FSSC 22000

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SCHEME INTERPRETATION ARTICLE: LABORATORY ANALYSIS FOR CRITICAL FOOD SAFETY PARAMETERS

Version 1 | June 2024

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REVISION HISTORY

Date Published	Issue	Changes
June 2024	1	First publication

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 2.5.1 (a) is in place to provide further clarification on the laboratory analysis requirements and the implementation thereof.

FSSC 22000 additional requirement 2.5.1 (a) on laboratory analysis of parameters critical to food safety, is applicable to all food chain categories.

This additional requirement was updated as BoS decision #4 within the Version 6 Board of Stakeholders Decision List, published in March 2024. The update was made to align with GFSI benchmarking requirements and is applicable to all Version 6 audits as of 1 April 2024.

2. FSSC 22000 SCHEME REQUIREMENTS

Part 2 – Requirements for organizations to be audited - Version 6.
Amended by BoS Decision # 4 of the Version 6 BoS Decision List.

2.5.1 MANAGEMENT OF SERVICES AND PURCHASED MATERIALS (ALL FOOD CHAIN CATEGORIES)

a) In addition to clause 7.1.6 of ISO 22000:2018, the organization shall ensure that where laboratory analysis is used for the verification and/or validation of parameters critical to food safety, these shall be conducted by a competent laboratory (including both internal and external laboratories as applicable) that has the capability to produce precise and repeatable test results using validated test methods and best practices (e.g. successful participation in proficiency testing programs, regulatory approved programs or accreditation to international standards such as ISO/IEC 17025). The analyses shall be performed in accordance with the applicable requirements of ISO/IEC 17025.

3. INTERPRETATION

3.1 GENERAL INTERPRETATION

- This requirement is not requiring the laboratory to be accredited, however, that the laboratory used shall operate in accordance with the applicable requirements of ISO/IEC 17025 when performing analyses for parameters critical to food safety.
- Organizations that utilize unaccredited laboratories should have a copy of the latest version of ISO/IEC 17025 available.
- Where the laboratory holds accreditation to ISO/IEC 17025, and the organization has a valid copy of the accreditation certificate, covering the test methods for the specific scope, then this requirement is considered to be met. Where the laboratory holds accreditation to ISO/IEC 17025, however, not for the required test methods, then the requirements included within this Scheme Interpretation Article still apply.

3.2 APPLICABLE REQUIREMENTS OF ISO/IEC 17025:2017 RELEVANT TO LABORATORIES

3.2.1 IMPARTIALITY, CONFIDENTIALITY, RESPONSIBILITY, AND AUTHORITY

- The laboratory shall implement and maintain procedures to ensure that impartiality and confidentiality is met, for the analysis of parameters critical to food safety. The laboratory shall not allow commercial, financial or other pressures to compromise impartiality.
- The laboratory shall specify the responsibility, authority and interrelationship of all personnel who manage, perform or verify work affecting the results of laboratory analyses. Documentation includes job descriptions, organizational structure, etc.

3.2.2 RESOURCES

- The laboratory shall have available the personnel, facilities, equipment, systems and support services necessary to manage and perform its laboratory activities.
- The laboratory shall ensure that the personnel have the competence to perform laboratory activities for which they are responsible and to evaluate the significance of deviations/noncompliance's observed.
- The facilities and environmental conditions shall be suitable for the laboratory activities and not adversely affect the validity of testing results.
- The laboratory shall have access to equipment (including, but not limited to, measuring instruments, software, measurement standards, reference materials, reference data, reagents, consumables or auxiliary apparatus) that is required for the correct performance of laboratory activities and that can influence the results. The equipment used for measurement shall be capable of achieving the measurement accuracy and/or measurement uncertainty required to provide a valid result. The requirements of ISO 22000:2018 clause 8.7 apply.

3.2.3 SELECTION AND VERIFICATION OF TEST METHODS

- The laboratory shall use appropriate methods and procedures (recognized international or country specific methods) for all laboratory analyses.
- All methods, procedures and supporting documentation, such as instructions, standards, manuals and reference data relevant to the laboratory activities, shall be kept up to date and be readily available to relevant personnel.

