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Criteria for Food Product Quality and Safety, Analysis of Factors Affecting the Effectiveness of a Food Safety Management System (FSMS)

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Abstract

ISO 22000:2018 specifies requirements for a Food Safety Management System (FSMS) for organizations in the food chain and integrates Codex and HACCP principles. This paper aims to systematize quality and safety criteria for food products using clear indicators and limit values, assess drivers that influence FSMS performance, and propose a composite FSMS Performance Index (FSMS-PI) based on key performance indicators (KPIs). The methodology was built on the Codex CXC 1-1969 (Rev. 2020) GHP/HACCP approach, ISO/TS 22002-1:2009 prerequisite programme (PRP) requirements, and limit values from relevant product standards. As illustrative objects, a criteria registry was developed for wheat flour and refined vegetable oil. For wheat flour, moisture content ≤15.5% (m/m) was selected as a core quality indicator. For refined vegetable oils, acid value ≤0.6 mg KOH/g, peroxide value (PV) ≤10 meq O_2/kg, and limits for Cu ≤0.1 mg/kg and Fe ≤1.5 mg/kg were set as baseline indicators.

Keywords: FSMS; ISO 22000; Codex; HACCP; PRP; GHP; quality criteria; safety criteria; KPI; FSMS-PI; risk analysis; peroxide value

1. Introduction

Despite the measures implemented by food safety authorities and specialists, food safety remains a pressing issue and continues to attract media attention due to outbreaks that may lead to significant adverse consequences. Food quality is a complex and broad concept that has evolved rapidly in recent years and is expected to continue changing because it is dynamic and influenced by both objective and subjective factors. Since ensuring food quality requires long-term, coordinated effort, it can be considered the cumulative outcome of all actors in the food chain working to prevent problems in production, storage, distribution, marketing, traceability and safety. [1]

Because multiple HACCP methodologies are used worldwide and mutual recognition among countries is not always consistent, and because HACCP alone may not provide a comprehensive administrative framework for managing potential risks, the International Organization for Standardization issued ISO 22000:2005 in September 2005. [2] The standard promotes coordinated efforts by all parties involved in the food chain to achieve food safety. This chain includes animal feed producers, raw-material suppliers, manufacturers, transporters, warehouses, retailers and food service outlets, as well as indirectly related organizations such as equipment manufacturers, packaging suppliers, sanitation-material providers, and food additive and ingredient producers. ISO 22000 integrates effective communication, system management, prerequisite programmes and the fundamentals of HACCP. [3]

A Food Safety Management System (FSMS) enables an organization to identify, assess and control food hazards; establish monitoring and verification; address nonconformities; and continually improve, thereby demonstrating its capability to produce safe food. [4]

Although quality and safety are interrelated, in many companies' quality indicators (e.g., moisture or oxidation indicators) are managed separately from FSMS audit results and nonconformities (NCs). This separation limits management decisions from being grounded in a single, systemic evidence base. FSMS performance is directly influenced by organizational context (e.g., raw-material risk, technological complexity, hygienic environment and supply-chain uncertainty). Therefore, assessing "context riskiness" helps select an appropriate level of control. [5]

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Leadership, resources, internal audits and documentation have also been identified as critical factors influencing performance when ISO 9001 and HACCP systems are implemented together. [6] For KPI-based evaluation of FSMS performance, it is practical to group indicators at the process, product and company levels. [7] When integrated with ISO 9001:2015 (quality management), process approach, risk-based thinking and documentation discipline are strengthened, which can positively influence the operational stability of an FSMS. [8]

The main objectives of this paper are to: (i) develop a criteria registry (indicator–limit–method–frequency); (ii) assess drivers affecting FSMS performance through audits/surveys; (iii) provide a KPI dashboard and a composite FSMS-PI index to quantify system status; and (iv) present risk matrices and HACCP schemes in a practical, ready-to-use form.

2. Materials and Methods

2.1. Study design and approach

The paper follows a methodological and analytical design: regulatory review → criteria registry → drivers' model → KPI dashboard/FSMS-PI → risk and HACCP tools. To demonstrate the methodology in the Results section, synthetic (simulated) data were used.

