

Article

Study and Analysis of Requirements for Food Safety Management Systems in Manufacturing Enterprises

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Abstract: The article provides a systematic study and analysis of international and national requirements for food safety management systems at manufacturing enterprises. Based on ISO 22000:2018, the Codex Alimentarius General Principles of Food Hygiene, ISO/TS 22002-1, FSSC 22000 and ISO 22005, the architecture of an FSMS is examined together with the logical relationship between prerequisite programmes, operational PRPs and critical control points. Particular attention is paid to the metrological assurance of CCP monitoring: calibration of measuring instruments, metrological traceability of measurement results and evaluation of measurement uncertainty are substantiated as the decisive factors for the reliability of conformity decisions against critical limits. Based on the analysis, typical shortcomings in FSMS implementation at Uzbek enterprises are classified and seven practical recommendations are proposed.

Keywords: food safety, FSMS, ISO 22000:2018, HACCP, critical control point, prerequisite programmes, metrological assurance, measurement uncertainty, calibration, traceability.

1. Introduction

Food safety is one of the most responsible sectors of modern industrial production, directly linked to public health, demographic stability, and the nation's food sovereignty. According to estimates by the World Health Organization, a significant portion of the global population falls ill each year as a result of consuming contaminated food. The economic damage manifests not only in healthcare costs but also in product recalls, loss of brand reputation, and forfeited export opportunities. Traditional quality control—sampling and testing finished products—has already been proven insufficient in modern industrial conditions. From a statistical standpoint, a sample taken from a finished product cannot guarantee the safety of the entire batch: microbiological contamination is distributed unevenly throughout the batch, and increasing the sample size is economically impractical [1]. For this very reason, starting from the second half of the 20th century, global practice shifted the focus of control from the output to the process itself. This approach found expression in the HACCP (Hazard Analysis and Critical Control Points) concept and subsequently evolved into a comprehensive management system in the form

of the ISO 22000 international standard. In the Republic of Uzbekistan, the regulatory and legal framework in the food sector has been rapidly updating in recent years [2]. The Law "On Quality and Safety of Food Products," adopted in 1997, has undergone several revisions, and in 2025, the Law "On Food Safety" was enacted to regulate sectoral relations at a new level. Simultaneously, within the framework of the country's accession process to the World Trade Organization, the task has been set to harmonize national requirements with Codex Alimentarius and European Union hygiene legislation. This creates an imperative for manufacturing enterprises to implement FSMS (Food Safety Management Systems) not merely as a formal certificate, but as a genuinely functioning management mechanism [3]. The purpose of the study is to systematically study the international and national requirements for FSMS in manufacturing enterprises, reveal their internal logical structure, identify the weakest links in meeting these requirements related to metrological assurance, and develop grounded proposals for their elimination. The scientific novelty of the study lies in the fact that FSMS requirements are analyzed not as a simple exposition of standards, but from the perspective of measurement reliability: it is demonstrated that every decision regarding compliance with a critical limit is actually based on a decision rule that takes into account the measurement result and its uncertainty. This approach has practical significance, bridging the fields of the food industry and metrology [4].

