



EAGLE Certification Group
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An In-depth Look at ISO 22000

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ISO 22000

- Published in September 2005
- Developed by joint effort of ISO and the food industry
- 14 different countries involved in development
- Designed similar to ISO 9001 as it includes many elements found in ISO 9001
- Comprised of 5 elements
- Food safety driven and HACCP based

ISO 22000 Clauses

- 4 Food Safety Management System (FSMS)
- 5 Management responsibility
- 6 Resource management
- 7 Planning and realization of safe products
- 8 Validation, verification and improvement of FSMS

Section 3 – Terms and Definitions

- Addresses food safety and HACCP terms
- Prerequisite Programs vs. Operational Prerequisite Programs (oPRP)
 - oPRP can only be found in ISO 22000



Section 4 – FSMS

Similar to requirements of ISO 9001

- Clause 4.1 - General requirements
- Clause 4.2 – Documentation Requirements
 - Control of Documents
 - Control of Records – More critical than ISO 9001 since it involves food safety instead of quality

Section 5 – Management Responsibility

- Clause 5.1 - Management Commitment
 - Committed to developing and implementing system and that it is continually improving
- Clause 5.2 - Food Safety Policy
 - Define, document, and communicate
 - Supported by measurable objectives
- Clause 5.3 – FSMS Planning
 - Integrity maintained when changes made

Section 5 – Management Responsibility

- Clause 5.4 – Responsibility and authority
 - Defined and communicated
 - All personnel responsible to report non-compliances
- Clause 5.5 – Food safety team leader
 - Appointed by top management
 - Responsible for effectiveness of system
- Clause 5.6 - Communication
 - Includes both internal and external

Section 5 – Management Responsibility

- Clause 5.7 – Emergency preparedness and response
 - Procedures to manage emergency situations
- Clause 5.8 – Management Review
 - Conduct at planned intervals
 - Review input (geared toward food safety)
 - Review output (includes assurance of food safety)

Section 6 – Resource Management

- Clause 6.1 – Provision of resources
 - Provide adequate resources for FSMS
- Clause 6.2 – Human resources
 - Competence, awareness and training
- Clause 6.3 – Infrastructure
- Clause 6.4 – Work environment