2.2. Criteria registry

Criteria were consolidated into four blocks: (A) Quality, (B) Safety, (C) Compliance, and (D) Sustainability. For each indicator, the following are defined: (i) limit or requirement, (ii) measurement method, (iii) frequency, (iv) responsible person, and (v) CAPA procedure in the event of deviation.

Table 1. Baseline criteria for wheat flour and refined vegetable oil (indicator–limit)

Product	Block	Indicator	Limit / requirement
Wheat flour	Quality	Moisture, % (m/m)	≤ 15.5
Wheat flour	Quality	Off-odour/off-taste	Absent
Wheat flour	Safety	Filth/contamination	Must not pose a health hazard
Wheat flour	Sustainability	Storage/transport conditions	Managed via SOPs and records
Oil (refined)	Quality	Acid value, mg KOH/g	≤ 0.6
Oil (refined)	Quality	Peroxide value (PV), meq O_2/kg	≤ 10
Oil (refined)	Safety	Cu, mg/kg	≤ 0.1
Oil (refined)	Safety	Fe, mg/kg	≤ 1.5
Oil (refined)	Sustainability	Light/oxygen/temperature	Minimized (SOPs + records)

2.3. Monitoring and sampling plan

Criteria are effective not only when a limit is specified, but also when measurement frequency, sample size and a rapid decision-making procedure for deviations are defined. [9]
Table 1a provides an example of how a monitoring plan can be documented for key indicators.

Table 1a. Example monitoring (sampling) plan

Indicator	Method/standard	Frequency	Sample	Action in case of deviation (CAPA)
Flour: moisture	Laboratory / NIR	Each batch	n = 1–3	Block the batch; check warehouse RH; re-test
Oil: PV	ISO 3960	Weekly / per batch	n = 1	Correct storage conditions; re-test; assess suitability

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Indicator	Method/standard	Frequency	Sample	Action in case of deviation (CAPA)
Oil: acid value	Titrimetric	Weekly / per batch	n = 1	Check process parameters; review raw-material COA
Traceability test	1-up/1-down	Monthly	Scenario	Root-cause analysis; improve digital records

2.4. Drivers affecting FSMS performance and scoring scale

The drivers model comprises six groups: (D1) supplier control, (D2) PRP/GHP, (D3) process control (OPRP/CCP), (D4) records and traceability, (D5) competence, and (D6) leadership and culture. Each group is scored from 0 to 100 based on an audit checklist and a questionnaire. [10]

The audit scoring scale and principles for managing the audit programme are designed in line with ISO 19011:2018 guidelines.

2.5. KPI dashboard and FSMS-PI index

KPIs are structured at three levels: process, product and company. A minimal “starter” dashboard includes audit results, laboratory compliance, nonconformity index, OPRP/CCP deviations, traceability test performance and complaint indicators. [7]

Table 2 lists a minimal set of KPIs that can be used to evaluate FSMS performance in a structured manner.

Table 2. Minimal KPI dashboard for FSMS performance evaluation

KPI	Level	Calculation	Frequency	Practical purpose
AuditScore, %	Company	Compliant clauses / total × 100	Quarterly / semi-annually	Demonstrate system conformity
LabPass, %	Product	Compliant tests / total × 100	Batch / week	Control compliance with limits
NCIndex, 0–100	Company	min (100, 5×Major + Minor)	After audit	Nonconformity burden
Deviations (OPRP/CCP)	Process	# deviations per month	Daily / monthly	Monitoring discipline
Traceability time	Process	Time to complete 1-up/1-down	Monthly test	Readiness for rapid block/recall
Complaint rate	Product	# per 1 million units	Monthly	Consumer signal

A sample composite index FSMS-PI (0–100) is proposed as follows:
FSMS-PI = 0.55 × AuditScore + 0.30 × LabPass + 0.15 × (100 − NCIndex)
ISO 22004:2014 provides practical guidance for the PDCA cycle (planning–implementation–verification–improvement) of FSMS; the KPI dashboard and FSMS-PI index are intended to be used within this PDCA cycle. [11]

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2.6. Synthetic data generation and analysis (illustrative case)

To demonstrate the methodology, a synthetic dataset was generated: (i) 60 batches of wheat flour for moisture; (ii) 50 batches of oil for PV and acid value; and (iii) KPI values for 24 hypothetical enterprises (audit, NC and lab compliance). The synthetic data were simulated based on typical ranges and limit values reported in standards and practice.

