FSSC 22000

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GUIDANCE DOCUMENT: EQUIPMENT MANAGEMENT

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REVISION HISTORY

Date Published	Issue	Changes
September 2023	1	First publication

1. PURPOSE

Guidance Document to assist FSSC 22000 certified organizations on how to implement equipment management in their food safety management systems.

2. INTRODUCTION

FSSC 22000 additional requirement 2.5.15 on equipment management is applicable to all food chain categories, except subcategory FII on brokering and trading.

The definition of equipment as per GFSI (v2020.1) is as follows:

Machines and equipment (including their parts and components necessary to link them together, and their services and utensils necessary for their operation), feed and food transport systems to bring ingredients/packaging to them, together with food storage and display units to allow the processing and retail of food, feed and packaging materials in GFSI scopes of recognitions.

The equipment management requirement included within the Scheme has been incorporated to ensure hygienic design has been taken into consideration at the purchasing stage, as well as to ensure that the associated risks of new equipment or changes to existing equipment have been considered within the organization's FSMS.

Hygienic design is a design that minimizes the risk of contributing to the microbiological, chemical, and physical contamination of food. It ensures the equipment accommodates and withstands the cleaning, sanitizing, and inspection processes involved. The equipment's hygienic design enables it to hold up against high temperature and high-pressure washdown, including, where applicable, exposure to cleaning chemicals depending on the industry[3].

Good hygienic design of equipment can have a significant impact on the safety of the food to be consumed, and if done incorrectly, it would have adverse effects on the people who consume the final products and the brand integrity of the manufacturing organizations.

Principles of hygienic design include[1]:

- Accessibility
- Cleanability
- Drainability
- Material compatibility
- Segregation
- Surface and Geometry

EHEDG (The European Hygienic Engineering and Design Group), the European Committee for Standardization (CE), NAMI (The North America Meat Institute), 3-A SSI, etc., are some of the agencies that provide support and guidance for industry in relation to hygienic design of equipment.

Some of these organizations also provide hygienic design training courses based on recognized training programs, e.g., EHEDG, 3-A SSI[1].

GFSI also identifies equipment hygienic design to be of importance in the food industry and has specific requirements for Category JI and JII organizations[1]. Although the FSSC 22000 Scheme does not cover Category JI and JII, some of these requirements identified by GFSI for the hygienic design of equipment is a valuable source of information for organizations to consider when implementing the FSSC 22000 Additional Requirement 2.5.15 on Equipment Management.

3. SCOPE

This FSSC 22000 Guidance document is meant as a guideline for the food industry to provide practical information and guidance on implementing FSSC 22000 Additional Requirement 2.5.15 Equipment Management for All Food Chain Categories, excluding FII.

4. FSSC 22000 SCHEME REQUIREMENTS

Part 2 – Requirements for organizations to be audited in Version 6

2.5.15 EQUIPMENT MANAGEMENT (ALL FOOD CHAIN CATEGORIES, EXCLUDING FII)

In addition to clause 8.2.4 of ISO 22000:2018, the organization shall:

a) Have a documented purchase specification in place, which addresses the hygienic design, applicable legal and customer requirements, and the intended use of the equipment, including the 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.

5. GUIDANCE FOR IMPLEMENTATION

5.1 GENERAL GUIDANCE

In the context of the FSSC 22000 Scheme:

- This requirement relates to significant changes to equipment, which can affect its hygienic design. It does not cover maintenance-related activities such as changing a fuse or replacing a fraying conveyor belt. This is addressed under the maintenance section of the relevant PRP sector-specific standard, such as clause 8.6 of ISO/TS 22002-1. Whereas modifications such as installing an additional conveyor belt to an existing line for the purpose of speeding up production would be considered a significant change that would require a review of the design of the existing line, and therefore a hygienic design risk assessment would be required. Another example would be installing a stainless-steel tray beneath a conveyor belt that transfers bread rolls from the cooling line to a packing machine to minimize the build-up of product crumbs beneath the packing line.

