ISO 22000:2018

Food Safety Management System

Full Course Content – Units 1 to 5

Online Certificate Short-Course

Course Code	ISO 22000:2018 – FSMS
Format	Pure Online – Fully Self-Paced
Duration	Intensive 5-Unit Short Course (recommended 3-4 hours per unit)
Level	Intermediate (Foundation → Implementer / Internal Auditor readiness)
Institution	SFP International Quality Institute
Certificate	Certificate of Completion (upon successful completion of examination)

Course Overview

This course content develops the learner's understanding of food safety management, the requirements of ISO 22000:2018, the seven principles of HACCP, prerequisite programmes (PRPs), hazard analysis, operational prerequisite programmes (OPRPs), traceability, emergency preparedness, performance evaluation and continual improvement of food safety performance. Substantial portions of the text below are drawn directly from the three source documents supplied for this course: the UNIDO HACCP Textbook, the FSSC 22000 Scheme Version 6.0 (Foundation FSSC, April 2023), and the IFC / World Bank Food Safety Handbook: A Practical Guide for Building a Robust Food Safety Management System.

Learning Pathway

- Unit 1 – Foundations of Food Safety Management, ISO 22000 and HACCP Principles
- Unit 2 – Organisational Context, Leadership, Planning and Prerequisite Programmes (PRPs)
- Unit 3 – Support Processes, Hazard Analysis, HACCP Plans and Operational Control
- Unit 4 – Performance Evaluation, Internal Audit, Management Review, Traceability and Improvement
- Unit 5 – Implementation Roadmap, Gap Analysis, Audit Skills and Certification Preparation

UNIT 1 – Foundations of Food Safety Management, ISO 22000 and HACCP Principles

1.1 The Global Importance of Food Safety

Food safety is a global issue that is more urgent than ever as the global population races toward a projected 9 billion by 2050. The demand for safe food is growing, pressuring the world's food supply chains, and leaving no room for complacency or slack standards. In addition to posing health risks, foodborne illnesses can wreak considerable economic damage. The Safe Food Imperative, a 2018 World Bank report, estimates that food safety issues cost developing countries a staggering $110 billion in lost productivity and medical treatment in 2016 alone. A single serious food safety lapse can badly tarnish the brands of restaurants, hotels, and food producers and processors, which can require years of investment and trust-building to repair.

The good news is that most food safety issues are preventable, especially if they are addressed systematically. Businesses that establish rigorous food safety systems are also in a better position to expand and attract investment. In surveys conducted in 2010–18, approximately 27 client companies of the International Finance Corporation (IFC) attributed $478 million in increased sales and $564 million in investment to better food safety practices.

(IFC, 2020, Food Safety Handbook)

1.2 What is HACCP?

The concept of Hazard Analysis and Critical Control Points (HACCP) is a preventive system to guarantee the safety of food for the consumer. It focuses on the prevention of physical, chemical and biological hazards rather than on carrying out inspection of the finished products.

The HACCP approach was developed in 1959, when NASA commissioned the Pillsbury Company to produce food for astronauts. The food had to be absolutely safe to exclude any risk to the health of the astronauts, who would be cut off from medical care for weeks. The company applied the FMEA method (Failure Mode and Effect Analysis) to the production of food. Later on this approach was further developed, and was first released in 1971. Since 1993 the application of HACCP has been recommended by the Codex Alimentarius published by FAO (Food and Agriculture Organization of the United Nations).

The HACCP concept requires a company:

- To analyse all risks within its control related to the safety of its products;
- To identify critical points for control of the quality of food;
- To define critical limits for relevant parameters at the critical points;
- To establish procedures for continuous control of food safety;
- To define corrective measures for deviations;
- To regularly check whether this system is appropriate and effective;
- To document all measures taken.

The European regulation 178/2002 requires all companies which produce, package and sell food in Europe to apply this concept. From 1st January 2006 only food that complied with the HACCP-requirements could be imported and traded within the European Union. Companies intending to supply food to EU member states are required to have a documented HACCP system.

(UNIDO HACCP Textbook)

1.3 Application of Good Hygiene Practices – The Starting Point

The application of HACCP starts with the application of good hygiene practices. The Codex Alimentarius and a general description of good hygiene practices can be found on the FAO web page. It also includes Codex codes for hygienic practices in the following sectors: Meat; Fish and fishery products; Milk and milk products; Fresh fruits and vegetables; Egg products; Coffee production.

Good hygienic practices include the following measures:

Environmental hygiene – Food production must not be carried out where potentially harmful substances would lead to an unacceptable level of such substances in food.