The analysis used descriptive statistics (median, percentiles), compliance share (LabPass), correlation (Pearson r) and multivariate regression (OLS) to illustrate relationships between drivers and outcomes.

3. Results

The following figures and tables present the practical form of the methodological package. Each diagram and tables are intended to make the FSMS “visible” by managing criteria, drivers and outcomes in an integrated way.

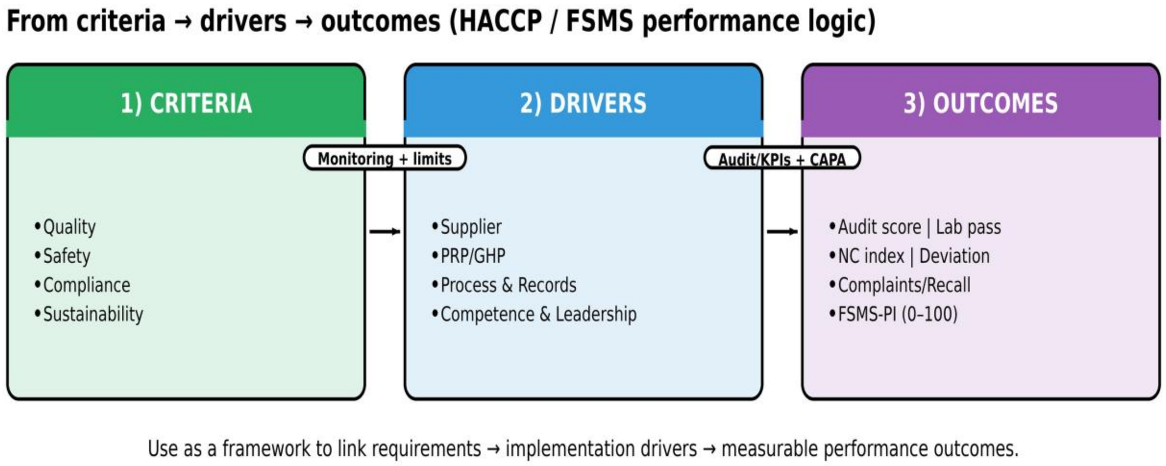

Figure 1. Criteria → Drivers → Outcomes: conceptual model for indicator-based FSMS management

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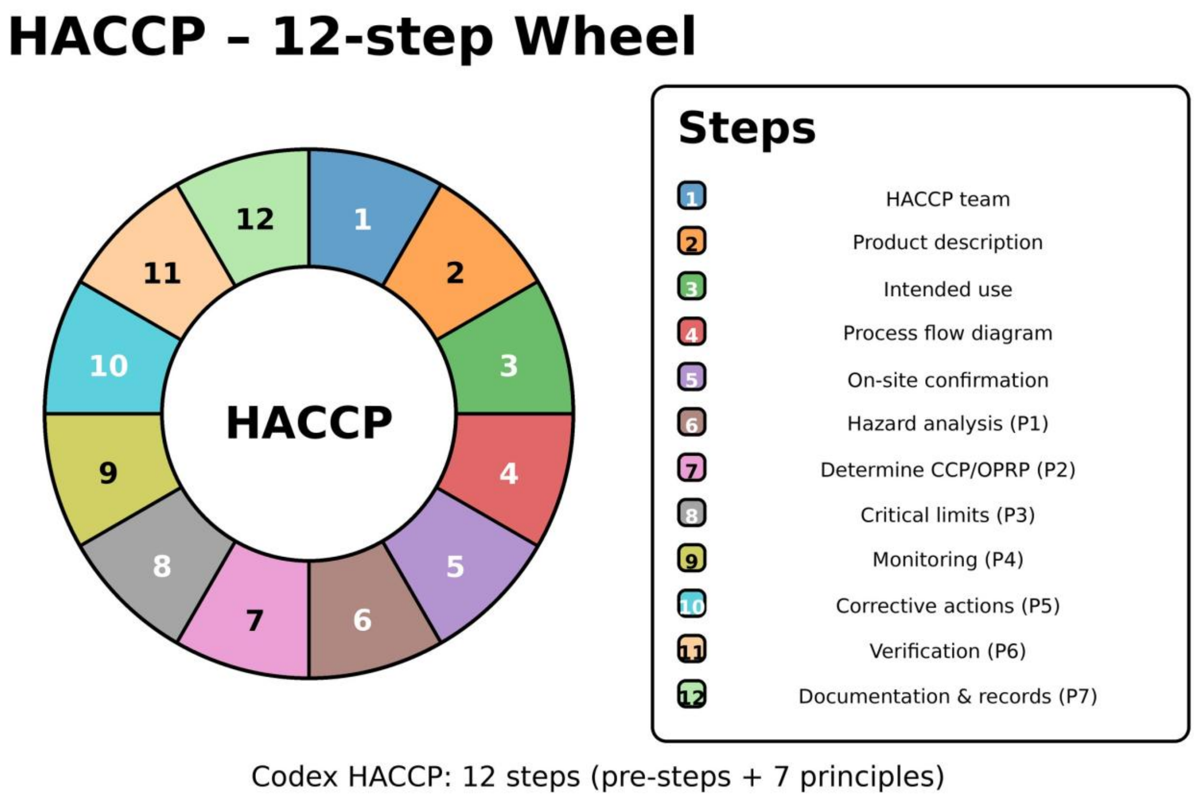

