31. Designing Food Safety Management System

T.V.Sankar[1]
E-mail: tvsankar.cift@gmail.com

Food provides the basic requirements of growth and sustenance of life. It goes beyond saying that whatever is being consumed should be good and safe to the consumers. The concept is important not only from the individual point of view but across the globe as food is an important health, social and economic issue. The abuse of safety leads to incidence of food borne illness and it is estimated that food and waterborne diseases kill 2.2 million people annually and about 87% of this are children (WHO, 2002). From the point of consumer health protection, world organisations are taking collective steps and the training material from the WHO bearing title "Five Keys to safer food" assumes significance in reducing the burden of food-borne diseases.

Most important issues come from the question that who is responsible for food safety. Obviously, each and every player concerned with all activities are responsible for safety of the consumer. Over the years systems are developed or being developed continuously with the aim of consumer protection. Food safety means that food will not harm the consumer if consumed in the recommended way (CAC, 2017). Food safety is also referring to the absence of hazards entering the system at any stage of processing and causing foodborne illness (Jevsnik et al., 2008). Therefore, the food safety system should be designed to control the food production process based on the available prevention principles and understanding. The food safety producers have to implement the food safety management system to ensure safety of the food to the expectations of the consumers. The world food summit in 2002, view this as the right of everyone to have access to nutritious and safe food making every effort to establish, implement and upgrade the food safety and quality control systems everywhere (Kondakci & Zhou, 2017).

It is clearly demonstrated world over that the food borne illness are the consequence of unhealthy and unhygienic food production environment which have direct impact on the quality of food. This not only impact the consumers health but also economic consequences (Matthews, 2013). In the context of global market reach, the requirement of systematically managed safety in food supply chains is strong and has been staunchly followed in the regulatory framework. Besides, the regulatory measures are given priority and often harmonised to the requirements of international consumers as well, signifying the importance of food safety.

The concept of food safety and the consequences of unsafe food are well understood by the consumers today and their expectations from the food industries are high with respect to quality, diversified products, safe certificates etc. while looking for a food. This is the primary driving force for the food industries to go for improved quality standards by adopting the better food safety standard systems (FSMS) in the production systems and to focus on safety, quality, efficiency, reliability and environmentally friendly as well as economic products and packaging (Wentholt et al., 2009; Al-Busaidi et al., 2017).

[1] Principal Scientist, PME cell incharge, ICAR- CIFT, Cochin-29

As per the guidelines of Codex Alimentarius Commission the food meant for consumption shall provide guarantee of its safety to the consumers and it becomes the necessity of the producers to prevent the incidence of hazards at any point from "farm to fork" or from any other system.

In order to provide the basic understanding on this very principle, the International Organization for Standardization (ISO) provided the requirements of a food safety management system and reiterates that it is the responsibility of the organisation concerned to control and coordinate by setting quality objectives and implementation of quality policy for food quality assurance with a system of continuous improvement.

What is Food Safety Management System?

Food Safety Management System (FSMS) is a written document which discusses the details of managing food safety and hygiene in a production system. The system has its own risk profile and is also under the governance of regulatory provisions and therefore the FSMS shall detail the procedures used to maintain compliance by indicating hazards and risks specific to the system and their control and other relevant information necessary to manage the food safety successfully. The established global standard ISO 22000:2005 was used extensively since its release in 2005 and has undergone revisions and updates over the year to accommodate the changes (Table 1).

Table 1 Chronology of developmental old FSMS

FSMS	Scope	Year of Implementation
ISO 22000: 2005 FSMS: Requirements for organization in food sector	Ensuring the absence of feeble links in food chain	2005
ISO/TS 22002-1:2009: PRP on food safety-part 1: Food manufacturing	Technical specifications specify requirements for establishing, implementing, and maintaining PRPs to assist in controlling food safety hazards	2009
ISO/TS 22003:2007: FSMS—Requirements for bodies providing audit and certification of FSMS	Technical specifications define the applicable rules for the audit of a FSMS and offer synchronized guidance for accreditation of certification bodies compliant with ISO 22000	2007
ISO/TS 22004:2005 FSMS-Guidance on the application of ISO 22000:205	Providing guidelines for implementation of ISO 22000 for food safety	2005
ISO 2005:2007: Traceability in the feed and food chain: General principles and basic requirements for system	Standard gives the principles and specify the basic requirements for the design and implementation of a feed and food traceability system	2007

design and implementation		
ISO/TS 22002-3:2011 Specific prerequisites for farming		2011
ISO/TS 22002-6:2016 PRP on food safety Part 6: Feed production	Providing guidelines for implementation of ISO 22000 in feed production	2016

The ISO incorporated the principles of Hazard Analysis and Critical Control Point (HACCP) and pre requisite programmes in to the ISO 22000 quality management system in 2005 and the standard includes rules, definitions, or test procedures of different characteristics and technical specifications (Raspor & Ambrozic, 2012).

