Change Management

Definition

Change Management is a systematic approach to managing changes to processes, products, systems, and organizational structures, among other things, to ensure they achieve their desired outcomes without unintended consequences. In the context of food safety systems, it involves planning, evaluating, documenting, communicating, and verifying changes to maintain the integrity and effectiveness of the food safety system.

Organizational change is like a makeover for businesses. It's all about adapting to the world around us and making things better. By doing so, we can help our organizational change strategy succeed.

Implementation & Audit Guidance

What does it mean?

A robust change management process forces the organization to ask critical questions before proceeding:

- Will this change introduce new hazards? Does it affect prerequisite programs, critical limits or other preventive controls in our food safety plan?
- Could it cause compliance issues with the FDA or other regulations?

For example, adjusting a cooking time to save energy might reduce the lethality of a heat treatment, risking survival of pathogens like Salmonella. Or, changing packaging film might introduce chemicals that migrate into food if the substances used to manufacture it are not approved by regulations. Change management safeguards the process by requiring validation studies, supplier checks, updated procedures, and clear communication to staff so everyone knows how to handle the change safely.

Why is it in the Code & why is it important?

Change management is an essential part of an effective food safety system because the entire system is interconnected, and all elements interact with each other. Processes, ingredients, people, and equipment all work together to maintain safe and quality food production. A change in one area can ripple through others unexpectedly. For example, a facility switching to a new sanitizer might find that while it kills bacteria effectively, it leaves residues requiring longer rinsing times, creating delays or product quality issues. Without a formal change management process, such impacts might only surface after a food safety incident or regulatory non-compliance, when it's too late.

Moreover, change management demonstrates due diligence and regulatory compliance, which is critical under laws like FSMA. Regulators and auditors want proof that a company proactively evaluates changes rather than reacting to problems after they occur. A documented change process provides that evidence. It shows that decisions were made deliberately, hazards were assessed, and risks controlled. It also helps ensure consistent product quality, protects brand reputation, and fosters a culture of continuous improvement. Ultimately, change management is not about preventing change but about ensuring that change happens safely, legally, and in a way that strengthens—not weakens—the food safety system.

It's always better to invest time in properly evaluating and monitoring changes upfront than to wait for a deviation or incident to reveal a problem. Proactive change management allows organizations to detect trends, identify subtle shifts in processes, and implement preventive actions before any product becomes unsafe or non-compliant. Waiting until a deviation occurs can result in costly recalls, damaged customer trust, and regulatory consequences, not to

mention wasted product and resources. Careful change management helps prevent these outcomes by ensuring that changes are controlled and risks are mitigated before they can impact finished products.

The site shall document and implement a procedure for evaluating any change that could affect food safety and quality, including:

- Product formulations and manufacturing processes for products included in the scope of certification.
- Materials, ingredients, labels, other inputs, or equipment.
- Specifications for raw materials, packaging, chemicals, processing aids, contract services, and finished products.
- Food safety plans, including critical control limits.

Procedure Content

A change management procedure may include, among others, the following steps:

1. Initiation of Change: This step begins when someone identifies a need for change—whether to improve efficiency, reduce costs, resolve problems, address supplier issues, or implement corrective actions from audits or complaints. Changes can be planned (e.g., a scheduled formulation update), unplanned (e.g., sudden supplier unavailability), temporary (e.g., using substitute material for a limited time), or emergency (e.g., urgent equipment replacement due to breakdown).
    a. Identify the proposed change and its rationale.
    b. Classify the change as planned, unplanned, temporary, or emergency.
    c. Example:
        i. A marketing team requests a new flavor of yogurt for a seasonal promotion (planned change).
        ii. A key spice supplier's crop failed, and the site must find a substitute urgently (unplanned change).
        iii. Equipment breaks down, and a temporary processing workaround is proposed (emergency change).
2. Impact Assessment: At this stage, the team evaluates how the proposed change might affect food safety, product quality, compliance with legal and regulatory requirements, customer requirements, and business operations. It's crucial to look at how the change could introduce new hazards or increase existing risks.
    a. Assess potential impacts on food safety, legal compliance, quality, and business continuity.
    b. Determine if new hazards are introduced or existing hazards are increased.
    c. Consider the implications for preventive controls, CCPs, critical limits, and monitoring activities.
    d. Also, consider how changes in one element may impact other elements, positively or negatively.
    e. Examples:
        i. Switching to a different gelatin supplier requires reviewing allergen risks and verifying halal or kosher certifications to ensure product claims remain valid.
        ii. Replacing an ingredient might alter the product's pH, affecting microbial safety and shelf life.
3. Risk Assessment: A documented risk assessment should be performed using the facility's risk matrix to quantify both the likelihood and severity of any hazard the change may introduce. The goal is to ensure risks remain at acceptable levels.
    a. Perform a documented risk assessment for any proposed change using the site's risk

