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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 (**reference FSSC22000 GUIDANCE DOCUMENT: ENVIRONMENTAL MONITORING, Version 2 | July 2023**).

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:

- a. Provision of data on the overall effectiveness of the sanitary program, personnel practices, and operational procedures
- b. Provision of data about indicator organisms, spoilage organisms, and pathogens, thus supporting the prevention of outbreaks
- c. Identify potential routes of contamination
- d. Prevention of possible microbial contamination by identifying and responding to adverse trends
- e. 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 BIII, C, I, and K, in line with the GFSI

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requirements.

4. FSSC 22000 SCHEME REQUIREMENTS

Part 2 – requirements for organizations to be audited V6.

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

- a) A risk-based environmental monitoring program for the relevant pathogens, spoilage, and indicator organisms;
- b) A 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; and shall comply with legal and customer requirements.
- c) Data on the environmental monitoring activities, including regular trend analysis; and
- d) The environmental monitoring program shall be reviewed for continued effectiveness and suitability, at least annually and more often if required, including when the following triggers occur:
 - i. Significant changes related to products, processes, or legislation;
 - ii. When no positive testing results have been obtained over an extended period of time;
 - iii. Trend in out-of-specification microbiological results, related to both intermediate and finished products, linked to environmental monitoring;
 - iv. A repeat detection of pathogens during routine environmental monitoring; and
 - v. When there are alerts, recalls, or withdrawals relating to product/s produced by the organization.

5. GUIDANCE FOR IMPLEMENTATION

5.1 ENVIRONMENTAL MONITORING PROGRAM

Organizations should consider the following when implementing their environmental monitoring program:

- 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

a. Define relevant microbiological hazards, including relevant pathogen, spoilage, and/or indicator organisms.

- 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 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 spp</i>
<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)
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 spp.</i>
<i>Pseudomonas spp.</i>

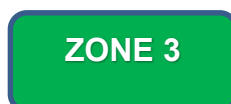
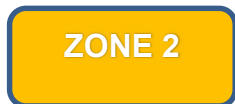
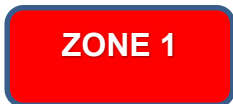
The introduction of hazards to the production environment can occur via the following routes, examples: Raw materials, pests, water, air supply, and cross-contamination from external sources, as well as via employees.

b. Define environmental monitoring sampling zones of risk related to the different hazards

Note: The environmental monitoring sampling zones are different from hygienic zoning. Hygienic zoning should be considered a prerequisite to the environmental monitoring program. Hygienic zoning is the division of a food manufacturing facility into different areas to avoid food contamination

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risks. Areas are designated based on risk and can include non-production areas (e.g., offices), basic GMP areas (e.g., raw material storage), and the primary pathogen control area (PPCA) where processed RTE product is exposed to the environment prior to packaging. Hygienic zones should not be confused with environmental monitoring sampling zones, which are used to designate target areas for environmental sampling (i.e., Zones 1-4).¹



ZONE 1: Product contact surfaces (Direct contact) (e.g., slicers, peelers, fillers, hoppers, screens, conveyor belts, air blowers, employee hands, knives, racks, worktables)

ZONE 2: Non-food contact surfaces in close proximity to food and food contact surfaces (Indirect contact) (e.g., processing equipment exterior and framework, refrigeration/cooling units, equipment control panels, switches)

ZONE 3: More remote non-food contact surfaces located in or near the processing areas (Close proximity) (e.g., forklifts, hand trucks, carts, wheels, air return covers, hoses, walls, floors, drains)

ZONE 4: Non-food contact surfaces outside of the processing areas (General areas) (E.g., locker rooms, cafeterias, entry/access ways, loading bays, finished product storage areas, maintenance areas)

