FSSC 22000

FSSC 22000 FOOD SAFETY MANAGEMENT SYSTEM CERTIFICATION

SCHEME INTERPRETATION ARTICLE: QUALITY CONTROL

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CONTENTS

REVISION HISTORY

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1 INTRODUCTION

In accordance with the FSSC 22000 Scheme V6, Part 2, Section 2.2, the Foundation publishes interpretation articles related to Scheme requirements that include further clarification on requirements and the application and/or implementation thereof. Certification Bodies and Certified Organizations need to adhere to these interpretation articles, and it is the responsibility of the FSSC 22000 contact person to keep up to date with the interpretation articles and communicate it to the relevant parties within the CB or to Certified organizations, as applicable.

This Scheme Interpretation Article on Additional Requirement 2.5.9 is in place to provide further clarification on the quality control requirements and the implementation thereof.

The quality control requirement is applicable to all food chain categories and includes basic quality control requirements. It was added to the Scheme as a result of the output of the FSSC 22000 V6 development survey; and due to quality control being closely linked to food safety in a manufacturing environment.

Whilst the Foundation has included the requirement for a quality policy with objectives, it is not designed to replace a full ISO 9001 quality management system certification but rather to focus on the synergies and add value to the FSSC 22000 audit.

ISO 9000:2015 includes the following as the fundamental concept of quality:

"An organization focused on quality promotes a culture that results in the behavior, attitudes, activities, and processes that deliver value through fulfilling the needs and expectations of customers and other interested parties. The quality of an organization's products and services is determined by the ability to satisfy customers and the intended and unintended impact on relevant interested parties. The quality of products and services includes not only their intended function and performance but also their perceived value and benefit to the customer".

The following are relevant definitions as per ISO 9000:2015:

- Quality control is defined as being part of quality management focused on quality requirements.
- Quality is defined as the degree to which a set of inherent characteristics of an object (product, service, process) fulfills requirements.
- Characteristic is defined as a distinguishing feature. A characteristic can be inherent or assigned and can be qualitative or quantitative. There are various classes of characteristics.

In the context of the Scheme, quality characteristics may include, however, is not limited to:

- Physical
- Chemical (e.g., pH, acidity, Brix)
- Microbiological
- Functional
- Composition (e.g., proportion of ingredients)
- Sensory/organoleptic, e.g., related to texture, mouthfeel, flavor (taste and aroma), appearance (color), etc.

2 FSSC 22000 SCHEME REQUIREMENTS

Part 2 – Requirements for organizations to be audited - Version 6.

2.5.9 QUALITY CONTROL (ALL FOOD CHAIN CATEGORIES)

a. The organization shall:

   i. In addition to, and aligned with, clauses 5.2 and 6.2 of ISO 22000:2018, establish, implement, and maintain a quality policy and quality objectives.
   ii. Establish, implement, and maintain quality parameters in line with finished product specifications for all products and/or product groups within the scope of certification, including product release that addresses quality control and testing.
   iii. In addition to, and aligned with, clauses 9.1 and 9.3 of ISO 22000:2018, undertake analysis and evaluation of the results of the quality control parameters, as defined under 2.5.9 (a)(ii) above, and include it as an input for the management review; and
   iv. In addition to, and aligned with, clause 9.2 of ISO 22000:2018, include quality elements as defined in this clause within the scope of the internal audit.

b. Quantity control procedures, including for unit, weight, and volume, shall be established, and implemented to ensure products meet the applicable customer and legal requirements. This shall include a program for calibration and verification of equipment used for quality and quantity control.

c. Line start-up and change-over procedures shall be established and implemented to ensure products, including packaging and labeling, meet applicable customer and legal requirements. This shall include having controls in place to ensure labeling and packaging from the previous run have been removed from the line.

3 INTERPRETATION OF ADDITIONAL REQUIREMENT 2.5.9

The information included under Chapter 3 of this article is considered to be Scheme Interpretation and, therefore, in accordance with Scheme V6, Part 2, Section 2.2, shall be adhered to and implemented by (certified) organizations and audited against by CB auditors.

In accordance with **2.5.9 (a)(i)**, the organization shall establish, implement, and maintain a **quality policy**. The quality policy shall be consistent with the overall policy of the organization, be aligned with the organization's vision and mission, and provide a framework for the setting of quality objectives[3].

The quality policy must:

- Be appropriate to the purpose and the context of the organization and support its strategic direction,
- Provide a framework for setting quality objectives,
- Be communicated, understood, and applied within the organization,
- Be available to relevant interested parties, as appropriate[2].

It is not required for an organization to have a separate quality policy; it is possible to integrate it into the food safety policy, for example, as long as it is clearly defined and distinguishable.