- The laboratory shall ensure that it uses the latest valid version of a test method.
- International, regional or national standards or other recognized specifications that contain sufficient and concise information on how to perform laboratory activities do not need to be supplemented or rewritten as internal procedures if these standards are written in a way that they can be used by the operating personnel in a laboratory. Where necessary, the laboratory shall provide additional documentation for optional steps in the method or additional details.
- The laboratory shall verify that it can properly perform methods before introducing them by ensuring that it can achieve the required performance. Records of the verification shall be retained. If the method is revised, verification shall be repeated to the extent necessary.

3.2.4 VALIDATION OF TEST METHODS

- The laboratory shall validate non-standard methods, laboratory-developed methods and standard methods used outside their intended scope or otherwise modified. The validation shall be as extensive as is necessary to meet the needs of the given application or field of application. Validation should also consider procedures for sampling, handling and transportation of samples.
- The techniques used for method validation can be one of, or a combination of, the following:
    a. Calibration or evaluation of bias and precision using reference standards or reference materials.
    b. Systematic assessment of the factors influencing the result.
    c. Testing method robustness through variation of controlled parameters, such as incubator temperature, volume dispensed.
    d. Comparison of results achieved with other validated methods.
    e. Interlaboratory comparisons.
    f. Evaluation of measurement uncertainty of the results based on an understanding of the theoretical principles of the method and practical experience of the performance of the sampling or test method.
- When changes are made to a validated test method, the influence of such changes shall be determined and where they impact the initial validation, a new test method validation shall be performed.
- The performance characteristics of validated methods, as assessed for the intended use, shall be relevant to the organization's needs and consistent with specified requirements.
- Performance characteristics can include, but are not limited to, measurement range, accuracy, measurement uncertainty of the results, limit of detection, limit of quantification, selectivity of the method, linearity, repeatability or reproducibility, robustness against external influences or cross-sensitivity against interference from the matrix of the sample, and bias.
- The laboratory shall retain records of the validation.

3.2.5 SAMPLING INCL. HANDLING OF SAMPLES

- The laboratory shall have a sampling plan and method when it carries out sampling. The sampling method shall address the factors to be controlled to ensure the validity of testing results. The sampling plan and method shall be available at the site where sampling is undertaken. Sampling plans shall, whenever possible, be based on appropriate statistical methods.
- The sampling method shall describe the selection of samples or sites; the sampling plan; and the preparation and treatment of sample(s).

- The laboratory shall retain records of sampling data that forms part of the testing that is undertaken.
- The laboratory shall have a procedure for the transportation, receipt, handling, protection, storage, retention, and disposal of test samples. Precautions shall be taken to avoid deterioration, contamination, loss or damage to the sample during handling, transportation, storage/waiting, and preparation for testing.
- The laboratory shall have a system for the traceability of test samples. Traceability shall be retained while the sample is under the responsibility of the laboratory.
- Upon receipt of the test sample, deviations from specified conditions shall be recorded, and actions taken where deviations are noted.
- When items need to be stored or conditioned under specified environmental conditions, these conditions shall be maintained, monitored and recorded.

3.2.6 ENSURING THE VALIDITY OF THE RESULTS

The laboratory shall have a procedure for monitoring the validity of results, including undertaking trending. The resulting data shall be recorded in such a way that trends are detectable and, where practicable, statistical techniques shall be applied to review the results. This monitoring shall be planned and reviewed and shall include the following, where appropriate, but not limited to:

a) Use of reference materials or quality control materials. Use of alternative instrumentation that has been calibrated to provide traceable results.
b) Functional check(s) of measuring and testing equipment.
c) Use of check or working standards with control charts, where applicable.
d) Intermediate checks on measuring equipment.
e) Replicate tests using the same or different methods.
f) Retesting of retained samples.
g) Correlation of results for different characteristics of a sample.
h) Review of reported results.
i) Intralaboratory comparisons; and
j) Testing of blind sample(s).

The laboratory shall monitor its performance by comparison with results of other laboratories. This monitoring shall be planned and reviewed and shall include, but not limited to, the following:

a) Participation in proficiency testing; (Refer to ISO/IEC 17043 for additional information on proficiency tests and proficiency testing providers). Note: In relation to the frequency of the proficiency testing, it is recommended that the laboratory participates in proficiency testing annually, with all test methods covered over a four (4) year period.
b) Participation in interlaboratory comparisons other than proficiency testing, where proficiency testing is not available.