The scientific foundation of the FSMS concept originated in the 1960s in the United States out of the necessity to prepare completely safe food for space programs. The approach, developed through the collaboration of the Pillsbury Company, NASA, and military laboratories, was later elevated to the level of an international regulatory document by the Codex Alimentarius Commission. Codex's "General Principles of Food Hygiene" (CXC 1-1969) established the seven principles of the HACCP system and the twelve steps for its implementation; the 2020 revision further clarified the link between hygiene practice and HACCP [5]. The International Organization for Standardization released the first edition of the ISO 22000 standard in 2005, combining HACCP principles with the general methodology of management systems. In the current 2018 revision, the standard was transitioned to ISO's High-Level Structure (HLS), enabling its integration with the ISO 9001:2015 quality management system. An important conceptual innovation is risk management at two levels: the organizational level (business risks and opportunities) and the operational level (food safety hazards). In Uzbekistan, this standard operates as a national standard under the designation O'z DSt ISO 22000:2019. ISO 22000 sets general requirements for prerequisite programs (PRPs) but does not define their specific content. This gap is filled by technical specifications in the ISO/TS 22002 series; for food manufacturing enterprises, the ISO/TS 22002-1:2009 document establishes specific requirements regarding facility location, layout of premises, utilities, waste management, equipment maintenance, pest control, personal hygiene, rework, product recall procedures, and food defense. In international trade practice, ISO 22000 alone is often considered insufficient [6]. Schemes recognized by the Global Food Safety Initiative (GFSI)—such as FSSC 22000, BRCGS, and IFS—incorporate additional requirements. Specifically, the FSSC 22000 scheme comprises a combination of ISO 22000, the relevant ISO/TS 22002 document, and the scheme's own additional requirements (product labeling accuracy, food fraud prevention, allergen management, environmental monitoring, and safety culture). It is precisely these schemes that have become a practical prerequisite for supplying major international retail chains. In national literature, FSMS issues have mostly been covered from the perspective of certification procedures and standard translation [7], [8]. At the same time, local research has virtually left unstudied the metrological reliability of measurements at critical control points, the justification of calibration intervals for measuring instruments, and the impact of measurement uncertainty on compliance decisions. This article is aimed at filling that gap.

3. Research Methodology

The research is based on a qualitative analysis methodology and utilizes the following set of methods:

- Comparative-legal analysis of normative-legal and standardization documents (across national legislation – Codex Alimentarius – ISO standards – GFSI schemes);
- Structural decomposition of requirements: categorizing standard clauses into organizational, process-related, and measurement-control groups;
- Process approach and application of the PDCA (Plan – Do – Check – Act) cycle to two levels of the FSMS;
- Metrological analysis: justifying accuracy requirements for measuring instruments regarding monitored parameters and formulating a decision rule that accounts for measurement uncertainty;
- Classification of typical non-conformities and development of corrective measures based on root-cause analysis.

The empirical basis of the study comprises ISO 22000:2018, ISO/TS 22002-1:2009, ISO 22005:2007, ISO/IEC 17025:2017, Codex CXC 1-1969, FSSC 22000 (v6) documents, as well as the legislation and technical regulations of the Republic of Uzbekistan in the field of food safety.

4. Analysis and Results

4.1. General Structure of FSMS Requirements.

It is advisable to categorize the requirements placed on a manufacturing enterprise into four layers based on their origin. The first layer consists of mandatory legal requirements (laws, technical regulations, and sanitary rules and norms). The second layer comprises voluntary—yet practically essential—international standards (ISO 22000, ISO/TS 22002-1). The third layer represents market requirements, namely the GFSI schemes required by customers and retail chains [9]. The fourth layer includes the enterprise's own internal norms, which should typically be stricter than external requirements, because if an internal norm equals an external one, even minor fluctuations can lead to a compliance breach.

Table 1. Main normative and standardization documents related to FSMS

Document	Name and Subject	Practical Significance for the Enterprise
ISO 22000:2018 (O'z DSt ISO 22000:2019)	FSMS requirements for any organization in the food chain	The main framework of the system: context, leadership, planning, PRP, hazard analysis, verification, improvement
Codex CXC 1-1969 (Rev. 2020)	General Principles of Food Hygiene and the HACCP system	The 7 principles and 12 steps of HACCP; methodological basis during audits
ISO/TS 22002-1:2009	Prerequisite programs on food safety — Part 1: Food manufacturing	Specific content of PRPs: premises, equipment, hygiene, pest control, product recall

ISO 22005:2007	Traceability in the feed and food chain	Batch identification, "one step back – one step forward" principle
FSSC 22000 (v6)	GFSI-recognized certification scheme	Condition for entering export markets; additional requirements (food fraud, food defense, allergens)
ISO/IEC 17025:2017	Competence of testing and calibration laboratories	Ensuring the reliability of internal and external laboratory results
ISO 9001:2015	Quality management system	Integration with FSMS; common documentation and audit mechanism

As can be seen from the table, the requirements do not duplicate each other; rather, they complement each other hierarchically. The most common error in practice is when an enterprise implements ISO 22000 while ignoring the requirements of ISO/TS 22002-1. In such a scenario, the system exists on paper, but because the sanitary and hygienic foundation is weak, all conclusions of the hazard analysis remain unjustified [10], [11].