matrix.
   b. Ensure the risk remains acceptable.
   c. Example:
      i. Introducing a new spice blend requires evaluating whether it might introduce Salmonella risk based on known recalls and incidents in spice supply chains.
      ii. Adjusting a thermal process requires reassessing whether the new time/temperature combination will still effectively inactivate pathogens.
4. Approval: Authorized personnel, including food safety, quality assurance, and operations management, must formally approve any proposed change before implementation. Approval ensures accountability and that no single department can introduce changes without considering food safety impacts on other elements of the food safety system or the systems of other departments of the organization.
   a. Obtain approval from authorized personnel (e.g., QA, Food Safety Team, Management).
   b. Example:
      i. The food safety team and plant manager sign off on a plan to replace a sauce ingredient after confirming allergen labeling updates and supplier documentation.
5. Implementation: Once approved, the change(s) is/are executed. This step includes training relevant personnel, updating procedures or work instructions, and ensuring all teams know how to operate under the new conditions.
   a. Plan and execute the change with documented responsibilities and timelines.
   b. Example:
      i. After approval of a new filling machine, maintenance staff install it, and production staff receive training on cleaning and operation procedures.
      ii. Use statistical process control as a monitoring tool to identify trends and minor changes in the process to implement preventive actions before a deviation happens.
6. Validation and Verification: Validation confirms that the change will achieve the intended result, while verification checks that the change has been implemented correctly and is working as planned. Validation often involves tests, trials, or data analysis.
   a. Validate those changes maintain or improve food safety controls.
   b. Perform verification activities to confirm effectiveness.
   c. Example:
      i. Validation: Conduct microbial challenge studies to prove the new thermal process effectively controls pathogens.
      ii. Verification: Review process records over several production runs to confirm the new process consistently achieves critical limits.
7. Documentation and Communication: Every change must be documented clearly. Records should include the reason for the change, risk assessments performed, decisions made, validation results, and any updates to procedures. Communication is essential so all stakeholders know what has changed and how it affects them.
   a. Record the change, the assessment outcomes, and decisions taken.
   b. Communicate relevant details internally and externally as required.
   c. Example:
      i. Updating SOPs to reflect the new cleaning process for a piece of equipment.
      ii. Sending an internal memo to operators highlighting new CCP parameters after process changes.
8. Review and Closure: A post-implementation review evaluates the change's success and ensures no unintended negative impacts occurred. The change is only considered closed

once the review is complete and all documentation is finalized.

a. Conduct a post-implementation review to ensure no unintended consequences.
b. Example:
    i. After implementing new packaging material, the team reviews quality data over several weeks to confirm no seal failures or product contamination issues have arisen.
    ii. Documenting the review findings and archiving records for audit purposes.

Audit Expectations

Auditors will look for, among other things:

- A documented, approved change management procedure.
- Evidence that all changes since the last audit have gone through the documented process.
- Records demonstrating:
    - Description of the change.
    - Impact and risk assessments conducted.
    - Approvals obtained from relevant personnel.
    - Results of validation and verification activities.
    - Updates made to procedures, work instructions, or records.
    - Internal communication to affected personnel.
- Confirmation that hazards potentially introduced by changes were effectively controlled.