Data from monitoring activities shall be analysed, used to control and, if applicable, improve the laboratory's activities. If the results of the analysis of data from monitoring activities are found to be outside pre-defined criteria, appropriate action shall be taken to prevent incorrect results from being reported.

3.2.7 DOCUMENTED INFORMATION AND REPORTING OF RESULTS

The laboratory shall document its procedures to the extent necessary to ensure the consistent application of its laboratory activities and the validity of the results. The laboratory shall have processes in place to control data and information management.

Results shall be reviewed and authorized prior to release. The laboratory shall demonstrate that the records of the testing results for the parameters critical to food safety have been verified and maintained.

The results shall be provided accurately, clearly, unambiguously and objectively, usually in a report format, and shall include all the information agreed with the organization and necessary for the interpretation of the results and all information required by the method used. All issued reports shall be retained as documented information.

Each report shall include the following information, where applicable:

- The name and address of the laboratory.
- Confirmation of whether it was analyzed internally, or if outsourced, confirmation of who conducted the analysis. The report shall clearly identify when results are from outsourced providers.
- Traceability identification of the report (unless this is internal analysis), and the samples tested.
- The name and contact information of the organization requesting the testing (unless this is internal analysis).
- Identification of the method used.
- A clear and unambiguous description of the sample, and, when necessary, the condition of the sample, location of sampling, method of sampling, sampling plan, and the environmental conditions during sampling.
- The date of receipt of the product and the date sampling was undertaken.
- The date(s) the laboratory analysis(es) were performed.
- The date the report was issued.
- It may also include a statement to the effect that the results relate only to the samples tested.
- The results with, where appropriate, the units of measurement.
- Additions to, deviations, or exclusions from the method.
- For internal laboratories, the name(s) of the persons conducting the analysis(es) and of those authorizing/verifying the report.
- For external laboratories, the identification of the person(s) authorizing/verifying the report.
- Information on specific test conditions, such as environmental conditions.
- A statement of conformity with requirements or specifications may be included.
- The measurement uncertainty presented in the same unit as that of the measurand or in a term relative to the measurand (e.g. percent) when:
    - It is relevant to the validity or application of the test results.
    - The measurement uncertainty affects conformity to a specification limit.
- Information required to evaluate measurement uncertainty for testing.
- Any further comments, opinions and interpretations as deemed necessary by the laboratory and/or organization.

3.2.8 MANAGEMENT OF NONCONFORMITIES

The laboratory shall have a nonconformity management process in place when any aspect of its laboratory activities or results do not conform to procedures or the agreed requirements of the organization (e.g. equipment or environmental conditions are out of specified limits, results of monitoring fail to meet specified criteria). The requirements of ISO 22000:2018 clause 10.1 shall be met. In addition, the impact of nonconformities on previous results shall be considered.

3.3 APPLICABLE REQUIREMENTS OF ISO/IEC 17025:2017 RELEVANT TO ORGANIZATIONS

3.3.1 ONSITE/INTERNAL LABORATORIES

In addition to the requirements included within the relevant section of ISO 22000:2018, the applicable sector specific PRP standard, and the additional requirement 2.5.1 (a) of Part 2 of the FSSC 22000 Scheme, the organization shall adhere to Section 3.2 of this Scheme Interpretation Article. The laboratory shall be included in the FSMS of the organization and be included in the internal audit and management review.

3.3.2 EXTERNAL LABORATORY SERVICE PROVIDERS

In accordance with ISO 22000:2018 clause 7.1.6, the organization is required to implement suitable controls for external service providers, which includes laboratories undertaking analysis for parameters critical to food safety. The organization shall undertake the following in relation to external service providers:

- Establish and apply criteria for the evaluation, selection, monitoring of performance and re- evaluation of external service providers.
- Ensure adequate communication of requirements to the external provider(s).
- Ensure that externally provided services do not adversely affect the organization's ability to consistently meet the requirements of the FSMS.
- Retain documented information of these activities and any necessary actions as a result of the evaluations and re-evaluations.