The standard can be implemented by anybody connected with food chain business directly or indirectly. ISO 22000 includes all standards that reinforce implementation of this system in trustworthy and professional manner. The food chain covers all steps of production and manufacturing operations including consumption of processed and unprocessed food products. There are also instances that food chain includes organizations that are not directly involved with food processing but with production of ingredients or certain raw materials which also come under the purview of food production system (Jung, Jang, & Matthews, 2014). The ultimate objective of ISO 22000 is to deliver safe and quality food to the consumer. The ISO 22000:2005 has clauses discussing the FSMS requirements followed by management requirements, Pre-requisite programmes for hazard control and verification, hazard analysis, validation, verification and documentation (Table 2). The standard also provides a sort of comparison between ISO 22000:2005 and ISO 9001:2005, comparison between HACCP and ISO 22000:2005 as well as examples of control measures and PRPs and the selection of appropriate control measures. ISO 22000 helps to plan, establish, and implement FSMS for an organization. The ultimate principle of food safety is to control the hazards with a view to protect consumer health.

Table 2 Clause-wise description of ISO 22000

Clause		Description
1	Scope	Defines the scope of ISO 22000 and identifies certain limitations and exclusions.
2	Normative references	Refers to other publications that provide information or guidance
3	Terms and definitions	Identification and definition of key terms that are of fundamental importance for FSMA and for using ISO 22000
4	FSMS	It discusses about the general requirements, documentation requirements for ISO 22000 Standards.

5	Management responsibility	It discusses about the management responsibility, food safety policy, responsibility and authority, food safety team leader, communication, and management review
6	Resource management	It details out the human resources, competence, awareness and training, infrastructure, and work environment
7	Planning and realization of safe products	It describes the PRPs, preliminary steps to enable hazard analysis, product characteristics, flow diagrams, process steps and control measures, hazard analysis, establishment of OPRP, HACCP plan, verification plan and traceability, control of nonconformity.
8	Validation, verification, and improvement of FSMS	It discusses about validation, verification, and improvement of FSMS

The regulatory and statutory requirements applicable to food safety in an organization are focused through food safety management system. Capacity building in the area of food safety with specific reference to trade related requirements along the different stages of the production, procurement, processing and distribution is an important element of the FSMS system (Matthews et al., 2014), besides minimising food safety hazards in order to provide safe food for human consumption (Pan, Huang, & Wan, 2010). Therefore, FSMS provides a framework of planned systematic activities to identify, minimise or eliminate the possibility of hazard in food, besides providing control at all stages in the food chain. The important aspect of ISO 22000 is the assurance given by the standard in the whole of value chain namely raw materials, process, product distribution chain and management beside the peripheral requirements contributing to the overall quality of the product including upgradation of technology, machinery manpower and product safety aspects (Psomas et al., 2018).

Components of ISO 22000: 2005 standard

The ISO 22000 quality management systems includes verifiable parameters with reference to incidence, analysis and mitigation of hazards, communications (external and in-house), responsibility designation, implementation of risk management, continuous improvement, and good health practices. The system also facilitates differentiating with the help of ISO 22000 organizations can easily differentiates between critical control points (CCPs), operational PRP (OPRP) and PRP.

Prerequisite programme

The pre requisite programmes are "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". These are defined by different nomenclature for different environment namely good agriculture practice (GAP), good laboratory practice, good hygienic practice (GHP), good manufacturing practice (GMP), good aquaculture practices (GAqP),

good transport practice (GTP), good storage practice (GSP), good retail practice, good catering practice, good veterinarian practice, good housekeeping practice, good production practice, good distribution practice, good trading practices etc. (Raspor & Ambrozic, 2012).