- The equipment management requirement would not directly impact on existing equipment except when there are significant changes to the equipment. In this case, the organization would need to assess the impact on the process and system to ensure adequate control measures have been implemented to address any hazards and food safety.
- Purchasing second-hand equipment would be seen as "new" equipment, and therefore the organization would need to make sure that hygienic design has been considered as part of the purchase specification and the requirements of this clause would apply.
- The organization is not required to assess its current existing equipment against this requirement, unless existing equipment undergoes significant change; however, it is important to note that hazards and associated risks relating to current equipment would still need to be addressed within the hazard analysis under clause 8.5 of ISO 22000:2018.

5.2 PURCHASE SPECIFICATION

In accordance with **2.5.15 (a),** an organization shall have a **documented purchase specification** in place that addresses the hygienic design, applicable legal and customer requirements, and the intended use of the equipment, including the product handled.

It is important for food safety management that expectations and interpretations of needs, capabilities, and intended use are clear during the development, realization, or handover of food processing equipment when it is newly purchased from the manufacturer.

In accordance with the requirement, the organization needs to document a purchase specification for each piece of equipment prior to purchasing the equipment. This specification needs to address the specific hygienic design parameters for the specific type of equipment being ordered/manufactured.

The intended use of the equipment must be specified, including the product handled, e.g., burger patty packing machine or corn chip fryer, etc. To establish the purchase specification, the organization should conduct an equipment design risk assessment that takes into account the intended use of the equipment, food safety hazard identification, and evaluation (risk assessment).

Once the intended use is known, and the risks related to the type of products to be packed or manufactured have been identified based on the outcome of the risk assessment, the hygienic design principles required to ensure food safety should then be adopted/specified within the purchase specification. Where there are specific customer and legal requirements, these must be incorporated in the purchase specification as well.

The design of the equipment must ensure that the equipment is suitable for the intended use and that (potential) contamination of the product is minimized. This can include features such as see-through covers over the burger patty forming line to minimize handling of the products by the operator or a fail-safe lid for the fryer to control/limit opening and closing while the frying process is taking place. Recognized hygienic design standards for the specific industry should be considered. The specification must be documented and implemented every time new equipment is planned to be purchased.

Organizations should also include a requirement in the purchase specification that the equipment manufacturers have the responsibility of informing the organization of any food safety risks that could not be eliminated by hygienic design and also of providing the organization with an

instruction manual covering information needed for hygienic safe operation within the limits of use of the respective equipment. This includes but is not limited to:

- Instructions regarding limitations and operational use
- Instructions regarding technical measures (e.g., control or inspection devices)
- Instructions regarding disassembling for inspection, cleaning, and maintenance
- Instructions for cleaning[1]

For changes to existing equipment or even equipment custom-made by the Certified Organization's own engineers or maintenance technicians, specifications can be written by using the expertise from different departments that form part of the Food Safety Team, or if the expertise does not exist within the company's own personnel, the assistance of external experts can be used.

Items to consider, for example, can include the hygienic design of the materials used for the construction of the equipment, i.e., stainless steel, smooth and continuous edges where welding is done, fasteners are to be avoided in or above the product contact zone, rounding of piping and ductwork instead of sharp bends and corners to prevent dead ends in enclosed fittings, mounting on legs/ wheels to facilitate cleaning and sanitation around the piece of equipment, ease of disassembly for deep clean purposes, etc.

A service-level agreement should be drawn up between the supplier/manufacturer and the purchasing organization.

In accordance with **2.5.15 (a),** the supplier shall provide evidence of meeting the purchase specification prior to installation.

The equipment manufacturer/supplier must provide evidence of meeting the purchase specification(s) and the requirements set out therein, including any customer and regulatory requirements, e.g., the manufacturer's manual can be compared to the purchase specification and evidence of this review maintained.