Figure 2. Codex HACCP: 12 steps (pre-steps + 7 principles)

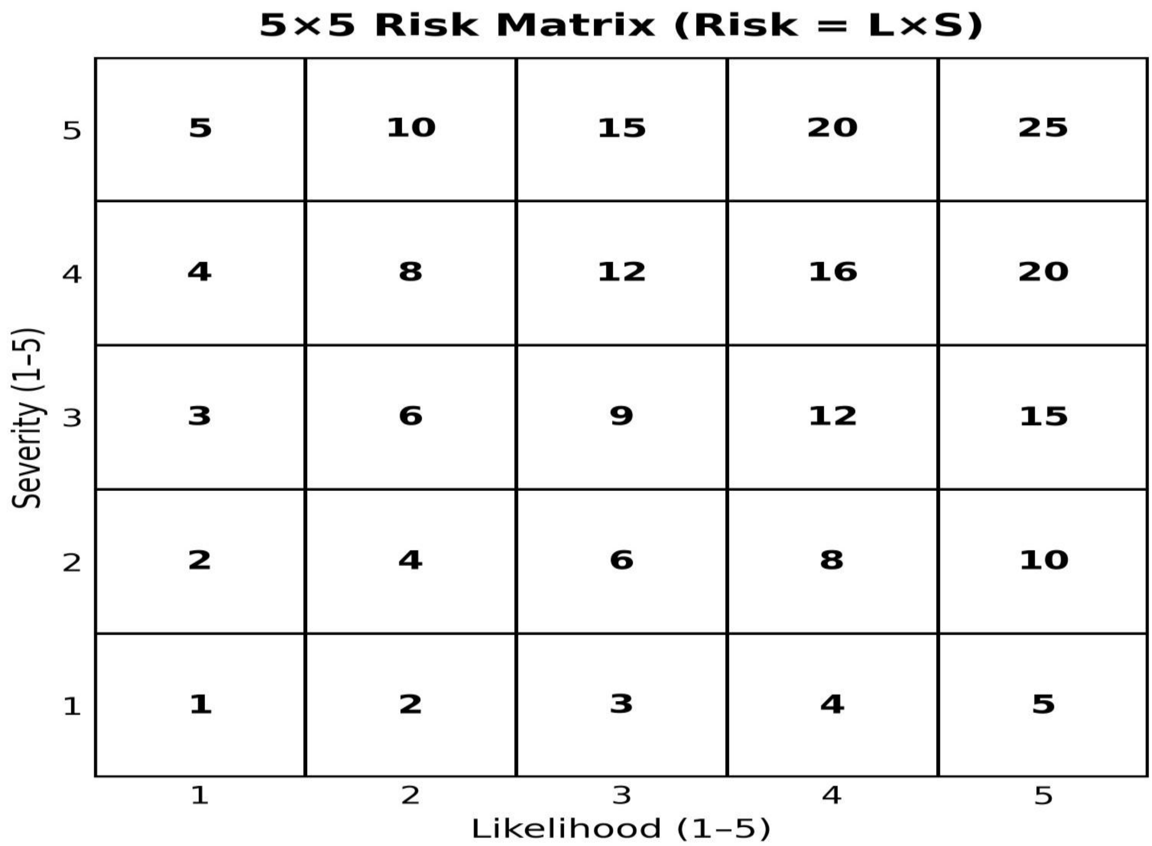

Figure 3. 5×5 risk matrix (Risk = L×S)

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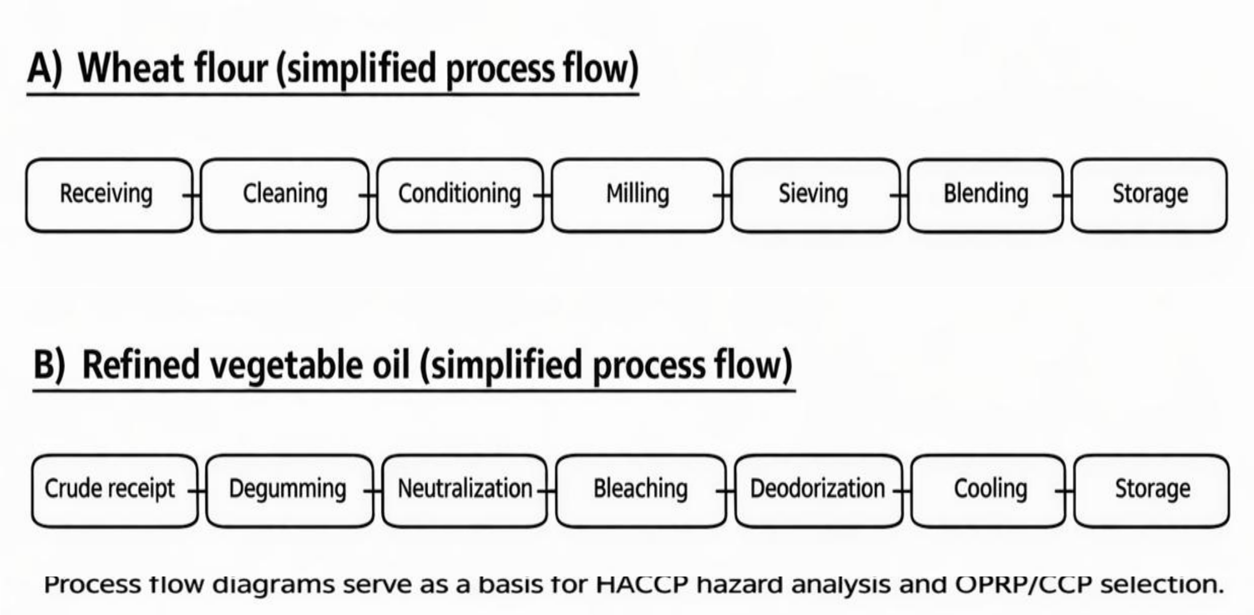

Figure 4. Process flow diagrams (wheat flour and refined oil) as a basis for HACCP hazard analysis

3.1. Risk register (hazard analysis) – illustrative result

In the Codex approach, hazard analysis considers product characteristics, process steps and control measures. In practice, risk is often simplified as the product of likelihood (L) and severity (S). [9]

Table 3. Priority hazards and control measures for wheat flour and oil (illustrative)

Product	Hazard type	Example hazard	L	S	Risk	Control measures (summary)
Flour	Chemical	Mycotoxin risk (grain raw material)	3	5	15	Supplier approval + incoming testing + batch blocking
Flour	Microbiological	Mould growth if warehouse RH is high	3	4	12	PRP (warehouse hygiene) + RH/temperature monitoring
Flour	Physical	Metal/foreign bodies	2	4	8	Sieving + magnets/metal control + equipment checks
Oil	Chemical	PV increase (oxidation)	3	4	12	Control storage + PV monitoring + CAPA
Oil	Chemical	Acid value increase (hydrolysis)	2	4	8	Raw-material control + process discipline + re-testing
Oil	Chemical	Cu/Fe traces (pro-oxidant metals)	2	4	8	Filtration/equipment control + lab testing + COA review