Section 7–Planning & Realization of Safe Products

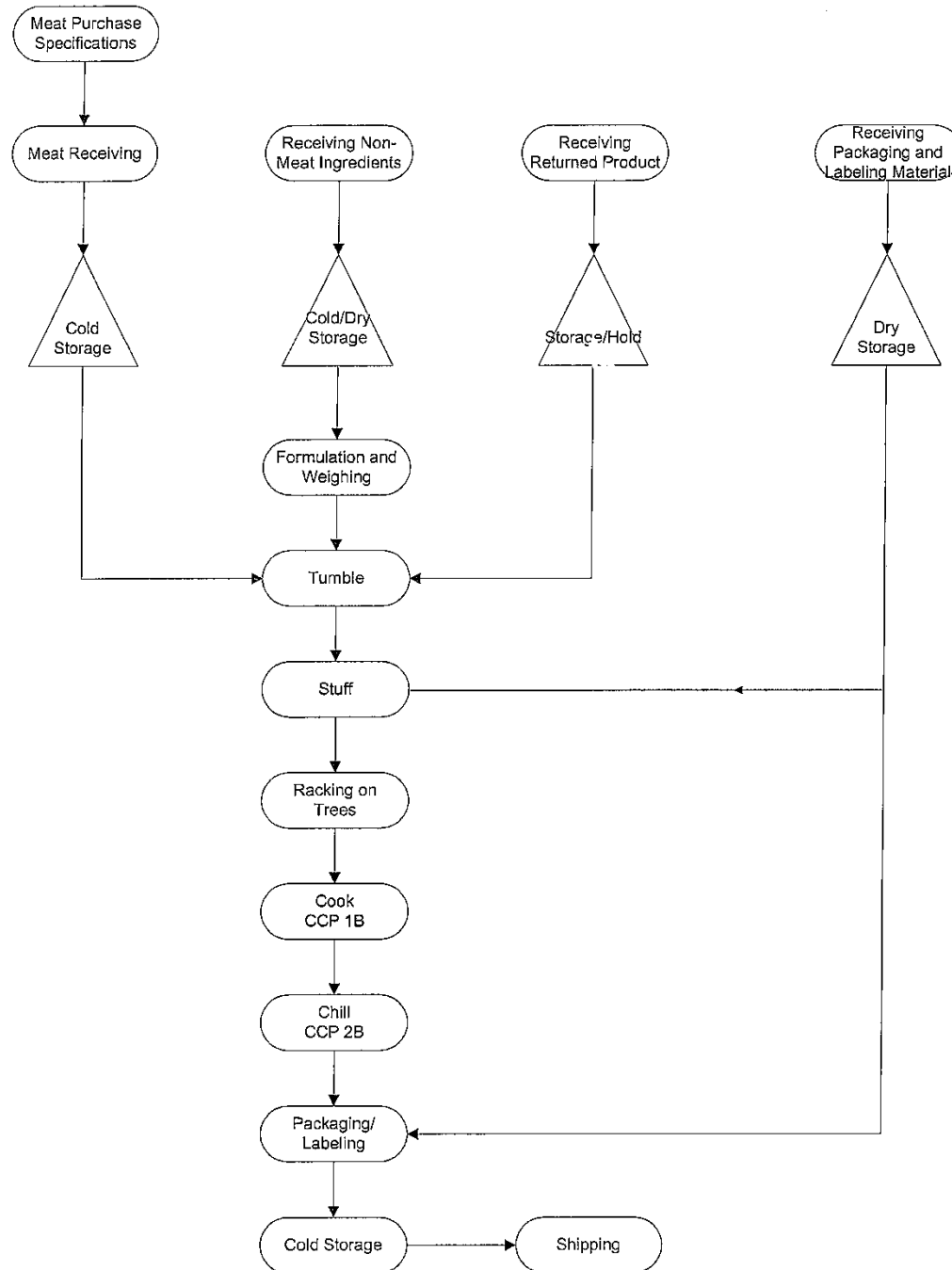
- Clause 7.2 Prerequisite programs (PRPs)
 - Satisfy regulatory requirements
 - Not detailed enough so PAS 220 created
 - Planned verification of PRPs



Section 7–Planning & Realization of Safe Products

- Clause 7.3 – Preliminary steps to enable hazard analysis
 - Follows the 5 initial steps of a 12 step HACCP plan as outlined by Codex
 - Appoint a food safety team
 - Identify product characteristics (both raw materials and finished product)
 - Intended use
 - Develop a flow diagram
 - Describe process steps and control measures

Flow Diagram



Section 7–Planning & Realization of Safe Products

Clauses 7.4 – 7.10 address the 7 Principles of HACCP

Section 7–Planning & Realization of Safe Products

- Clause 7.4 – Hazard Analysis
 - Identify hazards
 - Include biological, chemical, and physical
 - Determine acceptable level of food hazard
 - Selection and assessment of control measures
 - Based on hazard assessment
 - Must be able to prevent, eliminate or reduce hazard to an acceptable level



Section 7–Planning & Realization of Safe Products

- Clause 7.5 – Operational PRPs
 - Only found in ISO 22000
 - Control the food safety hazard
 - Must be measurable
 - More specific than a general PRP
 - Must record monitoring

