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1. PURPOSE

Guidance Document for FSSC 22000 certified organizations on how to implement environmental monitoring in their food safety management systems.

2. INTRODUCTION

It is a valid observation that there have been a substantial number of foodborne illness outbreaks from poor environmental controls and hygienic practices worldwide. Codex Alimentarius made several recommendations to authorities to include environmental monitoring as part of their regulatory activities with an emphasis on the criticality of enhanced control of sanitation, including appropriate use of environmental monitoring.

An environmental monitoring program oversees the effectiveness of the overall hygienic practices in facilities and provides the necessary information to prevent possible microbial contamination of food products. Therefore, it is instrumental in ensuring food safety at the facility level. It also identifies potential risks in open product areas that can lead to the production of non-conforming products, customer or consumer complaints, or even an incident.

GFSI Benchmarking Requirements v2020.1 (June 2020) requires Environmental monitoring to be included within the content of standards that are benchmarked by the GFSI.

The GFSI requirement is as follows:

A risk-based approach shall be in place to define the microbiological environmental monitoring program, which shall be established, implemented, and maintained to reduce the risk of food contamination.

After a site has conducted validation of its cleaning and sanitation programs, it is crucial to implement effective environmental monitoring to assist with verifying the effectiveness of the cleaning and sanitation program with the removal of microbiological hazards. Additional benefits of having a successfully implemented environmental monitoring program, in addition to verification, include but are not limited to the following:

- Provision of data on the overall effectiveness of the sanitary program, personnel practices, and operational procedures
- Provision of data about indicator organisms, spoilage organisms, and pathogens, thus supporting the prevention of outbreaks
- Identify potential routes of contamination
- Prevention of possible microbial contamination by identifying and responding to adverse trends
- Understanding the microbiological ecology of the organization's processing environment

3. Guidance Document: Environmental Monitoring

The FSSC 22000 Guidance document is meant as a guideline for the food industry to provide practical information and guidance on implementing FSSC Additional Requirement 2.5.7

Environmental Monitoring for Food Chain Categories C, I, and K, in line with the GFSI requirements.

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3.1 REFERENCE

- FSSC 22000 V5.1 Board of Stakeholders decision list [September 2022]
- FSSC 22000 v5.1 Guidance document: Environmental monitoring, October 2022
- JOINT FAO/WHO FOOD STANDARDS PROGRAMME. CX/FH 08/40/5 of October 2008.
- World Health Organization Factsheets (Microorganisms).
URL: <https://www.who.int/news-room/fact-sheets>
- Ellin Doyle M. "Microbial Food Spoilage — Losses and Control Strategies." July 2007. Food Research Institute, University of Wisconsin–Madison.
- Research Gate Article: Microbiological environmental monitoring in food processing.
URL: https://www.researchgate.net/publication/352378688_Microbiological_environmental_monitoring_in_food_processing

4. FSSC 22000 SCHEME REQUIREMENTS (revised according to BoS Decision List, september 2022)

Part 2 – requirements for certification V5.1: FSSC Additional Requirements

2.5.7 ENVIRONMENTAL MONITORING (FOOD CHAIN CATEGORIES C, I & K)

The organization shall have in place:

- a) Risk-based environmental monitoring program.
- b) Documented procedure for the evaluation of the effectiveness of all controls on preventing contamination from the manufacturing environment, and this shall include, at a minimum, the evaluation of microbiological controls present.
- c) Data of the monitoring activities, including regular trend analysis.

5. GUIDANCE FOR IMPLEMENTATION

5.1 ENVIRONMENTAL MONITORING PROGRAM

To assist with the implementation of the FSSC 22000 Environmental monitoring requirements, the following guideline steps are recommended for the evaluation of microorganisms:

1) Create a team (made up of multidisciplinary members with a background in microbiology, food safety, specific production processes of the organization, maintenance/equipment design, etc.).

2) Conduct the risk assessment to build an environmental monitoring program that meets the specific needs of your organization:

a. Define relevant microbiological hazards

- More details on potential microorganisms of concern are detailed in Table 1. The nature of the microorganism should be considered, including the ability to survive/ grow in certain conditions. These can include pathogens, spoilage organisms, and indicator organisms.
- As an organization, the specific hazards that may be relevant to your production environment, including specific hazards of concern linked to the type of product produced, should be considered. As an example, a facility producing ready-to-eat (RTE) chilled products likely needs to consider including sampling for *Listeria monocytogenes* and *Listeria* spp. within

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its cooling units and drains. The hazard analysis, as required by clause 8.5 of ISO 22000:2018, is a useful source of information as to your microorganisms of concern.