Hygienic production of food sources – Points where a high probability of contamination may exist should be identified and specific measures should be taken to minimize the probability of contamination. Producers need to implement measures to: minimize contamination from air, soil, water, feedstuffs, fertilizers (including natural fertilizers), pesticides, veterinary drugs or any other agent used in primary production; control plant and animal health so that it does not pose a threat to human health through food consumption; protect food sources from faecal and other contamination; manage waste and store harmful substances appropriately.

Handling, storage and transport – Procedures should be in place to: sort food and food ingredients to segregate material which is evidently unfit for human consumption; dispose of any rejected material in a hygienic manner; and protect food and food ingredients from contamination by pests, or by chemical, physical or microbiological contaminants or other objectionable substances during handling, storage and transport. This may include controlling temperature, humidity, and/or other controls.

Cleaning, maintenance and personnel hygiene at primary production – Appropriate facilities and procedures should be in place to ensure that any necessary cleaning and maintenance is carried out effectively and an appropriate degree of personal hygiene is maintained.

(UNIDO HACCP Textbook – Good Hygienic Practices)

1.4 Establishments, Equipment and Facilities

Establishments should normally be located away from: environmentally polluted areas and industrial activities which pose a serious threat of contaminating food; areas subject to flooding unless sufficient safeguards are provided; areas prone to pest infestations; areas where waste, either solid or liquid, cannot be removed effectively.

Structures within food establishments should be soundly built of durable materials and be easy to maintain, clean and where appropriate, able to be disinfected. In particular the following specific conditions should be satisfied where necessary to protect the safety and suitability of food:

- The surfaces of walls, partitions and floors should be made of impervious materials with no toxic effect in intended use;
- Walls and partitions should have a smooth surface up to a height appropriate to the operation;
- Floors should be constructed to allow adequate drainage and cleaning;
- Ceilings and overhead fixtures should be constructed and finished to minimize the build-up of dirt and condensation, and the shedding of particles;
- Windows should be easy to clean, be constructed to minimize the build-up of dirt and where necessary, be fitted with removable and cleanable insect-proof screens. Where necessary, windows should be fixed;

- Doors should have smooth, non-absorbent surfaces, and be easy to clean and, where necessary, disinfect;
- Working surfaces that come into direct contact with food should be in sound condition, durable and easy to clean, maintain and disinfect. They should be made of smooth, non-absorbent materials, and inert to the food, to detergents and disinfectants under normal operating conditions.

Equipment and containers (other than once-only use containers and packaging) coming into contact with food, should be designed and constructed so that they can be adequately cleaned, disinfected and maintained to avoid the contamination of food. Equipment and containers should be made of materials with no toxic effect in intended use. Equipment used to cook, heat treat, cool, store or freeze food should be designed to achieve the required food temperatures as rapidly as necessary in the interests of food safety and suitability, and maintain them effectively. Such equipment should also be designed to allow temperatures to be monitored and controlled.

These requirements are intended to ensure that: harmful or undesirable micro-organisms or their toxins are eliminated or reduced to safe levels or their survival and growth is effectively controlled; where appropriate, critical limits established in HACCP-based plans can be monitored; temperatures and other conditions necessary for food safety and suitability can be rapidly achieved and maintained.

(UNIDO HACCP Textbook)

1.5 Water, Waste, Personal Hygiene, Air Quality, Lighting and Storage

Drinking water should conform to the requirements specified in the latest edition of the WHO Guidelines for Drinking Water Quality, or be of a higher standard. Non-drinking water (for use in, for example, fire control, steam production, refrigeration and other similar purposes where it would not contaminate food), shall have a separate system. Non-drinking water systems shall be clearly identified and shall not connect with, or allow reflux into, drinking water systems. The drainage and waste disposal systems and facilities should be designed and constructed so that the risk of contaminating food or the drinking water supply is avoided.

Personnel hygiene facilities should include: adequate means of hygienically washing and drying hands, including wash basins and a supply of hot and cold (or suitably temperature controlled) water; lavatories of appropriate hygienic design; and adequate changing facilities for personnel. Such facilities should be suitably located and designated.

Adequate means of natural or mechanical ventilation should be provided, in particular to: minimize air-borne contamination of food, for example, from aerosols and condensation droplets; control ambient temperatures; control odours which might affect the suitability of food; and control humidity, where necessary, to ensure the safety and suitability of food. Ventilation systems should be designed and constructed so that air does not flow from contaminated areas to clean areas and, where necessary, it has to be ensured that they can be adequately maintained and cleaned.

Adequate natural or artificial lighting should be provided to enable the company to operate in a hygienic manner. Where necessary, lighting should not be such that the resulting colour is misleading. The intensity should be adequate to the nature of the operation. Lighting fixtures should, where appropriate, be protected to ensure that food is not contaminated by breakages.