5.3 RISK-BASED CHANGE MANAGEMENT PROCESS

In accordance with **2.5.15 (b),** an organization shall 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.

The objective of change control is to handle changes in such a manner that the impact on food safety by a change is foreseen and not missed and that the correct mitigation actions and control measures are executed.

Change control consists of the organization undertaking a risk assessment, determining risk mitigation based on hygienic design principles as well as documenting the changes[1]. The Food Safety Team should ensure that the relevant managers are aware of these requirements in order to ensure that the change management process is followed.

Installation and commissioning phase[1]:

- Installation: During installation, check that the correct equipment has been received and has been installed according to the approved specification. For equipment that has been prefabricated (assembled and/or assigned) at the equipment suppliers' site, a factory-

acceptance test (FAT) should be performed by the purchasing organization at the supplier's site prior to delivery at the purchasing organization.

- Commissioning: After installation and before use at the organization's premises, it should be verified that all functional (operational) parameters and specifications, limits, and tolerances detailed in the purchase specification and user manual/guide can be met to achieve the required hygienic performance. A site-acceptance test (SAT) should be done after the equipment components are installed and commissioned at the organization and typically includes functional testing.
- The organization should conduct a validation study to confirm that newly installed equipment functions as designed according to the manual/guide. This should include food safety, quality, cleanability aspects, and cleaning validation activities. The validation, which may have been initiated and planned prior to equipment being built, should be completed as part of the process qualification, taking into consideration the planned or projected usage in production.

Although it is separate from the FSSC 22000 additional requirement, it recommended that existing equipment, which has not previously been evaluated in respect of their hygiene-related performance, should undergo hygienic design risk assessments and a retrospective cleaning validation based on historical data[1]. In this context, based on the risk assessment, the organization should undertake a cleaning validation of the equipment if they have not done so already to determine whether the cleaning is appropriate or whether changes to the cleaning program should be made to ensure hygienic operation.

When implementing this requirement related to the management of equipment changes, clause 6.3 of ISO 22000:2018 has to be considered. Organizations should incorporate the risk-based change management process for equipment into the change management process currently in place as part of the FSMS. The change should be documented according to the existing process, keeping note of the requirements of clause 6.3 for retained evidence.

An example of a documented change summary can include the indication of owner/ requester, the due date or target date for installation and/ or commissioning, the required resources for commissioning in terms of personnel, time, and capex, as well as the status (in progress or complete). The team should hold a review meeting to facilitate the review of the change progress until completed.

In accordance with **2.5.15 (b),** possible effects on existing systems shall be assessed, and adequate control measures determined and implemented.

The organization needs to assess the impact of the changes/modifications to equipment and determine whether the change in equipment changes or increases the risk relating to existing hazards identified in the hazard analysis or whether new hazards are introduced. If so, the organization needs to evaluate the current control measures and amend them if needed, e.g., increase the frequency of monitoring, etc., or establish additional control measures.

The organization should look to undertake the following (as applicable) if changes to equipment are planned:

- Update the hazard analysis.
- Update the cleaning and sanitation program (procedures, cleaning schedules, records, etc.). Establish whether outsourced services are required or whether cleaning and sanitation can be done internally.
- Update the maintenance program (procedures, maintenance schedules, equipment checks, etc.) and establish whether outsourced services are required or whether maintenance and servicing can be done internally.
- Update production records, if necessary.
- Review and update the environmental monitoring program.
- Review and update the allergen management program, if applicable.
- Review and update the training program, and train relevant personnel on updated procedures.
- Update any other relevant verification activities.
- Determine if additional resources are needed and whether they will be available should breakdowns or faulty operations be experienced with the equipment.