Table 1: Potential microorganisms of concern (non- exhaustive list)

Pathogens
<i>Salmonella</i> spp
<i>Listeria monocytogenes</i> (Commonly found in wet or cool/chilled environments and in drains)
<i>Staphylococcus aureus</i> (Commonly linked to food handlers, e.g., personnel hands)
<i>Bacillus cereus</i> (Dried food production environments)
<i>Campylobacter jejuni</i> (Found in meat and poultry processing environments)
Spoilage organisms
Yeast and molds (Air and surface testing are important in identifying their presence)
Indicator organisms
Coliforms
<i>Escherichia coli</i> (Associated with contaminated water and areas where fecal contamination may occur, such as personnel hands)
Enterobacteriaceae
Aerobic Plate Count
Lactic Acid Bacteria (LAB)
<i>Listeria</i> spp.
<i>Pseudomonas</i> spp.

The introduction of hazards to the production environment can occur via the following routes, examples: Raw materials, pests, water, air supply, and cross-contamination from external sources, as well as via employees.

b. Define areas or zones of risk related to the different hazards

b. Definiți zonele de risc legate de diferitele pericole

ZONE 1

ZONE 2

ZONE 3

ZONE 4

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ZONE 1: Food contact surfaces such as

- Table surfaces
- Slicers
- Pipe interiors
- Tank interiors
- Conveyor belts
- Storage bins
- Utensils
- Water filters

ZONE 2: Non-food contact surfaces near food and food contact surfaces such as

- Equipment housing and framework
- Maintenance tools
- Compressor air used on machinery which is in contact with foodstuffs
- Ceilings, walls, floors, or drains in the immediate area of food contact surfaces. In relation to drains, they should be included in the map with an indication of the flow direction of the wastewater, as well as indicating the equipment in place preventing backflow of the wastewater, if present.
- Cooling units in chillers/freezers
- Personnel, including employee hands and their PPE, including coats, aprons, and gloves.

ZONE 3: Remote non-food contact surfaces that are in or near the processing areas and could lead to potential contamination of zones 1 and 2, such as

- Handling equipment, forklifts, hand trucks, and carts that move within the plant
- Ceilings, walls, floors, or drains not in the immediate vicinity of food contact surfaces
- Sinks, hoses, boot wash facilities
- Areas with positive air pressure
- Air filters (including air compressors)

ZONE 4: Remote non-food contact surfaces in areas outside of the processing range

- Washrooms/hand wash areas
- Locker rooms, cafeterias, and break rooms outside the production or storage areas
- Offices
- Warehouse

NOTE: An organization can also consider the concept of site hygienic zoning.

c. Define suitable monitoring techniques

- i. Sample types: such as swabs, water samples, and air plates. Protein swabs and ATP swabs may also be used for the verification of cleaning.
- ii. Sampling tools: such as dry or wet cotton swabs, sponge swabs, RODAC

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plates, and air samplers.

iii. Sampling techniques (including which surface size to consider)

iv. Sample location/sites: based on the zones listed on the previous page

v. Test methods: could be rapid or laboratory-based; requirements of FSSC Additional Requirement 2.5.1(a) apply.

d. Define appropriate monitoring frequencies for routine sampling.

As an example, facilities that typically produce food products supporting pathogens' growth would require higher frequencies.

e. Define appropriate methods for sample collection, storage, and transport, to ensure the integrity of the sample is maintained prior to analysis.

f. Define action limits, (proposed) corrective actions and responsibilities should any out-of-specification results be detected.

This should link to the organization's corrective action/nonconformity management system. Investigative sampling may also be used as part of root cause analysis.

g. Conduct trending of the results obtained from the environmental monitoring program and implement necessary action to address the results of the trends identified.

3) Once the environmental monitoring program is established, it is important that it is subjected to constant verification and monitoring. The following are some of the items that would trigger the review of the environmental monitoring program:

- a. Changes related to products, processes, or legislation, where relevant
- b. When no positive testing results are obtained over a long period of time
- c. Any testing failures related to both intermediate and finished products within the scope of the environmental monitoring program
- d. Any pathogen detection during routine environmental monitoring
- e. When there are alerts, recalls, or withdrawals relating to products produced by the organization

4) Document required procedures and training programs to ensure the principles and role of environmental monitoring are understood across the workforce, and any relevant rules are adhered to.

NOTE: *Legal requirements shall always be adhered to within the environmental monitoring program.*

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6. GUIDANCE FOR AUDITORS

The following is a non-exhaustive list of questions that an auditor can use to assess the FSSC Additional Requirement 2.5.7:

- Is there a team with the correct competencies/knowledge?
- Has an environmental monitoring program been developed based on a risk assessment, and is it documented? Does the risk assessment consider relevant microorganisms?
- Are sampling points determined and documented (e.g., on a site map)?
- Is the sampling frequency determined based on risk and inclusive of trends from the previous period?
- Is there a verification system present in line with ISO 22000 paragraph 8.8?
- Is the program regularly reviewed, and is the frequency adequate?
- Are all the above effectively included and implemented through the organization's FSMS (e.g., records, awareness of people, internal audits, management reviews)?