Change control principles

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What is change control / change management?

- ISO 22000:2018 => Clause 6.3: Planning of Changes
- FSSC 22000: v6.0 => Includes ISO 22000:2018

+ Change is mentioned in most of the clauses

6.3 Planning of changes
When the organization determines the need for changes to the FSMS, including personnel changes, the changes shall be carried out and communicated in a planned manner.
The organization shall consider:
- the purpose of the changes and their potential consequences;
- the continued integrity of the FSMS;
- the availability of resources to effectively implement the changes;
- the allocation or re-allocation of responsibilities and authorities.

2.5.7 ENVIRONMENTAL MONITORING (FOOD CHAIN CATEGORIES B, I & K)
The organization shall have in place:
- a) A risk-based environmental monitoring program for indicator organisms;
- b) A documented procedure for the monitoring and audit of the processes for preventing contamination from the environment to a minimum, the evaluation of microbiological and chemical parameters, and customer requirements.
- c) Data of the environmental monitoring program;
- d) The environmental monitoring program shall be reviewed and updated at least annually, and if triggers occur:
  - Significant changes related to the changes indicated in the environmental monitoring program.

2.5.13 PRODUCT DESIGN AND DEVELOPMENT (FOOD CHAIN CATEGORIES B, C, D, E, F & K)
A product design and development procedure shall be established, implemented, and maintained for new products and changes to product or manufacturing processes to ensure safe and legal products are produced. This shall include the following:
- a) Evaluation of the impact of the changes on the FSMS taking into account any new food safety hazards (incl. allergens) introduced and updating the hazard analysis accordingly;
- b) Consideration of the impact on the process flow for the new product and existing products and processes;
- c) Evaluation of the change in the process;
- d) Resource and training needs;
- e) Equipment and maintenance requirements;
- f) Identification of the change in the product label or packaging shall be validated to ensure food safety is maintained.

2.5.15 EQUIPMENT MANAGEMENT (ALL FOOD CHAIN CATEGORIES, EXCLUDING F & I)
In addition to clause 8.2.4 of ISO 22000:2018, the organization shall:
- a) Have a documented purchase specification in place, which addresses hygienic design, applicable legal and customer requirements, and the intended use of the equipment, including product handled. The supplier shall provide evidence of meeting the purchase specification prior to installation.
- b) Establish and implement a risk-based change management process for new equipment and/or any changes to existing equipment, which shall be adequately documented including evidence of successful commissioning. Possible effects on existing systems shall be assessed and adequate control measures determined and implemented.
What does that mean?

=> Changes shall be controlled by a system in place to ensure that all department and senior management are fully aware of these changes and brainstorming together all risks that could be in place in case you implement that change.

=> done prior to the change
  • Assessment of change: risk analysis
  • Decision: Yes/No
  • Plan the change
  • Implement the change
Why is change control important?

Change management is not a reactive response if change happens; it is preparation for when change happens. Change management allows you to assess your situation and why change is needed, align your efforts and resources, and manage the change itself.
### Different types of changes

<table>
<thead>
<tr>
<th>Product related</th>
<th>Production process</th>
<th>Premises / equipment</th>
<th>Organization</th>
<th>Subcontracted activities</th>
</tr>
</thead>
</table>
| • Specification / regulatory  
• Formula / ingredients  
• Supplier  
• … | • New step in process  
• New parameters in process (e.g. heat treatment)  
• … | • New line  
• Zoning: eg interlocks, pressure differential...  
• Utility system: air, water... | • Staff: management, HACCP team, CCP monitoring staff  
• IT: ERP, QMS software, maintenance software  
• New organization  
• … | • Laboratory  
• Pest control  
• … |

Permanent  
Temporary  
Emergency

=> important to identity / classify the different changes
The different steps of change control

**Request**
- Who
- What
- Why ($$$, food safety...)
- ...

**Evaluation Risks / consequences**
- Regulation, legal requirements
- Specifications
- Technical requirements
- Food safety (HACCP...)
- Security
- HR: new staff?
- Feasibility
- ...

**Decision**
- Change approved / not approved
- Team decision, endorsed by high management
- Communication to customers?

**Plan**
- Qualification of equipment
- Maintenance & calibration
- HR, Training!
- Documentation procedures, batch records...
- Cleaning plan
- EMP
- Premises (e.g., warehouse capacity)
- Communication

**Implement**
- Track

**Evaluate**