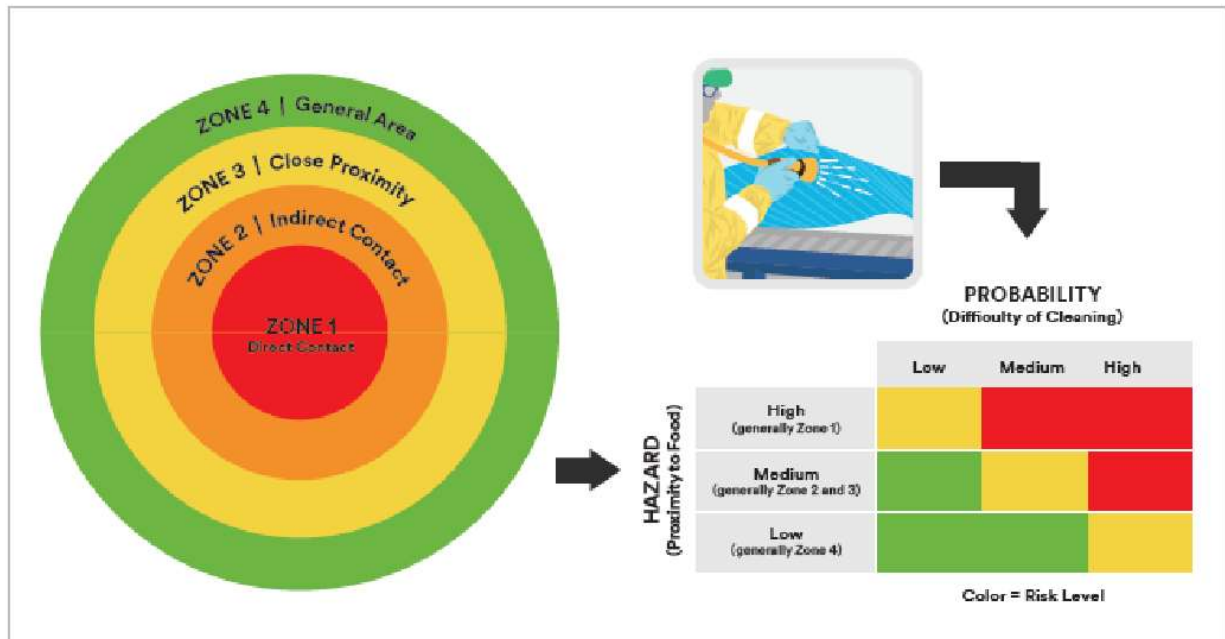


Figure 1. Zone concept in relation to risk¹

c. Define suitable monitoring protocols:

- 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 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 when sampling is conducted:

- Before cleaning (post-production after disassembly and initial rinse, but before application of cleaning chemicals)
- After cleaning and sanitation
- Pre-production
- During production

When sampling is taken, it is dependent on the intent of the sampling and needs to be determined by the organization.

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

g. 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.

h. The environmental monitoring program should also consider additional sampling, over and above routine sampling, in the case of extraordinary circumstances, such as during construction and as a follow-up due to a positive test result.

i. 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 regular review, at least annually, as well as when triggers occur as per the FSSC 22000 additional requirement 2.5.7.

In relation to 2.5.7 (d)(ii), consistent negative results may be due to false negatives being obtained. False negatives can be due to, for example, incorrect testing method(s) or sampling technique(s). It is, therefore, important to review your environmental monitoring program when consistent negative results are obtained over an extended period of time.

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.

Additional considerations when developing your environmental monitoring program:

- Legal requirements shall always be adhered to within the environmental monitoring program. When establishing the acceptable levels and action limits for their environmental monitoring program, an organization would need to consult the relevant countries' legislation; consider reviewing relevant standards, codes of practice, and guidelines, as well as industry best practices and customer requirements, whilst taking into consideration the type of product produced by the site.

- The risk assessment undertaken by the organization shall be used to determine the extent of the environmental monitoring program required, and therefore one organization's environmental monitoring program may be more extensive than that of another, based on the outcome of the risk assessment.

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- As an example, the outcome of a risk assessment for a cannery may require substantially less environmental monitoring than that of a facility that manufactures ready-to-eat salads. This is due to canned products undergoing commercial sterilization and due to the enclosed nature of the manufacturing process. Therefore, microbial contamination from the environment is less likely than in an open production environment.

- However, even though less environmental monitoring may be required in certain cases based on risk, the basic hygiene requirements as per the relevant sector- specific PRP standard still apply and needs to be verified in accordance with clause 8.8.1 of ISO 22000:2018.

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)?

7. REFERENCES

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3. World Health Organization Factsheets (Microorganisms).

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4. Ellin Doyle M. "Microbial Food Spoilage — Losses and Control Strategies." July 2007. Food Research Institute, University of Wisconsin–Madison.

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8. RELATED INDUSTRY INFORMATION

The below references 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.

- Codex Alimentarius Commission. CXC 1-1969 – General principles of food hygiene, 2022.
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- ICMSF. Microorganisms in Foods 7 Microbiological Testing in Food Safety Management, Chapter 12. URL: International Commission for the Microbiological Specifications of Foods (ICMSF).
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