3.2. Compliance with laboratory criteria (LabPass) – synthetic monitoring

For wheat flour, the moisture criterion is ≤15.5%; an increase in moisture may also indicate deterioration of storage and logistics conditions. [12]

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Table 4. Wheat flour moisture in 60 batches: descriptive statistics and compliance

Indicator	Value (synthetic)
Number of batches	60
Compliance share (≤15.5%)	88.3%
Median	14.49%
95th percentile	16.07%

Note: an increasing share of nonconforming batches requires review of warehouse RH/ventilation, packaging quality and storage time.

For refined oils, PV and acid value are sensitive to oxidation and hydrolysis processes and may be associated with storage conditions (light/temperature/oxygen) and trace metals (Cu/Fe). [13]

Table 5. Oil PV and acid value: compliance share and percentiles (50 batches, synthetic)

Indicator	PV (≤10)	Acid value (≤0.6)	Both compliant
Number of batches	50	50	50
Compliance share	84.0%	92.0%	80.0%
Median	7.66	0.463	—
95th percentile	11.54	0.626	—

If PV is determined in a standardized manner according to ISO 3960:2017, comparability of results and reliability of verification improve. [14]

3.3. Enterprise KPIs and FSMS-PI index – synthetic results

Company-level audit/NC indicators combined with product-level LabPass provide a more comprehensive view of system performance. Table 6 summarizes results for 24 hypothetical enterprises.

Table 6. KPI results by group (12 flour and 12 oil enterprises; mean ± SD, synthetic)

Group	AuditScore (mean ± SD)	LabPass (mean ± SD)	NCIndex (mean ± SD)	FSMS-PI (mean ± SD)
Flour (n=12)	59.1 ± 6.0	63.4 ± 3.6	51.1 ± 6.1	58.8 ± 4.7
Oil (n=12)	58.7 ± 4.0	66.1 ± 7.3	50.0 ± 8.4	59.7 ± 4.2

3.4. Relationship between drivers and outcomes

In high-risk contexts, management factors such as PRP and leadership can be important for selecting an appropriate level of control. [5] Table 7 reports illustrative Pearson correlation coefficients based on synthetic data.

Table 7. Drivers and outcomes: Pearson r (synthetic, illustrative)

Outcome \ Driver	Supplier	PRP/GHP	Process	Records	Competence	Leadership
FSMS-PI	-0.06	0.51	0.43	0.31	-0.19	0.44
NCIndex	0.12	-0.49	-0.08	-0.37	0.20	-0.49
LabPass	0.22	0.35	0.56	0.01	0.03	0.27
AuditScore	-0.18	0.40	0.31	0.34	-0.25	0.34

These results are logically consistent: stronger PRP/GHP and leadership are associated with fewer nonconformities and a higher system index, while process control is more strongly linked to product criteria (LabPass).

3.5. Multivariate model (OLS): coefficients affecting FSMS-PI

When drivers are assessed jointly, their contributions to FSMS-PI can be estimated using multivariate regression. [7]

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Table 8. Multivariate model coefficients for FSMS-PI (synthetic, illustrative)

Driver	Coefficient (β)	Interpretation
Supplier control	-0.052	Improved supplier assurance is expected to increase performance, but the effect is small in the synthetic case.
PRP/GHP	0.241	Stronger hygiene foundations increase the index substantially.
Process control	0.134	Monitoring and parameter control strongly affect product compliance.
Records & traceability	0.155	Documentation and traceability support timely decisions.
Competence	0.011	Competence matters, but the effect is small in the synthetic case.
Leadership & culture	0.233	Leadership and culture increase system stability.
Model fit	$R^2 = 0.764$	Drivers explain ~76% of FSMS-PI variance (synthetic).