Where necessary, adequate facilities for the storage of food, ingredients and non-food chemicals (e.g. cleaning materials, lubricants, fuels) should be provided. Where appropriate, food storage facilities should be designed and constructed to: permit adequate maintenance and cleaning; avoid pest access and harbourage; enable food to be effectively protected from contamination during storage; and where necessary, provide an environment which minimizes the deterioration of food (e.g. by temperature and humidity control). The type of storage facilities required

will depend on the nature of the food. Where necessary, separate, secure storage facilities for cleaning materials and hazardous substances should be provided.

(UNIDO HACCP Textbook)

After establishing Good Hygienic Practices, an HACCP system should be established to minimize the potential impact of the remaining risks.

1.6 The Seven Principles of HACCP (Codex / FAO)

HACCP is based on seven established principles, as defined by FAO / Codex Alimentarius:

Principle 1: Conduct a hazard analysis. The Codex defines a hazard as "A biological, chemical or physical agent in, or condition of, food with the potential to cause an adverse health effect". The hazard analysis identifies which hazards need to be controlled to prevent the contamination of food.

Principle 2: Identify critical control points. According to the Codex a critical control point (CCP) is a point, step, or procedure in a food process at which control should be applied so that a food safety hazard can be prevented, eliminated, or reduced to an acceptable level.

Principle 3: Establish critical limits for each critical control point. A critical limit represents the boundaries that are used to ensure that a process step produces safe products. Critical limits are set for factors such as temperature, exposure time, physical product dimensions, water quality, moisture level, etc.

Principle 4: Establish requirements for monitoring critical control points. Monitoring activities are necessary to ensure that the process is under control at each critical control point. Therefore, it is important to specify fully how, when and by whom monitoring is to be performed.

Principle 5: Establish corrective actions. The Codex defines corrective action as "any action to be taken when the results of monitoring at the CCP indicate a loss of control". Loss of control is considered as a deviation from a critical limit for a CCP. All deviations must be controlled by taking action(s) to control the non-compliant product and to correct the cause of non-compliance.

Principle 6: Establish verification procedures. The Codex guidelines define verification as "the application of methods, procedures, tests and other evaluations, in addition to monitoring to determine compliance with the HACCP plan".

Principle 7: Establish documentation and record-keeping. Efficient and accurate record-keeping is essential to the application of a HACCP system. Documentation and record-keeping should be appropriate to the nature and size of the operation and sufficient to assist the business to verify that the HACCP controls are in place and being maintained.

(UNIDO HACCP Textbook; Codex Alimentarius)

1.7 Examples of Biological Hazards

Biological hazards may be associated with the raw materials from which meat and poultry products are made. Biological hazards may also be introduced during the processing of meat and poultry products from people who are involved in the processing, from the environment in which the foods are processed, or from other ingredients in the products. Identifying the biological hazards to which the production processes might be subjected is clearly a difficult and important task that requires all the expertise that the HACCP team can bring to it.

Examples of biological hazards (source: FAO, Food quality and safety systems training manual):

- Bacteria (spore-forming): Clostridium botulinum; Clostridium perfringens; Bacillus cereus.

- Bacteria (non-spore-forming): Brucella abortis; Brucella suis; Campylobacter spp.; Pathogenic Escherichia coli (E. coli O157:H7, EHEC, EIEC, ETEC, EPEC); Listeria monocytogenes; Salmonella spp. (S. typhimurium, S. enteritidis); Shigella (S. dysenteriae); Staphylococcus aureus; Streptococcus pyogenes; Vibrio cholerae; Vibrio parahaemolyticus; Vibrio vulnificus; Yersinia enterocolitica.
- Viruses: Hepatitis A and E; Norwalk virus group; Rotavirus.
- Protozoa and parasites: Cryptosporidium parvum; Diphyllobothrium latum; Entamoeba histolytica; Giardia lamblia; Ascaris lumbricoides; Taenia solium.

(UNIDO HACCP Textbook)

1.8 ISO 22000 and Its Relationship to HACCP and FSSC 22000

ISO 22000 specifies the requirements for a food safety management system aimed at providing products that, according to their intended use, are safe for the consumer; to demonstrate compliance with applicable statutory and regulatory food safety requirements; to evaluate and assess customer requirements and demonstrate conformity with those mutually agreed customer requirements that relate to food safety; to effectively communicate food safety issues to their suppliers, customers and relevant interested parties in the food chain; to ensure that the organization conforms to its stated food safety policy; to demonstrate such conformity to relevant interested parties; and to seek certification or registration of its food safety management system by an external organization, or make a self-assessment or self-declaration of conformity.