4.2. Structural Analysis of ISO 22000:2018 Requirements.

The standard is built on a High-Level Structure, and its Clauses 4–10 logically correspond to the PDCA cycle. Determining the organization's context and the needs of interested parties (Clause 4) defines the boundaries of the system; leadership responsibility (Clause 5) requires a food safety policy and allocation of responsibilities; planning (Clause 6) involves addressing risks and opportunities as well as setting measurable objectives. The support section (Clause 7) covers resources, employee competence, awareness, communication, and documented information. It is precisely in this clause that a requirement of critical importance to the enterprise resides: monitoring and measuring resources must be suitable for demonstrating conformity, calibrated or verified, and identified [12]. In practice, the fulfillment of this clause determines the reliability of the entire HACCP plan, because a conclusion that "the critical limit was met" based on readings from an uncalibrated thermometer is metrologically unfounded. The operation section (Clause 8) forms the core of the system and can be conditionally divided into three sequential blocks: (a) establishing prerequisite programs; (b) preparing background information for hazard analysis—characteristics of raw materials and finished products, intended use of the product, flow diagrams, and their on-site confirmation; (c) identifying and assessing hazards, selecting control measures, and categorizing them into OPRPs and CCPs. Following this, the monitoring system, corrections and corrective actions, the verification plan, and procedures for managing non-conforming products are established. Performance evaluation (Clause 9) includes analyzing verification activity results, internal audits, and management review; improvement (Clause 10) requires updating and continually improving the system. An important aspect is that system updating is highlighted as a distinct requirement in ISO 22000: whenever the product, technology, equipment, or raw material suppliers change, the hazard analysis must be reviewed.

4.3. Prerequisite Programs, OPRPs, and CCPs: Differentiation Criteria

The issue that generates the most debate in practice is determining which category a control measure should belong to. Incorrect classification leads to two types of errors: downgrading a genuine CCP to the PRP level results in a loss of safety control, whereas declaring every process a CCP scatters monitoring resources and makes the system unmanageable.

Table 2. Differentiation criteria for PRPs, OPRPs, and CCPs

Criterion	PRP	OPRP	CCP
Purpose	To ensure a general hygienic environment and reduce the likelihood of contamination	To reduce an identified significant hazard to an acceptable level	To eliminate a significant hazard or reduce it to an acceptable level
Relation to hazard analysis	Established prior to hazard analysis	Selected as a result of hazard analysis	Selected as a result of hazard analysis
Control parameter	Usually not measured, observed	Measurable or observable action criterion	Measurable critical limit
Nature of monitoring	Periodic inspection, according to schedule	According to plan, at a frequency where deviations can be detected	Continuous or on every batch
Action upon deviation	Restore hygienic conditions	Correction + evaluation of affected product	Immediate product hold and evaluation; release for distribution prohibited until cleared
Example	Facility cleaning schedule, pest control	Metal detector, filtration, sanitation regime	Pasteurization temperature and time, sterilization regime, freezing temperature

Analysis shows that the objective criterion for identifying a CCP is that the control measure must have a measurable critical limit, and its breach renders the product unsafe for consumption. Therefore, most CCPs in the food industry are related to heat treatment, cooling, freezing, and storage, where the primary control parameters are temperature and time. This directly links FSMS with the metrology of temperature measurement.

4.4. Structure of the HACCP Plan and Documentation Requirements

The HACCP plan is structured around Codex's seven principles: conducting hazard analysis; determining critical control points; establishing critical limits for each CCP; implementing a monitoring system; establishing corrective actions when deviations occur; establishing verification procedures; and maintaining documentation and records. These principles are implemented through a twelve-step practical sequence, where the first five steps are preparatory in nature. Justifying critical limits is the weakest link in the plan. Limits must have a scientific basis: a regulatory document, scientific literature, validation test results, or expert consensus. For example, in milk pasteurization, the temperature-time combination is based on the thermal death curve (D- and z-values) of the target pathogen.