Table 3 Major components of pre-requisite programme

1.	Structure and layout of buildings and linked utilities
2.	Layout of premises, including workspace and employee facilities
3.	Supplies of air, water, energy and other utilities
4.	Supporting services, including waste and sewage disposal
5.	Equipment suitability and accessibility for easy cleaning, repairs and preventative maintenance
6.	Management of purchased materials (e.g., raw materials, ingredients, chemicals, and packaging), supplies (e.g., water, air, steam, and ice), disposals (e.g., waste and sewage), handling of rework and products (e.g., storage and transportation)
7.	Measures for the prevention of cross-contamination
8.	Cleaning and sanitizing
9.	Pest control
10.	Personal hygiene
11.	Trainings

These PRPs must be put in practice before implementing HACCP. The PRP and HACCP together contribute to the required effect along the value chain in the elimination hazards. Most important requirements for implementation PRPs, as given in ISO 22000, are given in Table 3 (Allata et al., 2017). PRPs ensure hygienic conditions throughout the food chain suitable for the production of safe food for human consumption. The decision tree which can be followed in finalising the type of control namely PRP, OPRP or HACCP etc. is given in Fig 1.

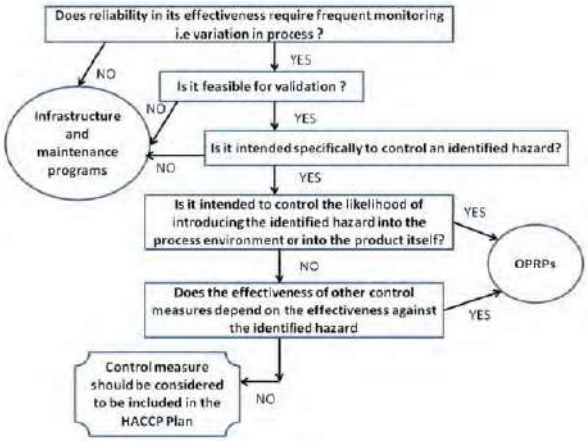

Fig 1 Decision tree approach to categorize PRPs *(Adopted from Panghal et al., 2017)*

Operational prerequisite programme (OPRP)

The pre-requisite programme identified by hazard analysis which are crucial to control the entry of hazard in to the production environment is called operational PRP and are essential to control product-specific hazards that are not controlled through CCP. It is therefore very important to identify during hazard analysis whether the incidence of hazard is controlled by PRP or OPRP.

The ISO 24000 clearly indicates that the decision on the type of control is important to get a full proof control on the system as higher the hazard level or its frequency of occurrence, the control measure belongs to the HACCP plan. Similarly, more severe is the hazard on consumer health the higher the possibility that the control belongs to HACCP plan. PRP, OPRP and CCP can be a standalone or combination measure in control hazards in a food production system but frequently OPRP is product specific. In other words, OPRPs control the likelihood of introduction of contamination and its proliferations while PRPs ensure strictly ensure sanitary and hygiene production environment. Also, PRP is general applicable to the whole system while the OPRP and CCP are product specific (Fig 2).

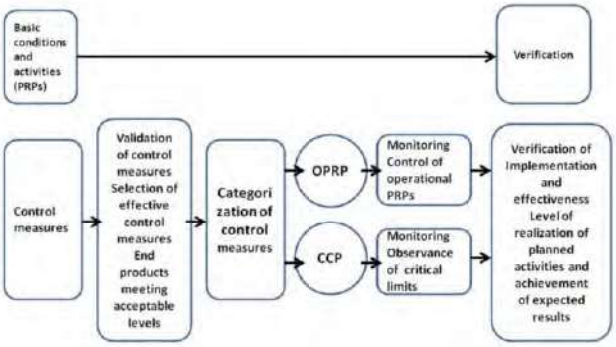

Fig 2. System approach to control and verification

(Adopted from Panghal et al., 2017)

Hazard Analysis and Critical Control Point (HACCP):

HACCP is a systematic and science-based HACCP system identifies specific hazards

and measures for their control in order to ensure food safety. HACCP mainly focusses on prevention instead of relying on end product testing only (Raspor & Ambrozic, 2012). The principle involved in HACCP are given in Table 4. The of HACCP is not a "stand alone" programme in a food processing facility but need to be built on other food safety programs such as GMP, PRP etc. that are practiced by the facility and will address food safety and food quality issues that are not critical for the reduction of food safety hazards.

The system is effective only when there is absolute a critical observation at different stages of the production process starting from raw material purchase to finished product and further till it reaches the consumer (Montville & Matthews, 2007). Greater emphasis is given on the continuous improvement with improved food safety performance, derived through the establishment and achievement of tangible food safety objectives. The important components for effective implementation include having a thoroughly understood food safety policy for the

organisation, emergency preparedness and quick response system to act in the event of a hazard incidence and presence of a traceability system for every component used in the production process.