ISO 22000 integrates the principles of the Hazard Analysis and Critical Control Point (HACCP) system and application steps developed by the Codex Alimentarius Commission to identify, prevent and control food safety hazards. HACCP systems apply a methodology with seven steps (7 HACCP principles) which are used to develop an HACCP plan.

(UNIDO HACCP Textbook – ISO 22000 section)

According to Foundation FSSC (2023): "With a growing world population, there is an increasing need for affordable, safe, and good quality food products. To fulfill this need, FSSC 22000 provides a trusted brand assurance platform to the food industry. Key in this mission is the availability of the FSSC 22000 certification Scheme for food safety management systems. This document contains the new Version 6.0 of the FSSC 22000 Scheme published in April 2023. The main factors that initiated the development of this version have been: Incorporating the requirements of ISO 22003-1:2022; Strengthening the requirements to support organizations in their contributions to meeting the Sustainable Development Goals (SDGs); Editorial changes and amendments as part of continuous improvement."

(Foundation FSSC, 2023, FSSC 22000 Scheme Version 6.0)

Practical Activity – Unit 1: Identify typical food safety hazards (biological, chemical, physical, allergen) for a chosen product/process. Map the seven HACCP principles against that process. List the key Good Hygienic Practice elements that must be in place before a HACCP plan can be effective.

UNIT 2 – Organisational Context, Leadership, Planning and Prerequisite Programmes (PRPs)

2.1 Context of the Organisation and Interested Parties (ISO 22000 Clause 4)

The organisation shall determine external and internal issues that are relevant to its purpose and that affect its ability to achieve the intended results of its Food Safety Management System. The organisation shall determine the interested parties that are relevant to the FSMS and the relevant requirements of these interested parties. The scope of the FSMS shall be determined and made available as documented information. The scope shall specify the products and services, processes and production sites that are included.

2.2 Leadership and Food Safety Policy (Clause 5)

Top management shall demonstrate leadership and commitment with respect to the FSMS by ensuring that the food safety policy and objectives are established and are compatible with the strategic direction of the organisation; ensuring the integration of the FSMS requirements into the organisation's business processes; ensuring that the resources needed are available; communicating the importance of effective food safety management and of conforming to the FSMS requirements; ensuring that the FSMS achieves its intended results; directing and supporting persons to contribute to the effectiveness of the FSMS; promoting continual improvement; and supporting other relevant management roles.

Top management shall establish, implement and maintain a food safety policy that is appropriate to the purpose and context of the organisation; provides a framework for setting and reviewing food safety objectives; includes a commitment to satisfy applicable food safety requirements (including statutory and regulatory requirements and mutually agreed customer requirements related to food safety); addresses internal and external communication; and includes a commitment to continual improvement of the FSMS.

2.3 Planning – Risks, Opportunities and Objectives (Clause 6)

When planning for the FSMS, the organisation shall consider the issues referred to in Clause 4 and the requirements of interested parties and determine the risks and opportunities that need to be addressed. Food safety objectives shall be established at relevant functions and levels. Objectives shall be consistent with the food safety policy, measurable, take into account applicable food safety requirements, be monitored, communicated, and updated as appropriate.

2.4 Prerequisite Programmes (PRPs) – Foundation of the FSMS

Prerequisite programmes are the basic conditions and activities that are necessary to maintain a hygienic environment throughout the food chain suitable for the production, handling and provision of safe end products and safe food for human consumption. The organisation shall establish, implement, maintain and update PRP(s) to assist in controlling the likelihood of introducing food safety hazards to the product through the work environment, biological, chemical and physical contamination of the product (including cross-contamination between products), and food safety hazard levels in the product and product processing environment.

The FSSC 22000 Scheme specifies mandatory application of technical specifications detailing the pre-requisite programs (PRPs) as referenced in clause 8.2 of ISO 22000:2018. These PRP requirements are specified in the ISO/TS 22002-x series and/or the BSI/PAS 221 standards.

(Foundation FSSC, 2023, Part 2 – Requirements for Organizations to be Audited)

Typical PRP categories include:

- Construction and layout of buildings and associated utilities;
- Layout of premises, including workspace and employee facilities;
- Supplies of air, water, energy and other utilities;
- Supporting services, including waste and sewage disposal;
- Suitability of equipment and its accessibility for cleaning, maintenance and preventive maintenance;
- Management of purchased materials (including ingredients, chemicals and packaging);
- Measures for the prevention of cross-contamination;
- Cleaning and sanitizing;
- Pest control;
- Personnel hygiene;
- Product information / consumer awareness;
- Allergen management, warehousing and transport as appropriate to the sector.