This shall include, but is not limited to, the organization having to undertake the following:

- Develop and implement a procedure for laboratory analysis for parameters critical to food safety, addressing requirements of ISO 22000:2018 clause 7.1.6, and FSSC 22000 Additional Requirement 2.5.1(a); as well as a signed service level agreement with the laboratory.
- For external laboratories that have valid accreditation to ISO/IEC 17025, no additional evidence to meet the requirement of ISO/IEC 17025 is needed, other than confirmation that the test methods are accredited for the specific scope. The organization needs to retain the accreditation certificate and schedule as documented information.
- For external laboratories that do not have accreditation to ISO/IEC 17025, or the accreditation does not include the required test method(s), then the service level agreement shall at least define the following for the non-accredited test methods: the testing parameters, agreed test methods (incl. verification and validation thereof), sampling protocol, successful participation in proficiency testing programs, regulatory approved programs, etc.
- The organization shall also ensure that the following is implemented, in relation to the activities that are not covered by the laboratories ISO/IEC 17025 accreditation scope:
    - Have the laboratory complete a laboratory specific questionnaire/assessment every year, to confirm the applicable requirements of ISO/IEC 17025 are being met; or,
    - Undergoes a second- or third-party audit at least once every three years e.g., a laboratory audit undertaken by the organization itself, or by a third party. This audit shall cover the requirements of Section 3.2 of this Scheme Interpretation Article, to ensure it covers the applicable requirements of ISO/IEC 17025. The auditor shall have the relevant competency to undertake the audit.

4. DEFINITIONS

COMPETENT LABORATORY

A laboratory that has the capability to produce precise, repeatable accurate test results using validated test methods and best practices (e.g. successful participation in proficiency testing programs, regulatory approved programs or accreditation to international standards).

(GFSI Benchmarking Requirements, V2020.1)

IMPARTIALITY

Presence of objectivity.

Note 1 to entry: Objectivity means that conflicts of interest do not exist, or are resolved so as not to adversely influence subsequent activities of the laboratory.

Note 2 to entry: Other terms that are useful in conveying the element of impartiality include “freedom from conflict of interests”, “freedom from bias”, “lack of prejudice”, “neutrality”, “fairness”, “open-mindedness”, “even-handedness”, “detachment”, “balance”.

(ISO/IEC 17025:2017)

INTERLABORATORY COMPARISON

Organization, performance and evaluation of measurements or tests on the same or similar items by two or more laboratories in accordance with predetermined conditions.

(ISO/IEC 17025:2017)

INTRALABORATORY COMPARISON

Organization, performance and evaluation of measurements or tests on the same or similar items within the same laboratory in accordance with predetermined conditions.

(ISO/IEC 17025:2017)

LABORATORY

Body that performs one or more of the following activities:

- testing;
- calibration;
- sampling, associated with subsequent testing or calibration

Note 1 to entry: “laboratory activities” refer to the three above-mentioned activities.

(ISO/IEC 17025:2017)

PARAMETERS CRITICAL TO FOOD SAFETY

OPRPs, CCPs; as well as PRPs that can have a direct impact on food safety such as environmental monitoring, verification of allergens, the analysis of key ingredient(s)/raw material(s), and/or the analysis of finished product(s) related to significant hazards identified.

Note 1: Additional Requirement 2.5.1 (a) only applies to parameters critical to food safety; it does not apply to quality related parameters. However, the requirements of the Scheme, Part 2, 2.5.9 (b) apply to quality related parameters.

PROFICIENCY TESTING

Evaluation of participant performance against pre-established criteria by means of interlaboratory comparisons.

(ISO/IEC 17025:2017)

VALIDATION, AS REFERENCED IN 2.5.1 (A)

Obtaining evidence that a control measure (or combination of control measures) will be capable of effectively controlling the significant food safety hazard.

Note 1 to entry: Validation is performed at the time a control measure combination is designed, or whenever changes are made to the implemented control measures.

Note 2 to entry: Distinctions are made in this document between the terms validation, monitoring and verification:

- validation is applied prior to an activity and provides information about the capability to deliver intended results;
- monitoring is applied during an activity and provides information for action within a specified time frame;
- verification is applied after an activity and provides information for confirmation of conformity.

(ISO 22000:2018)

VERIFICATION, AS REFERENCED IN 2.5.1 (A)

Confirmation, through the provision of objective evidence, that specified requirements have been fulfilled (ISO 22000:2018).

Note 2 of the definition for validation also applies to the definition of verification.

For the definition of validation and verification in the context of the verification and validation of test methods, please refer to the definitions within ISO/IEC 17025.

5. REFERENCES

1. GFSI Benchmarking requirements, Version 2020.1
2. ISO 22000:2018
3. ISO/IEC 17025:2017