5.4 ADDITIONAL GUIDANCE

The below are steps to follow when implementing this additional requirement, based on the EHEDG Whitepaper[1] developed in conjunction with GFSI:

Element	Guidance for implementation
Hygienic design process	• Establish a multi-disciplinary team to assess the hygienic design and risk assessment of new equipment. The team should be competent in: o Food safety and quality, including microbiology and allergen expertise. o Hygienic design requirements and principles for equipment and facilities o Hygienic engineering/maintenance o Product and process requirements and conditions o Operational and functional considerations that could affect hygienic design (e.g., cleaning method, operating conditions, possible future applications, etc.) o Interpretation of technical engineering drawings and PI&D o Legal requirements and industry standards o Hazard analysis and risk assessment methods o Cleaning & disinfection • Evaluate the hygienic design and suitability of the equipment throughout the life cycle of the equipment from the design concept through construction, purchasing, and during use until the end of the equipment's intended life. In relation to the lifecycle evaluation of equipment, the EHEDG White Paper provides further details on activities related to hygienic design, including the design phase, installation and commissioning phase, and operational use. As part of the purchase specification, the organization may require that the supplier confirms the equipment is in compliance with hygienic design criteria and the suitability for cleaning by certification according to recognized standards (e.g., EHEDG-procedures) carried out by authorized Certification Bodies. The supplier should also evaluate hygienic design based on the requirements of ISO 14159 and/or EN 1672-2.

Element	Guidance for implementation

Risk assessment	• Undertake a documented hygienic design risk assessment for food safety hazards on new equipment. This risk assessment should address the intended use, food safety hazard identification and evaluation (risk assessment).
	  ○ A hygienic design risk assessment is specific to an application (e.g., product, process, procedures, location) and can be seen as complementary to other existing risk assessments.
	  ○ Intended use is determined by the product and process requirements, operating modes, cleaning processes, end users, etc.
	  ○ Food safety hazards (biological, chemical, physical) and the contamination mechanisms (ingress, accumulation, growth) that should be considered and controlled during operational use.
	  ○ Evaluation (risk assessment) considers the severity or impact of the food safety hazard and the likelihood or probability that the food safety hazard occurs.
	• Hygienic design principles are used to eliminate or mitigate the hazards and reduce or eliminate the risks identified.
	• Review the hygienic design risk assessment when a change to the equipment, product or process is made, or other hazards arise. Recommend to also review at a minimum frequency as defined by applicable laws and regulations.
	EHEDG has established a hygienic design risk management guideline that can be used for new and existing equipment.

Intended use	• Describe the intended use of the equipment, as a specification for the intended purchase of the new equipment.
	• The following should be taken into consideration when establishing the intended use:
	  ○ Product
	  ○ Process
	  ○ Operating modes
	  ○ Cleaning
	  ○ Value chain
	  ○ Vulnerability of end users
	  ○ Machine users
	  ○ Life cycle
	  ○ Environment
	  ○ Laws and regulations
	Refer to the EHEDG White Paper for further guidance on these elements to be considered.

Element	Guidance for implementation
Hygienic design principles	Hygienic design principles are the basic design aspects and methods used to eliminate, reduce or mitigate biological, chemical and physical food safety hazards, as well as negative influences on product quality. An organization should adopt appropriate hygienic design principles such as: • Equipment should be of a cleanable design, to meet all cleaning objectives. • Equipment should be designed and constructed to avoid favorable growth conditions (for microorganisms, pests and their harborage), appropriate to their intended use. • Equipment should be designed to prevent contamination appropriate to their intended use. • Wherever relevant, recognized hygienic design standards/guidance should be consulted for the design and construction of equipment, appropriate for their intended use. • Appropriate hygienic design principles should be adopted for the installation of new equipment at sites handling food. • Hygienic design principles should be adopted to ensure the maintenance of the hygienic performance of the equipment, appropriate for their intended use. • Appropriate measures (with frequencies) should be specified, undertaken accordingly and documented to mitigate any remaining food safety risks identified in the hygienic design risk assessment following equipment construction, purchase and installation. The EHEDG White Paper[1] provides further detail on these hygienic design principles.
Legislation	Establish whether there are any legal requirements for the hygienic design of equipment, that the equipment needs to comply with in the country of installation.
Purchasing and supplier performance	Establish, implement and maintain a procedure to ensure that the newly purchased equipment will meet the hygienic design specification.
Change Management	Undertake and document change control, to evaluate the impacts of any changes/modifications on equipment hygienic design.
Product contamination risk and segregation	Establish procedures to ensure that following purchasing and installation, equipment is cleaned/commissioned by the organization before they are used for the processing of food. Organizations should verify the efficiency of the cleaning performed before starting any food production. Cleaning needs to be recorded and verified.