With respect to implementation there is always a confusion on the type of standard to be implemented for food products. It is clear that ISO 22000:2005 is concerned with food safety while the ISO 9001 ensures quality. Therefore, it is often considered together. It is also a fact that ISO 22000: 2005 includes both the systems namely HACCP and ISO 9001. The arrival of several private standards also leads to the confusion on the suitability of the standards but it is reported that the harmonisation of national with global standards takes care of this to a large extent (Fernandez-Segovia et al., 2014).

Certification process

The procedure for FSMS certification of organization involves first the implementation of management system, which after review need to be certified following the norms. Then a preaudit is carried out to demonstrate the gap between the documents and the system and appropriate measures are taken up to harmonise the gaps a full audit followed by the conformation audit to follow up the nonconformities in the audit which is followed by certification. After that surveillance audit is carried out as per the norms of the certifying organisation and the certification is maintained.

Table 4 Principles and description of HACCP

	Principle	Description of principle
1	Conduct a Hazard Analysis	Listing the steps in the process and identifying where significant hazards are likely to occur
2	Identify the Critical Control Points	A critical control point (CCP) is a point, step or procedure at which control can be applied and a food safety hazard can be prevented, eliminated or reduced to acceptable levels. Identification of the critical control points in the process. A critical control point may control more than one food safety hazard or in some cases more than one CCP is needed to control a single hazard. The number of CCP's needed depends on the processing steps and the control needed to assure food safety.
3	Establish Critical Limits	A critical limit (CL) is the maximum and/or minimum value to which a biological, chemical, or physical parameter must be controlled at a CCP to prevent, eliminate, or reduce to an acceptable level the occurrence of a food safety hazard. The critical limit is usually a measure such as time, temperature, water activity (Aw), pH, weight, or some other measure that is based on

		scientific literature and/or regulatory standards.
4	Monitor CCP	The monitoring procedures for the measurement of the critical limit at each critical control point is addressed. Monitoring procedures should describe how the measurement will be taken, when the measurement is taken, who is responsible for the measurement and how frequently the measurement is taken during production.
5	Establish Corrective Action	Corrective actions are the procedures that are followed when a deviation in a critical limit occurs. The steps that will be taken to prevent potentially hazardous food from entering the food chain will be identified along with the steps for correct measure. This usually includes identification of the problems and the steps taken to assure that the problem will not occur again.
6	Verification	Those activities, other than monitoring, that determine the validity of the HACCP plan and that the system is operating according to the plan. This includes activities such as auditing of CCP's, record review, prior shipment review, instrument calibration and product testing as part of the verification activities.
7	Documentation	A key component of the HACCP plan is recording information that can be used to prove that a food was produced safely. The records need to include information about the HACCP plan. Record should include information on the HACCP Team, product description, flow diagrams, the hazard analysis, the CCP's identified, Critical Limits, Monitoring System, Corrective Actions, Recordkeeping Procedures, and Verification Procedures.

Private Food Safety Standards

Another situation is the use of private FSMS standards designed by non-governmental entities, such as food industry stake holder groups (Manning et al., 2006), individual retailers or retailing groups and industry associations. The major player in this context is British Retail Consortium (BRC) Food, FSSC 22000, IFS Food, Dutch HACCP and other proprietary retailer standards. The BRC Global Standard for Food Safety developed and published in 1998 by BRC, a stakeholder group of British Retailers Consortium. FSSC 22000 developed by , which includes requirements of ISO 22000, ISO 22002-1 and other additional the Foundation for Food Safety Certification (FSSC), founded in 2004, IFS food standard developed by the collaboration of three retail federations from Germany, France and Italy, SCV certification by the National Board of Experts HACCP – The Netherlands, Global Red Meat Standard, published by the Danish Agriculture & Food Council, Safe Quality Food (SQF) owned and managed by the Food Marketing Institute (FMI) based in Virginia, the PrimusGFS food safety

audit scheme, owned and managed by Azzule Systems, United States and Proprietary FSMS standards owned by individual organizations such as a retail chains and are enforced in their supply chains (Rafeeque and Sekharan, 2018).

No doubt the presence of certification or accreditation increases customer acceptability and satisfaction. But the main issue is the sector wise non-availability of standards and is often developed based on the need of the sector as voluntary standard or adoption of a national standard. This creates a sort of confusion in the global business. Another issue for the industry is the increasing cost of certification or accreditation. However, standardization of guidelines simplifies the process, ensures better planning and resource optimization as well as reduces cost, enhances efficiency, wider applicability and improves documentation.

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