If a limit is established merely by referencing technical regulations without supporting evidence, it is considered unvalidated. Requirements for records are also frequently not taken seriously enough [13]. A monitoring record must include at least: date and exact time, batch identification, measured value, measuring instrument identification number, signature of the operator, and signature of the reviewer. A record without a measuring instrument identifier fails to ensure traceability—if a calibration shift is subsequently detected, identifying which batches have been compromised becomes impossible.

4.5. Metrological Assurance of Monitoring and Measurements

The reliability of an FSMS ultimately rests on the reliability of measurement results. Every decision regarding compliance with a critical limit is a decision made by comparing a measurement result with its associated uncertainty. According to the ISO/IEC 17025:2017 and JCGM 100:2008 (GUM) methodologies, a measurement result is incomplete without stating its measurement uncertainty [14]. The practical implication of this rule in food manufacturing is as follows. Suppose a critical limit is defined as "product core temperature must be no less than 72 °C, and the expanded uncertainty of the measuring instrument is $U = 0.8\text{ °C}$ ($k = 2$). If the measured value is 72.3 °C, the true value lies within the range of 71.5–73.1 °C, leaving a significant probability that the limit has been breached. Therefore, the enterprise must set an internal operating limit higher than the critical limit: operating limit = critical limit + U + process variation margin. This is a classic application of a decision rule, which is recommended to be documented for every CCP.

Table 3. Metrological requirements for measuring instruments used in typical CCPs

Control Object (CCP)	Measurable Quantity	Measuring Instrument	Recommended Permissible Error	Calibration Frequency
Pasteurization / Sterilization	Temperature, time	Resistance temperature detector (Pt100), thermocouple	Better than $\pm 0.3\text{ °C}$	12 months
Processing in thermostats and drying ovens	Temperature, temperature field uniformity	Multichannel temperature meter, calibrated temperature probes	$\pm 0.5\text{ °C}$; uniformity $\pm 1.0\text{ °C}$	12 months
Cooling and frozen storage	Temperature	Digital logger, automated recording system	$\pm 0.5\text{ °C}$	12 months
Acidity of finished/packaged product	pH	pH meter	$\pm 0.05\text{ pH}$	6 months (with daily buffer verification)

Control of metal impurities	Sensitivity (Fe, non-Fe, SS)	Metal detector, X-ray inspection system	Confirmed by test samples	Verification at the start and end of each shift
Packaging weight	Mass	Electronic scale	According to the relevant accuracy class	12 months
Water activity control	a _w	Water activity analyzer	±0.01 a _w	12 months

The intervals presented in the table should be taken as initial recommendations and must be justified by the enterprise [15]. Determining the calibration frequency is an engineering-metrological task, which is established based on the intensity of use of the measuring instrument, the severity of operating conditions (humidity, aggressive environments, vibration), the time-dependent trend of previous calibration results (drift), and the severity of the risk arising in the event of a deviation. For high-risk CCPs, it is advisable to shorten the interval or introduce intermediate control points. An issue requiring special attention is the metrological traceability of calibration results.

Conclusion

Calibration must be carried out only in accredited laboratories, connected through an unbroken chain of comparisons to national or international standards. If measurement uncertainty is not specified in the calibration certificate, such a document is considered invalid for FSMS (Food Safety Management System) purposes, as it cannot be used to establish a decision rule. For thermal processing equipment—such as thermostats, drying ovens, sterilizers, and climate chambers—calibrating only the indicating instrument is insufficient. It is necessary to qualify (validate) the uniformity and temporal stability of the temperature field throughout the working volume, as the product's "cold spot" is determined precisely by these characteristics. In practice, the temperature in the corners of the working chamber can differ by several degrees from the center; if the monitoring point is chosen incorrectly, part of the product may receive inadequate processing, even if the HACCP plan is formally satisfied.

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