days after the records are created.

Verification and Validation
Verification activities ensure that preventive controls are consistently implemented and effective at minimizing or preventing identified hazards. Validation must confirm that each preventive control is adequate, and this validation must be performed or overseen by a PCQI.

Section 9 Verification and Validation - 21 CFR 117.155 and 160

- □ Verification that the Preventative Control(s) is/ are consistently implemented and are effective and significantly minimizing or preventing the identified hazard(s).
- □ Validation that each preventive control identified and implemented is adequate to control the identified hazard(s).
- □ Validation has been performed or overseen by a PCQI.

Each Employee's Responsibility
Individuals working in the facility must be properly qualified, having received training in food hygiene, food safety, and the importance of health and personal hygiene. Supervisors must also be appropriately trained or experienced, and all training records must be maintained on-site for at least two years.

Qualifications of Individuals - 21 CFR 117.4

- □ The owner, operator or person-in-charge of the facility has ensured that all individuals who receive, handle, process, and package food products are qualified to perform their assigned duties.
- □ Each individual has received training in the principles of food hygiene and food safety, including the importance of employee health and personnel hygiene.
- □ Supervisory personnel have the necessary education, training, experience, or combination thereof, and ensure compliance by individuals with the requirements.
- □ Training records are established, maintained, and retained at the facility for at least two (2) years after the date they were prepared.

Records
The facility must maintain complete records demonstrating implementation of its Food Safety Plan, including monitoring, verification, and corrective-action documentation. All required records must be properly identified, signed or initialed, kept on-site for review within 24 hours of request, and retained for at least two years.

Records - 21 CFR 117.301

- □ Facility has established and is maintaining the required records documenting the implementation of the Food Safety Plan for preventive controls (e.g., monitoring,
- □ verification, and corrective actions.
- □ Required records are identified with the name and location of the facility or their facility code, dated and the signature or initials of the person performing the activity and on-site for review (e.g., records for metal detection or other preventive control(s) the facility may identify).
- □ The Food Safety Plan shall be on site for review.
- □ Preventive Control records were provided onsite within 24 hours of request (e.g., monitoring, verification, and corrective actions).
- □ Records that support the preventive control(s) required in the facility's Food Safety Plan are retained for at least two (2) years after the date they were created.