2.5 FSSC 22000 Scheme – Requirements for Organizations

Organizations shall develop, implement, and maintain all the requirements outlined below and shall be audited by a licensed Certification Body in order to receive a valid FSSC 22000 certificate. The audit requirements for FSSC 22000 certification consist of: (1) ISO 22000:2018 Food Safety Management System requirements; (2) Sector specific prerequisite program (PRPs) requirements (ISO/TS 22002-x series or other specified PRP standard); and (3) FSSC 22000 Additional requirements.

The Board of Stakeholders (BoS) Decision list is a document which contains decisions applicable to FSSC 22000 Scheme. The decisions overrule or provide further clarification on existing Scheme rules and shall be implemented and applied within the defined transition period. 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 as applicable.

(Foundation FSSC, 2023, Part 2)

International Quality Institute

2.6 Certification Scopes under FSSC 22000

The FSSC 22000 Scheme covers defined food-chain categories. These include: Handling of Plants (Category B); Food Manufacturing (Category C); Animal Feed Production (Category D); Catering (Category E); Trading, Retail, Wholesale and E-commerce (Category F); Transport and Storage (Category G); Production of Food Packaging and Packaging Materials (Category I); and Production of Bio/Chemicals (Category K). Category K involves the production of Chemical and Bio-Chemical products and applies to the production of food and feed additives, vitamins, minerals, bio-cultures, flavorings, enzymes, gases, and processing aids. Food supplements, where legally classified as food within the country of manufacture, may be included under food chain category K. If the product is classified as a pharmaceutical or medical product under the legislation, then it is outside the scope of FSSC 22000 certification. Packaging material used for personal care, pharmaceutical products or other non-food uses are outside the scope of the Scheme.

(Foundation FSSC, 2023, Part 1 – Scheme Overview)

Practical Activity – Unit 2: Draft an interested-party register. Write or critique a food safety policy against ISO 22000 requirements. Build a simple PRP checklist covering infrastructure, cleaning, pest control, personal hygiene and

supplier control for a chosen operation. Identify which FSSC food-chain category applies to your organisation (or case study).

UNIT 3 – Support Processes, Hazard Analysis, HACCP Plans and Operational Control

3.1 Support – Resources, Competence, Awareness, Communication and Documented Information (Clause 7)

The organisation shall determine and provide the resources needed for the establishment, implementation, maintenance, updating and continual improvement of the FSMS. This includes people, infrastructure, work environment, externally developed elements of the FSMS, and control of externally provided processes, products or services. The organisation shall determine the necessary competence of person(s) doing work under its control that affects food safety performance, ensure that these persons are competent on the basis of appropriate education, training or experience, and where applicable, take actions to acquire the necessary competence and evaluate the effectiveness of the actions taken. Appropriate documented information shall be retained as evidence of competence.

Persons doing work under the organisation's control shall be aware of the food safety policy, the objectives of the FSMS relevant to them, their contribution to the effectiveness of the FSMS, and the implications of not conforming with the FSMS requirements. The organisation shall determine the internal and external communications relevant to the FSMS. Documented information required by the FSMS and by ISO 22000 shall be controlled (create, update, control of changes, distribution, access, retrieval, use, storage, preservation, retention and disposition).

3.2 Operational Planning and Control; Traceability; Emergency Preparedness (Clause 8)

The organisation shall plan, implement, control, maintain and update the processes needed to meet requirements for the provision of safe products and services and to implement the actions determined in planning. According to the EU General Food Law, Regulation (EC) No. 178/2002, traceability is the ability to track a food, feed, food-producing animal, or substance intended to be, or expected to be incorporated into a food or feed, through all stages of production, processing, and distribution. Thus, a traceability system should be constructed to ensure an ability to identify any person supplying food business operators (FBOs) or other businesses with a food or feed product. It follows that labeling and identifying products through relevant documentation is an integral component of a traceability system.

(IFC Food Safety Handbook)

In the United States, many producers, manufacturers, and retailers must have product tracing systems in place as part of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002. The act requires all producers and manufacturers to be able to trace one step forward and one step back in the supply chain. Retailers need to be able to trace one step back only. The FSMA directs the FDA to build a system that enhances the FDA's ability to track and trace both domestic and imported foods that are adulterated.

(IFC Food Safety Handbook)

Top management shall ensure procedures are in place to respond to potential emergency situations or incidents that can have an impact on food safety and that are relevant to the role of the organisation in the food chain. The organisation shall respond to actual emergency situations and incidents and take action to reduce the consequences of the emergency situation. The organisation shall periodically test procedures where practical, review and, where necessary, update the documented information after the occurrence of any incident, emergency situation or tests.

3.3 Hazard Analysis – Preliminary Steps and Hazard Assessment

The organisation shall conduct a hazard analysis to determine which hazards need to be controlled, the degree of control required to ensure food safety, and which combination of control measures is required. The food safety team shall identify and record all reasonably expected food safety hazards associated with the type of product, process and process

environment. The identification shall be based on the preliminary information collected, experience, external information including epidemiological and other historical data, and information from the food chain on food safety hazards that may be relevant for the safety of the end products, intermediate products and the food at consumption.