Auditors will sample changes implemented since the previous audit to assess adherence to the documented procedure and regulatory compliance. Auditors may interview employees to confirm their awareness of changes and examine records to verify consistency with documented procedures and regulatory requirements

Change Management
Guidance Document

RIO Road to Audits (Records, Interviews, and Observations)

Records

The following are examples of records and/or documents to assist in the implementation and review of this topic:

- Change request forms, including:
  - Description of the proposed change.
  - Reason for the change.
  - Classification of the change (planned, unplanned, emergency, temporary).
- Impact assessments and risk assessments, with documented conclusions.
- Hazard analyses revised to incorporate new risks (where relevant).
- Records of management or authorized personnel approvals.
- Validation study results (e.g., microbial challenge studies, shelf-life studies).
- Verification records showing post-implementation checks.
- Training records for staff affected by the change.
- Updated SOPs, work instructions, or specifications reflecting the change.
- Communication records (e.g., internal memos, emails, meeting notes).
- Post-implementation review records documenting success or issues found.
- Audit reports referencing the change and its outcomes.
- Supplier documentation (e.g., new Certificates of Analysis, allergen declarations).

Interviews

The following are examples of people to interview to assist in the implementation and review of this topic:

- Food Safety or Quality Assurance Managers
- Food Safety Team leaders
- Production Supervisors
- Engineering or Maintenance Managers
- Research & Development (R&D) personnel
- Procurement or Purchasing Managers
- Sanitation/cleaning teams
- Warehouse and logistics staff
- Operators directly involved in processes affected by changes
- Senior management for overall oversight

The following are examples of questions to ask to assist in the implementation and review of this topic:

General Program Understanding

- Can you describe how change management is handled here?
- Is there a documented procedure for managing changes?
- Who is responsible for evaluating and approving changes?

Specific Change Examples

- Tell me about a recent change that occurred in this facility. How was it managed?
- How do you determine whether a change might affect food safety?
- What happens if you

Observations

The SQF auditor may observe the following or similar activities:

- Checking that all recent changes are documented in a change log or register.
- Reviewing SOPs or work instructions to ensure they reflect recent changes.
- Confirming that affected production staff can explain changes relevant to their work.
- Observing whether new equipment or process changes have visible labels, instructions, or signage indicating changes.
- Verifying that allergen labeling updates have been correctly implemented following a formulation change.
- Checking physical conditions (e.g., equipment layout, cleaning procedures) to ensure they align with documented changes.
- Comparing batch records or process logs before and after a change to verify implementation.
- Reviewing training attendance sheets or materials distributed to staff following a change.
- Looking for evidence that monitoring or verification activities are adjusted after changes (e.g., new critical limits).

▪ Records of customer notifications, where applicable (e.g., labeling changes). ▪	need to change suppliers for an ingredient? ▪ How do you handle emergency changes? Risk Assessment and Controls ▪ How do you assess risks when considering changes? ▪ What factors do you evaluate in an impact assessment? ▪ Have you ever found that a proposed change would introduce a new hazard? Validation and Verification ▪ How do you validate that a change won't affect product safety or quality? ▪ Can you show me records where verification was performed after a change? Training and Communication ▪ How do you ensure staff are informed and trained when a change is implemented? ▪ Can you give an example of how you communicated a change to your team? Recordkeeping and Review ▪ Where are change management records kept? ▪ How often do you review changes to ensure no issues have arisen afterward? ▪ Do you track trends from change management activities to improve the process?	

Additional References

Below is a list of reliable references that may support the development, implementation, and auditing of a Change Management Program in a food safety context. These references cover both the technical side (food safety laws and regulations) and the management side (change management principles and best practices).

- Codex Alimentarius – General Principles of Food Hygiene (CXC 1-1969, latest revision).
- ISO 10020, current version Quality Management Systems,