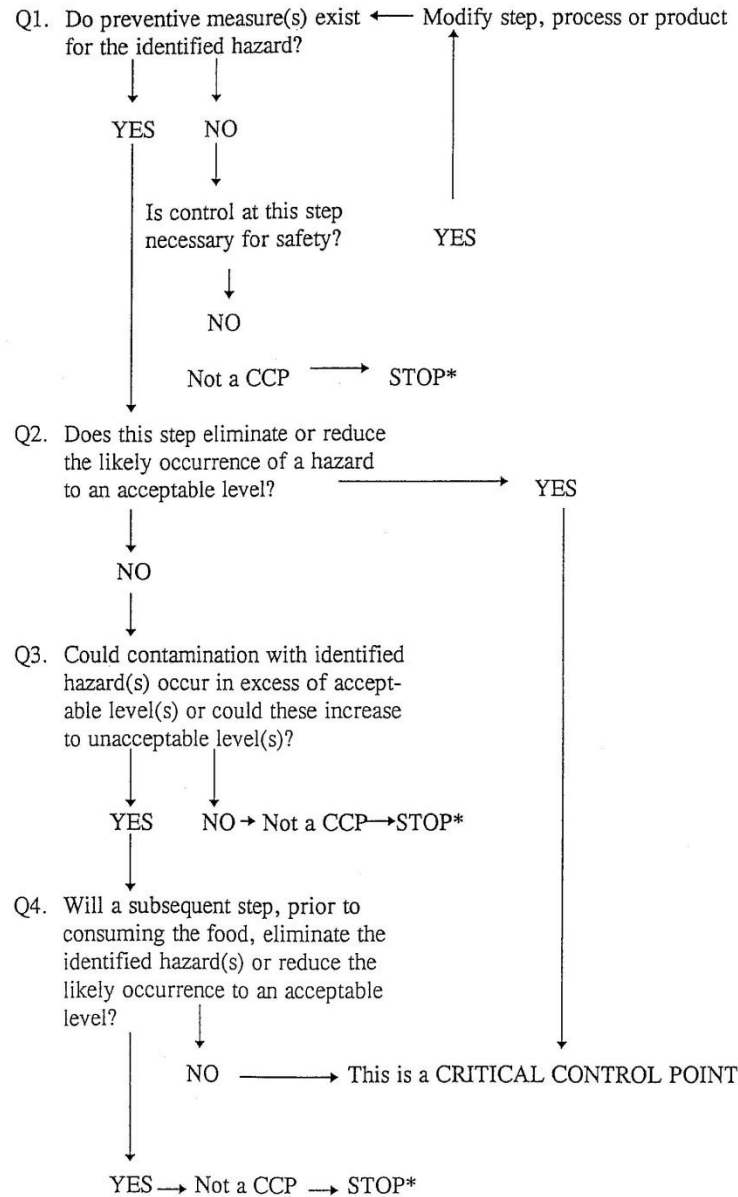


Section 7–Planning & Realization of Safe Products

- Clause 7.6 – Establish the HACCP plan
 - Identification of Critical Control Point (CCP)
 - Determine critical limits
 - Establish monitoring system for CCPs
 - Actions when critical limits are exceeded
 - Must follow requirements of Clauses 7.10.1, 7.10.2 (Corrective actions) and 7.10.3 (Handling potentially unsafe products)

CCP Decision Tree

The NACMCF (1992) CCP decision tree. (Apply at each point where an identified hazard can be controlled.)



* Proceed to the next step in the selected process

Section 7–Planning & Realization of Safe Products

- Clause 7.7 – Updating HACCP plan
 - Involves updating preliminary step information after HACCP plan is established
- Clause 7.8 – Verification Planning
 - Define purpose, methods, frequencies, and responsibilities
- Clause 7.9 - Traceability system

Section 7–Planning & Realization of Safe Products

- Clause 7.10 – Control of nonconformity
 - Food safety vs. quality
 - Critical limits are exceeded or lack of conformity with oPRPs
 - Corrections
 - Immediately adjust the process and hold product for further review and disposition
 - Corrective actions

Section 7–Planning & Realization of Safe Products

- Corrective actions must include:
 - Developed for each CCP
 - Identify cause
 - Eliminate cause
 - Prevent recurrence
 - Bring process back under control