Each of the food safety hazards identified shall be evaluated to determine whether its elimination or reduction to acceptable levels is essential to the production of a safe food, and whether its control is needed to enable the defined acceptable levels to be met. For each food safety hazard, the hazard assessment shall assess the likelihood of occurrence and severity of adverse health effects associated with the food. The methodology used shall be described, and the result of the hazard assessment shall be recorded.

3.4 Selection and Categorisation of Control Measures – CCPs and OPRPs

Based on the hazard assessment, the organisation shall select an appropriate combination of control measures that will prevent, eliminate or reduce the significant food safety hazards to defined acceptable levels. The selected control measures shall be categorised as to whether they need to be managed through operational PRP(s) or by the HACCP plan. The selection and categorisation shall be carried out using a logical approach that includes assessments with regard to the effect on identified significant food safety hazards, the feasibility of monitoring, the place within the system relative to other control measures, the likelihood of failure and the severity of consequence, and the specificity of the control measure.

Critical Control Points (CCPs) are steps at which control can be applied and is essential to prevent or eliminate a food safety hazard or reduce it to an acceptable level. Operational Prerequisite Programmes (OPRPs) are control measures identified by the hazard analysis as essential to control the likelihood of introducing food safety hazards and/or the contamination or proliferation of food safety hazards in the product or processing environment.

Some critical points where control can be applied in the process include (source: American Meat Institute Foundation / UNIDO Textbook): chilling to exact temperatures; cooking to specific temperatures with exact times; product formulations, such as the addition of cultures or adjustment of pH or water activity.

(UNIDO HACCP Textbook)

3.5 Establishing the HACCP / OPRP Plan and Control of Nonconformities

For each CCP and OPRP the organisation shall establish a plan that includes: the food safety hazard(s) to be controlled; the control measure(s); critical limits (for CCPs) or action criteria (for OPRPs); monitoring procedures (what, how, when/frequency, who); corrections and corrective actions to be taken if critical limits or action criteria are not met; responsibilities and authorities; and records of monitoring. Critical limits at CCPs shall be measurable. Conformance with critical limits shall ensure that the acceptable level is not exceeded. Monitoring systems at each CCP shall be capable of detecting any failure to remain within critical limits in time for product isolation before it is used or consumed.

The organisation shall ensure that products that do not conform to food safety requirements are identified and controlled to prevent their unintended use or delivery. When a nonconformity occurs, the organisation shall take action to control and correct it, deal with the consequences, and evaluate the need for action to eliminate the cause(s) so that it does not recur or occur elsewhere. The organisation shall establish, implement and maintain documented information for notification to interested parties, handling of products, and evaluation of the need for a withdrawal / recall. Withdrawn / recalled products shall be secured or disposed of under supervision until a decision is made on further handling.

Practical Activity – Unit 3: Conduct a simplified hazard analysis for a selected product. Decide CCP versus OPRP for key control measures. Draft monitoring, critical limit / action criterion, and corrective-action elements of a hazard control plan. Design a basic one-step-forward / one-step-back traceability test.

UNIT 4 – Performance Evaluation, Internal Audit, Management Review, Traceability and Improvement

4.1 Monitoring, Measurement, Analysis and Evaluation (Clause 9.1)

The organisation shall determine what needs to be monitored and measured, the methods for monitoring, measurement, analysis and evaluation needed to ensure valid results, when the monitoring and measuring shall be performed, and when the results shall be analysed and evaluated. The organisation shall evaluate the performance and the effectiveness of the FSMS. The organisation shall analyse and evaluate appropriate data and information arising from monitoring and measurement, including the results of verification activities related to PRPs and the hazard control plan, internal audits, external audits, inspections, analysis of results of verification activities, and performance of external providers.

4.2 Internal Audit (Clause 9.2)

The organisation shall conduct internal audits at planned intervals to provide information on whether the FSMS conforms to the organisation's own requirements for its FSMS and the requirements of ISO 22000, and is effectively implemented and maintained. The organisation shall plan, establish, implement and maintain an audit programme(s), including the frequency, methods, responsibilities, planning requirements and reporting, which shall take into consideration the importance of the processes concerned, changes in the FSMS, and the results of previous audits. Auditors shall be selected and audits conducted to ensure objectivity and the impartiality of the audit process. Results of the audits shall be reported to relevant management. Appropriate correction and corrective actions shall be taken without undue delay. Documented information shall be retained as evidence of the implementation of the audit programme and the audit results.