In accordance with **2.5.9 (a)(i)**, the organization shall establish, implement, and maintain **quality objectives**. Objectives are the results the organization wants to achieve. Quality objectives are (specific) objectives related to quality; they are generally based on the organization's quality policy. Quality objectives are also generally specified for relevant functions, levels, and processes in the organization[3].

The organization shall set quality objectives that are SMART:

- Specific
- Measurable
- Attainable
- Realistic, and
- Time-bound

These quality objectives shall be reviewed for suitability at regular intervals, such as during the food safety team meetings, etc., and shall be included in the management review.

In accordance with **2.5.9 (a)(ii)**, the organization shall establish, implement, and maintain **quality parameters** in line with finished product specifications for all products and/or product groups within the scope of certification, including product release that addresses quality control and testing.

Quality parameters in the context of the Scheme are the related quality characteristics of the product. In order to implement this requirement, the organization shall:

- Identify and list all final products manufactured by the site.
- Ensure each product specification is established and up to date and includes quality parameters as applicable to each product or product group. An organization may decide to detail the quality parameters in a separate document, which is acceptable as long as the quality parameters have been identified and established for all products and/or product groups.
- An example of quality parameters to be included within a specification for a jam or sauce product may include:
    - Sensory (e.g., flavor, aroma, color, etc.)
    - Brix
    - pH
    - Viscosity/consistency
    - Weight

The quality parameters for all products are to be monitored by the organization, and the organization shall establish monitoring procedures, including method, frequency of monitoring, responsible person, documented evidence to be maintained, action to be taken in the case of out-of-specification results, etc.

In relation to product release, in addition to organizations needing to have relevant food safety parameters in place, they also need to have relevant quality parameters in place that are used to establish that a product can be released. This does not require an organization to have a separate product release document; however, the organization does need to have parameters in place that they check during the production process OR at the end of the product's production before the product is released.

Note: This may be of a sampling nature; it does not require that all individual products are checked prior to release. This requirement also does not require that all products be put on hold or blocked prior to release.

Although requirement 2.5.9 specifically relates to quality parameters relating to finished products, if a raw material has an impact on the quality of the finished product, then the organization would still be required to manage this as well; the organization still needs to manage their raw materials in accordance with their raw material specifications as defined under FSSC 22000 Additional Requirement 2.5.1 (d) including compliance to quality specifications for raw materials.

The organization also needs to ensure that the control of monitoring and measuring devices that are used to check the above quality parameters are included in the calibration and maintenance schedules as applicable; refer to 2.5.9 (b) below for further details.

Specific requirements for Category F (Trading, Retail, Wholesale, and E-Commerce), and Category G organizations (Transport and Storage), include ensuring temperature and humidity control specifications are adhered to, where relevant. This also applies to retailers and wholesalers who store and transport products requiring temperature control and for traders and brokers in relation to the management of third-party logistic service providers' service level agreements. In addition, effective stock rotation shall be implemented to ensure FIFO (First-In-First-Out) and FEFO (First-Expired-First-Out) principles are adhered to. CoAs (Certificates of Acceptability) and CoCs (Certificates of Conformity), including quality parameters, shall also be available for batches/lots of products that are traded and brokered (category FII organizations only).

In accordance with **2.5.9 (a)(iii)**, the organization shall **undertake analysis and evaluation of the results of quality control parameters**, as defined under 2.5.9 (a)(ii), and include it as an input for management review.

The organization's process for analysis and evaluation of results from monitoring and measuring activities includes the results of the performance of quality parameters. The organization determines the frequency of analysis, i.e., weekly or monthly, depending on the product, related processes, and customer requirements as applicable.

The recorded results of the analysis and evaluation shall be included as input to the management review process. Therefore, the requirements of ISO 22000:2018 clause 9.3 shall also apply, and the outputs managed as per ISO 22000:2018 clause 9.3.3.

In accordance with **2.5.9 (a)(iv)**, the organization shall include quality elements as defined in clause 2.5.9 within the scope of the **internal audit**. The requirements of ISO 22000:2018 clause 9.2 shall therefore apply to this requirement. Including that the internal audit program must include the quality control elements as per 2.5.9 and shall be undertaken at a frequency based on the importance of the processes concerned, changes in the FSMS (related to quality), and the results of monitoring, measurement, 2.5.9 (a)(iii), and previous audits.

In accordance with **2.5.9 (b)**, **quantity control procedures**, including for unit, weight, and volume, shall be established, and implemented to ensure products meet the applicable customer and legal requirements. This shall include a **program for calibration and verification of equipment used for quality and quantity control**.