Completed HACCP Plan

HACCP Master Sheet - Battered and Breaded Chicken Pieces

Critical Control Point (CCP)	Hazard	Critical Limits of the Preventive Measures	Monitoring				Corrective Action	Records	Verification
			What	How	Frequency	Who			
Frying CCP2(B)	Bacterial pathogens	Oil temperature $\geq 450^{\circ}$ F	Temperature	Temperature recorder, low temperature alarm	Continual recording	Fryer operator checks and initials recorder chart	Hold product if low temperature. Notify Q.A. Evaluate effect of low temperature, adjust fryer if necessary.	Fryer operator log, recorder chart, record internal temp. of chicken, QA calibration records.	Q.A. will calibrate recorder and alarm each month. Daily record review and initial. Check oil temp. each shift and compare with recorder. Measure internal temp. of chicken.
		Chain speed < 4 feet per minute.	Time	Belt speed tachometer on drive shaft	Continual recording of speed	Fryer operator checks and initials recorder chart	Hold product if belt speed > 4 feet per minute and evaluate.	Fryer operator log, recorder chart, QA calibration records, verification records	Q.A. will calibrate tachometer every 2 weeks. Daily record review and initial. Operator measures belt speed once per shift according to SOP.

For illustrative purposes only.

Section 7–Planning & Realization of Safe Products

- Clause 7.10.3 – Handling potentially unsafe products
 - Prevent suspect product from entering the food chain
 - Product could be a food safety hazard
 - Evaluation for release
 - Disposition of nonconforming product
 - Reprocessing or disposal
 - Withdrawals
 - Used if product has entered the food chain

Section 8—Validation, Verification & Improvement

- Clause 8.2 – Validation of control measures
 - Capable of achieving intended control
 - Capable of meeting defined acceptable levels for end products
 - Validate after every change or modification
- Clause 8.3 – Control of monitoring and measuring
 - Instrument calibration



Section 8—Validation, Verification & Improvement

- Clause 8.4 – FSMS verification
 - Internal audits
 - Evaluation of individual verification results
 - Analysis of results of verification activities
 - Identify need for updating
 - Identify trends
 - Evaluate effectiveness of corrective actions

Section 8—Validation, Verification & Improvement

- Clause 8.5 – Improvement
 - FSMS must show continual improvement
 - Updating the FSMS
 - Reassess the system at planned intervals

General Comments

- The ISO 22000 Certification Process
 - Stage 1
 - on-site audit
 - Is the facility ready?
 - Stage 2
 - The actual certification audit
 - More detailed
 - Surveillance Audits
 - 2/3 the time of certification audit
 - Recertification Audit
 - Every three years



PAS 220

- Publicly Available Specification (PAS)
- Intended to be used in conjunction with ISO 22000
- Development sponsored by Confederation of the Food and Drink Industries of the European Union
- Developed by manufacturing companies and ISO working group for ISO 22000
- Developed to address the GFSI concern for ISO 22000

PAS 220

- Designed to support clause 7 in ISO 22000
- Specifies detailed requirements for Prerequisite Programs (PRPs)
- Applicable to all organizations, regardless of size and complexity (manufacturing)
- Identifies 15 different PRPs
 - Within many of these are detailed sub-categories



PAS 220

- Construction and layout of buildings
- Layout of premises and workspace
- Utilities – air, water, energy
- Waste disposal
- Equipment suitability, cleaning and maintenance
- Management of purchased materials
- Measures for prevention of cross contamination
- Cleaning and sanitizing
- Pest Control
- Personnel hygiene and employee facilities
- Rework
- Product recall procedures
- Warehousing
- Product information/consumer awareness
- Food defense, biovigilance, and bioterrorism

Safe Quality Food - SQF 2000

For more information on Safe Quality Food (SQF),
go to www.sqfi.com.

On their Web site, download the
SQF 2000 code at no cost!



Questions?

Contact Information

For more information please call **800.795.3641**,
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