4.3 Management Review (Clause 9.3)

Top management shall review the organisation's FSMS, at planned intervals, to ensure its continuing suitability, adequacy and effectiveness. The management review shall include consideration of: the status of actions from previous management reviews; changes in external and internal issues that are relevant to the FSMS; information on the performance and effectiveness of the FSMS (including trends in nonconformities and corrective actions, monitoring and measurement results, audit results, inspections, analysis of results of verification activities, performance of external providers, review of risks and opportunities and effectiveness of actions taken, extent to which objectives have been met); adequacy of resources; any need for updates or changes to the FSMS; and opportunities for continual improvement. The outputs of the management review shall include decisions and actions related to continual improvement opportunities, any need for changes to the FSMS, and resource needs. Documented information shall be retained as evidence of the results of management reviews.

4.4 Nonconformity, Corrective Action and Continual Improvement (Clause 10)

When a nonconformity occurs, the organisation shall react to the nonconformity and, as applicable, take action to control and correct it and deal with the consequences; evaluate the need for action to eliminate the cause(s) of the nonconformity, in order that it does not recur or occur elsewhere, by reviewing the nonconformity, determining the causes, and determining if similar nonconformities exist or could potentially occur; implement any action needed; review the effectiveness of any corrective action taken; and make changes to the FSMS, if necessary. Corrective actions shall be appropriate to the effects of the nonconformities encountered. Root-cause analysis tools commonly used include the 5 Whys technique and the fishbone (Ishikawa) diagram. The distinction between correction (immediate

action to deal with the nonconforming product or situation) and corrective action (action to eliminate the cause) is critical for effective improvement.

The organisation shall continually improve the suitability, adequacy and effectiveness of the FSMS. Top management shall ensure that the organisation continually improves the effectiveness of the FSMS through the use of the food safety policy, food safety objectives, audit results, analysis of results of verification activities, corrective actions and management review. The organisation shall continually improve the effectiveness of the FSMS by updating the food safety system when needed, taking into account new scientific or technological developments, emerging food safety hazards, changes in the environment or in the organisation, and results of verification activities.

4.5 Traceability Testing, Labelling and Recall Linkage

A robust traceability system must be tested periodically (mock recalls / mass-balance exercises) to verify that the organisation can, within a defined time, identify and locate affected product and relevant batches of ingredients and packaging. Results of these tests shall be documented and used to improve the system. The linkage between the traceability system and the withdrawal/recall procedure must be clear, with defined responsibilities, communication channels (customers, authorities, media if required), and decision criteria for initiating a recall.

Food labeling is the primary means of communication linking the producer and the seller of food with the purchaser and consumer of the food. The most important rule of labeling is that the consumer should not be misled. The Codex General Standard for the Labeling of Prepackaged Food establishes the information that must appear on the label (name of the food, list of ingredients, net contents, name and address of the producer or packager, country of origin, lot identification, date marking, storage instructions, and instructions for use).

(IFC Food Safety Handbook; Codex Alimentarius)

In addition to EU food law, specific traceability requirements have been established in EU legislation or regulations on certain categories of food, such as beef, fish, and genetically modified organisms. Examples include Regulation (EC) No. 1760/2000 (identification and registration of bovine animals and labeling of beef and beef products); Regulation (EC) No. 1420/2013 and Regulation (EU) No. 1379/2013 on fishery and aquaculture products; and Regulation (EC) No. 1830/2003 on the traceability and labeling of genetically modified organisms.

(IFC Food Safety Handbook)

International Quality Institute

Practical Activity – Unit 4: Design a simple internal-audit checklist for a food safety process (e.g., CCP monitoring or a PRP). Prepare a management-review agenda using the inputs required by ISO 22000. Complete a corrective-action report from a case scenario using 5 Whys or fishbone analysis. Outline a mock-recall protocol.

UNIT 5 – Implementation Roadmap, Gap Analysis, Audit Skills and Certification Preparation

5.1 Complete Implementation Roadmap

A practical implementation sequence for an ISO 22000 / FSSC 22000 FSMS typically follows these stages:

- Top management commitment and appointment of a Food Safety Team / FSMS Coordinator;
- Gap analysis against ISO 22000:2018 (and, if applicable, ISO/TS 22002 and FSSC additional requirements);
- Determination of organisational context, interested parties and FSMS scope;
- Establishment of food safety policy and measurable objectives;
- Design and implementation of Prerequisite Programmes;
- Product and process description, flow diagrams, hazard analysis, CCP/OPRP determination and hazard control plan;
- Development of documented information (procedures, work instructions, forms, records);
- Competence, awareness and training programmes;
- Operational implementation and monitoring;
- Internal audit programme and first full-cycle internal audits;
- Management review;
- Corrective actions and continual improvement;
- Stage 1 (documentation / readiness) and Stage 2 (implementation) certification audits by an accredited certification body;
- Surveillance and recertification cycles.