Organizations need to:

- Identify the method to be used for checking the quantity (unit, weight, and volume) and determine the frequency of these quantity control checks.
- Establish if there are applicable customer and legal requirements relating to product quantity applicable to products produced. Documented evidence needs to be maintained when the organization undertakes the quantity control checks.
- The quantity control procedures shall detail the legal requirements (if applicable), frequency of testing, responsible person, method used, and action to be taken in the case of out-of-specification results, etc.
- Establish a program for calibration and verification of equipment and devices used for **quantity** control and **quality** control. Equipment for quality control and quantity control may include measuring scales or devices, pH meters, refractometers, consistometers, viscosity meters, vernier calipers, online level inspectors, graduated cylinders, etc. The program needs to meet the requirements of clause 8.7 of ISO 22000:2018.

In accordance with **2.5.9 (c)**, **line start-up and change-over procedures** shall be established and implemented to ensure products, including packaging and labeling, meet applicable customer and legal requirements. This shall include having controls in place to ensure **labeling and packaging from the previous run have been removed from the line**.

To ensure that final products meet applicable customer and regulatory requirements, the organization shall create procedure(s) for verification of line clearance between change-over of products. Records of line clearance shall be maintained to ensure labeling and packaging from the previous run have been removed from the line, prior to commencing with the next run, and that the correct labeling and packaging are being allocated to the next run. These records shall be signed off to verify that the line is ready for the next product/batch to be packed and as confirmation that all previous product packaging and labeling have been removed before changing to the next run.

4 GUIDANCE ON ADDITIONAL REQUIREMENT 2.5.9

4.1 GUIDANCE FOR (CERTIFIED) ORGANIZATIONS

Unlike Chapter 3 of this Scheme Interpretation Article, the following is to be treated as guidance only. In accordance with 2.5.9 (c), the following may be considered as guidance for implementation:

- An organization should establish a process for issuing packaging and labeling to packing lines for current products being packed. This can be in the form of packaging material issuing, which is controlled and signed out by an authorized person from the packaging stores and accepted by the line leader/packing operator or quality controller for the packing line on which packaging will be used. The amount of packaging and labeling issued can be reconciled with the amount of packaging and labeling returned versus the number of products packed. Any deviations should be investigated, and necessary action taken.
- Where an organization produces products in specific batch sizes, the organization should establish a procedure to ensure that the number of labels or packaging material items issued is issued per batch size, i.e., the exact quantity required to pack the manufactured

product quantity or as close to this as possible. Example: issue 5000 x 200 g jars and 5000 metal caps to fill 1000 kg batch of powdered vanilla chai tea. This ensures that only the packaging for immediate use will be issued, and no, or minimal packaging returns should be expected.

- An organization can create packaging specifications for each product to be packed; this can include photographs of each component required for the final packaged product. In the example of the powdered chai tea above, this could include a photograph of the jar with dimensions, the lid clearly showing the color and size, which is to be confirmed during issuing, and the product label – a sample of which can be used in the specification, and the example of the date code method used. The organization can keep the packing specification at points of use for operators to reference prior to packing.
- Recommend that checks should be done at the beginning of packing, during packing, e.g., hourly, every 30 minutes, etc., and at the end of the run. A check should also be conducted when changing/adding different batches of packaging and labeling materials during packing.
- Where organizations produce similar products with different allergen profiles, extra attention needs to be paid to the correct packaging/labeling being issued to the line.
- The organization should also implement control procedures that only allow specific authorized individuals to make changes to variable data printed online, e.g., best before date and batch number; and provide for regular checking of information correctness and readability.

4.2 GUIDANCE FOR AUDITORS

The following is a non-exhaustive list of questions that an auditor can use to assess the FSSC Additional Requirement 2.5.9:

- Has a quality policy been established?
- Has the policy been communicated?
- Are quality objectives set by the certified organization?
- Have all quality objectives been met? If not, what actions has the organization implemented regarding unmet objectives?
- Have quality control parameters for product or product groups been established within finished product specifications as well as product release criteria?
- Are records of quality control check results maintained and available for review?
- Are results trended, analyzed, and evaluated? And have they been used as input into the management review?
- What are the outputs relating to the trends, including continuous improvements planned?
- Has the internal audit program been updated to include the quality control elements of this additional requirement?
- Has the quantity control procedures and calibration/verification program for equipment used for quality and quantity control been established?
- Have the line start-up and change-over procedures been established, and are records available for review?
- Are all the above effectively included and implemented through the organization's FSMS (e.g., records, awareness of people, internal audits, management reviews)?

5 REFERENCES

1. ISO 22000:2018 - Food safety management systems — Requirements for any organization in the food chain. URL: ISO 22000:2018
2. ISO 9001:2015 - Quality management systems – Requirements. URL: ISO 9001:2015
3. ISO 9000:2015 - Quality management systems – Fundamentals and vocabulary. URL: ISO 9000:2015