Element	Guidance for implementation
Training	Establish, implement and maintain procedures to ensure: • All employees and contractors involved in building and equipment evaluation, specification, purchase, maintenance and hygienic design are trained in hygienic design principles appropriate to their tasks and to the hygienic design requirements of the equipment for its intended use. • All employees and contractors involved in equipment installation, undertaken at a site handling food are trained in food safety principles appropriate to their task.
Transport	Manufactured equipment should be stored and transported to the final customer in a manner that prevents contamination of the equipment which may affect food safety.

6. GUIDANCE FOR AUDITORS

The following is a non-exhaustive list of questions that an auditor can use to assess the FSSC Additional Requirement 2.5.15:

- Are the purchase requirements established and known for all new equipment?
- Is there supporting documentation available for review, such as purchase specifications, commissioning reports, equipment user manuals, certification documents, etc., to confirm the hygienic design of the equipment and successful commissioning?
- Does it address the hygienic design of the equipment, the products handled, and the legal/customer requirements?
- Has the intended use been clearly identified, and the risks related to the equipment determined?
- Has a risk-based change-management process for new equipment or changes to existing equipment been established?
- Have the relevant updates been made to the FSMS based on the changes made to equipment? E.g., cleaning and maintenance schedules updated, environmental monitoring program updated, evidence of training available?

7. REFERENCES

1. EHEDG White Paper on GFSI Hygienic Design Scopes JI & JII October 2022. URL: EHEDG
2. ISO 22000:2018 - Food safety management systems — Requirements for any organization in the food chain. URL: ISO 22000:2018 - Food safety management systems — Requirements for any organization in the food chain
3. International Food Safety & Quality Network. URL: Food Safety with Hygienically Constructed Equipment Built to Sanitary Design - IFSQN
4. GFSI Benchmarking Requirements (v2020.1). URL: GFSI

8. RELATED INDUSTRY INFORMATION

The references below are not an exhaustive list and are for information purposes only, and may not apply to all organizations. The requirements of the Scheme shall be adhered to in all cases.

- EHEDG, The European Hygienic Engineering and Design Group. URL: EHEDG. Examples of some of the guideline documents established by EHEDG include:
    - Guideline Doc. 32:2005 Materials of construction for equipment in contact with food
    - Guideline Doc. 35:2006 Hygienic welding of stainless-steel tubing in the food processing industry
    - Guideline Doc. 44:2014 Hygienic Design Principles for Food Factories
    - Guideline Doc. 8:2018 Hygienic Design Principles
    - Guideline Doc. 50:2019 Hygienic Design Requirements for CIP Installations
    - Guideline Doc. 55:2020 Hygienic Design Requirements for Bakery Equipment
- The European Committee for Standardization. URL: CEN-CENELEC
- FDA, The US Food and Drug Administration. URL: U.S. Food and Drug Administration
- NAMI, The North American Meat Institute. URL: North American Meat Institute
- The International Organization for Standardization (ISO), ISO 14159:2002. URL: ISO 14159:2002 - Safety of machinery — Hygiene requirements for the design of machinery
- BS EN 1672-2:2020. Food processing machinery. Basic concepts – Hygiene and cleanability requirements. URL: BS EN 1672-2:2020
- Codex Alimentarius CXC 1-1969:2020. URL: CXC 1-1969 General Principles of Food Hygiene.