5.2 Mandatory Documented Information under ISO 22000:2018

Documented information to be maintained (documents) typically includes: the scope of the FSMS; the food safety policy; food safety objectives; documented information needed to support the operation of processes (including PRPs, hazard analysis methodology, hazard control plan). Documented information to be retained (records) includes, among others: evidence of competence; results of external provider evaluation; monitoring results at CCPs and OPRPs; verification results; internal audit programme and results; management review results; nonconformities and corrective actions; traceability records; and records related to withdrawals/recalls.

5.3 Writing Clear Nonconformity Statements and Types of Findings

A clear nonconformity statement normally contains three elements: (1) the requirement (the relevant clause or documented procedure that was not met); (2) the evidence (objective evidence observed, recorded or stated); and (3) the statement of nonconformity (how the evidence demonstrates that the requirement was not fulfilled). Types of findings commonly used by certification bodies include major nonconformity, minor nonconformity, observation, and opportunity for improvement.

5.4 Stage 1 versus Stage 2 Certification Audits

Stage 1 audit (documentation / readiness review) evaluates the documented information of the FSMS, the organisation's understanding of requirements, the allocation of resources, the status of internal audits and management reviews, and the readiness for Stage 2. Stage 2 audit evaluates the implementation and effectiveness of

the FSMS, including the hazard control plan, monitoring, verification, corrective actions, and the ability of the system to deliver safe product. Surveillance audits are conducted at planned intervals to ensure ongoing conformity. Common nonconformities in food safety audits relate to incomplete hazard analysis, inadequate CCP monitoring, weak PRP implementation, insufficient traceability, and ineffective corrective action.

5.5 FSSC 22000 Scheme Organisation (Version 6.0)

The Scheme consists of five Parts and two Appendices. PART 1 SCHEME OVERVIEW describes the Scheme context and details including its certification scopes. PART 2 REQUIREMENTS FOR ORGANIZATIONS TO BE AUDITED describes the Scheme requirements against which licensed Certification Bodies shall audit the Food Safety Management System of the organization. PART 3 REQUIREMENTS FOR THE CERTIFICATION PROCESS describes the requirements for the execution of the certification process. PART 4 REQUIREMENTS FOR CERTIFICATION BODIES describes the requirements for licensed Certification Bodies. PART 5 REQUIREMENTS FOR ACCREDITATION BODIES describes the requirements for recognized Accreditation Bodies. APPENDIX 1 contains definitions; APPENDIX 2 contains normative references. There are five mandatory Annexes: Annex 1 CB Certificate scope statements; Annex 2 CB Audit report requirements; Annex 3 CB Certificate templates; Annex 4 AB Accreditation certificate; Annex 5 CB Requirements for the use of information and communication technology (ICT). Foundation FSSC has voluntary Addenda and Modules that can be undertaken together with FSSC 22000 certification audits.

(Foundation FSSC, 2023)

5.6 Sustaining the FSMS and Examination Guidance

A sustainable FSMS is integrated into daily operations, supported by competent people, verified by meaningful internal audits, reviewed by top management with genuine engagement, and continually improved on the basis of real data (complaints, monitoring trends, audit findings, emerging hazards). Organisations should avoid treating documentation as an end in itself; the purpose of documented information is to support consistent control of food safety hazards and to provide evidence of that control.

The final online examination typically comprises multiple-choice questions covering all clauses of ISO 22000, the seven HACCP principles, risk-based thinking, process approach, PRPs, CCP/OPRP logic, and audit concepts, together with short essay / scenario-based questions (gap analysis interpretation, process approach application, risk treatment, nonconformity writing, corrective action, Stage 1 vs Stage 2 differences). Recommended pass mark is 70%. Successful completion leads to a Certificate of Completion issued by SFP International Quality Institute. Note that this short-course certificate does not itself certify an organization, but an individual; organisational certification is awarded by accredited certification bodies. Professional auditor registration (e.g., IRCA) may require additional recognised auditor training.

Practical Activity – Unit 5: Complete a mini gap-analysis checklist against ISO 22000 clauses 4–10 for your organisation or case study. Write three nonconformity statements from case evidence (requirement + evidence + statement). Outline a Stage 1 / Stage 2 preparation checklist. Undertake final examination preparation using the revision points above.

References

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End of Course Content — ISO 22000:2018 Food Safety Management System

This course content is intended for educational purposes within the SFP International Quality Institute pure-online certificate programme. Organisational certification to ISO 22000 or FSSC 22000 is awarded only by accredited certification bodies following successful Stage 1 and Stage 2 audits.