3.6. Traceability test (1-up/1-down): practical indicator

Within the framework of EU Regulation 178/2002, traceability is implemented according to the “one step back–one step forward” principle. [15]

In practice, a traceability test scenario (e.g., identifying the supplier and customer for a given batch number within 4 hours, locating remaining stock, and making a block/recall decision) can be measured as a KPI and incorporated into FSMS-PI analysis. [16]

4. Discussion

Full implementation of PRP/GHP requirements forms the foundation for effective HACCP operation. Where sanitation, zoning and hygiene discipline are weak, the hazard control system is more prone to deviations. ISO/TS 22002-1 requires systematic implementation of PRPs in food manufacturing (cleaning, pest control, personnel hygiene, storage/transport hygiene, etc.); once implemented, both process and product indicators (LabPass) tend to stabilize.

For oil products, deteriorating trends of PV and acid value indicate intensified oxidation and hydrolysis. This may be explained by storage conditions, packaging, oxygen exposure or pro-oxidant metal traces. [13]

The context-riskiness concept suggests that the same standard requirements should be applied with different intensity depending on the context: if raw-material risk is high, supplier assurance and incoming control should be strengthened; if the process is technologically complex, OPRP/CCP monitoring should be tightened. [5]

Maintaining ISO 19011 audit principles (impartiality, evidence-based approach and due professional care) increases the reliability of audit results and KPI trends. The KPI dashboard and FSMS-PI index help management quickly assess the system status; if the index decreases, root-cause analysis and resource allocation can be guided by the specific KPI(s) that deteriorated.

Measuring and developing food safety and quality culture improves employee discipline, awareness and intrinsic motivation, which directly affects monitoring and documentation quality.

Short rule sets such as the WHO "Five Keys to Safer Food" (keep clean; separate raw and cooked; cook thoroughly; keep food at safe temperatures; use safe water and raw materials) can be effective in training design. [17]

4.1. Implementation roadmap

1. Develop a criteria registry for each product (Table 1): indicator–limit–method–frequency–responsible person–CAPA.
2. Approve a monitoring and sampling plan (Table 1a) and define CAPA response times for deviations (e.g., 24–72 hours).
3. Develop HACCP process flow diagrams (Figure 4) and perform hazard analysis following the Codex 12-step approach (Figure 2).
4. Implement the KPI dashboard (Table 2) and include the FSMS-PI index in management review; review monthly/quarterly trends.
5. Update the risk register (Table 3) and set the intensity of PRP/OPRP/CCP controls according to risk level (Figure 3).
6. Conduct regular traceability tests as a KPI and strengthen the system with digital records. [16]

4.2. Limitations and future research

Results in this paper are presented using a synthetic dataset to demonstrate the methodology; when applied to real enterprises, criterion ranges, KPI targets and driver coefficients can be calibrated more accurately. Future work should: (i) expand criteria registries across product groups (meat, canned foods, beverages, infant foods); (ii) test the predictive value of FSMS-PI (e.g., association with complaints/recalls); and (iii) evaluate the impact of digitalization (IoT, real-time monitoring) and AI analytics on monitoring discipline and early detection of nonconformities.

5. Conclusion

- ISO 22000:2018 requirements enable systematic management, evaluation and continual improvement of an FSMS.
- For wheat flour, specific limits such as moisture ≤15.5% provide anchor points for a criteria registry.
- For oil products, PV ≤10 and acid value ≤0.6 are key indicators for managing oxidation and hydrolysis risks.
- The KPI dashboard and FSMS-PI index support quantitative assessment of "system health", trend tracking and CAPA prioritization.
- Traceability tests and digital records support rapid block/recall decisions.
- When the criteria–drivers–outcomes chain is implemented, the FSMS serves not only for audits but for data-driven management.

6. Practical Implications

- Criteria registry: 15–25 indicators per product (limit + method + frequency + responsible person + CAPA).
- PRP discipline: monthly/quarterly PRP audit score and trend; sanitation verification (swab, visual checks, checklists).
- Supplier assurance: supplier approval, COA review, risk-based incoming testing, batch blocking procedures.
- Process control: digitalize OPRP/CCP monitoring records; manage calibration and rapid response to deviations.
- KPI dashboard: review AuditScore, LabPass, NCIndex, deviations, traceability time, and complaints/recalls in management review.
- Audit quality: manage audit programme, auditor competence and evidence-based conclusions according to ISO 19011. [18]

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