



XVIII Annual International Conference of the Society of Operations Management (SOM-14)

A Study on implementing Food Safety Management System in Bottling Plant

Manish Kumar Singh*

Post Graduate Student, Department of Management Studies, Indian Institute of Technology Roorkee, Roorkee - 247667, India.

Abstract

This study provides the need for implementing Food Safety Management System (FSMS) to ensure the safety of the drinking water. Procedural challenges faced in adaptation of ISO 22000:2005 Food Safety Management Standards for a bottling company to achieve its safety goals. For implementing the FSMS, the general and documentation requirement with modular approach and the Management responsibility for their food safety policy, hygienic design, specifying the program for cleaning and sanitisation, equipment maintenance, control for strict raw materials and analysis of critical control point (CCP) are taken care of. For guarantee food safety, before the implementation the Pre-requisite Programs is followed for controlling the generic hazards. The systematic approach for Hazard analysis with the help of a practical approach model gets a control on non-conforming product/material and also for potentially unsafe products. The implementation of FSMS covers all the manufacturing operations, from receipt of raw materials, material storage, processing, packaging, warehousing and distribution.

© 2015 The Authors. Published by Elsevier Ltd. This is an open access article under the CC BY-NC-ND license (<http://creativecommons.org/licenses/by-nc-nd/4.0/>).

Peer-review under responsibility of the scientific committee of XVIII Annual International Conference of the Society of Operations Management (SOM-14).

Keywords: Food Safety Management System (FSMS); ISO 22000:2005 Food Safety Management Standards; Modular Approach; Critical Control Point (CCP); Hazard Analysis.

1. Introduction

The Carbonated or non-carbonated water which is bottled in the containers for drinking purpose either in PET or glass bottles with certain flavour, minerals or with no additions should go according to Food Safety Management System standards. “A Food Safety Management System (FSMS) is a network of interrelated elements that combine

* Corresponding author. Tel.: +91-8004443999.

E-mail address: manishkumarsingh.iitr@gmail.com

to ensure that food does not cause adverse human health effects. These elements include programs, plans, policies, procedures, practices, processes, goals, objectives, methods, controls, roles, responsibilities, relationships, documents, records, and resources.” (Davids, 2011) Bottled Drinking Water is the product of a company produced and distributed by their Trade name. Bore holes are used to draw water and then treated to comply with standards of drinking water through filtration and Reverse Osmosis Systems. The filling of water is done in different sizes of PET and glass bottles. Today PET bottles have replaced glass bottle as it can withstand the pressure of Carbon dioxide also for its light weight and resistance to breakage.

Let us take a situation where the company is producing in PET bottles with production of caps, labels and others used in water packaging which allows for complete control on value chain for both products and packaging material. With a well-established customer base and distribution system the company recognizes the need for establishing a Food Safety Management System to ensure safety for the drinking water. So, the company has therefore adopted ISO 22000:2005 Food safety Management standards to achieve its goal. The application covers the company’s drinking water operations from production of PET bottles, closures, ingredients (raw water), water purification process, filling water in PET bottles and storages.

Nomenclature

PET	Polyethylene Terephthalate
RO	Reverse Osmosis
FSMS	Food Safety Management System
HACCP	Hazard Analysis and Critical Control Point
CCP	Critical Control Point
SQA	Supplier Quality Assurance
PRP	Pre-requisite Program
OPRP	Operational Pre-requisite Program
QAM	Quality Assurance Manager
IMCR	Incident Management and Crisis Resolution
GMR	Good Manufacturing Practices

1.1. Definitions

HACCP	A system which identifies evaluates and controls hazards which are significant for food safety (Alimentarius, 2003).
Contamination	The introduction or occurrence of a contaminant in food or the food environment (Codex, 1997).
Contaminant	Any biological or chemical agent, foreign matter or other substances not intentionally added to food which may compromise food safety or suitability (Codex, 1997).
Corrective action	Procedures to be followed when a deviation occurs from the critical limits and the CCP goes out of control (Alimentarius, 2003).
Critical Control Point	A step/point or procedure at/through which control can be applied and is essential to Prevent, reduce or eliminate a food safety hazard to an acceptable level (Alimentarius, 2003).
Critical Limits	Criterion which separates acceptability from unacceptability or an absolute tolerance or value which must be met for each control measure at a CCP for significant hazards (NAC, 1992).
Food safety	Assurance that food will not cause harm to the consumer when it is prepared and/ or ingested according to its intended use (WHO, 2009).
Food safety hazard	A biological, chemical or physical agent in or condition of, food with the potential to cause an adverse health effect; or a property which may cause a food product to be unsafe for consumption (Echols, 2001).
HACCP Plan	A document(s) prepared by HACCP Team in accordance with the HACCP principles that define control of identified significant food safety hazards in a specific process to ensure

product safety (Alimentarius, 2003).

Hazard analysis	The process of collecting and evaluating information on hazards and conditions leading to their presence to decide which are significant (evaluate likelihood and severity) (Alimentarius, 2003).
Prerequisite program	Documented program that need to be in place prior to the application of HACCP (Mortimore & Wallace, 2013).
Operational Pre-requisite-Program	A program identified by the hazard analysis as essential to control the likelihood of introducing food safety hazards, the contamination or proliferation of food safety hazards in the product(s) or in the processing environment (Mortimore & Wallace, 2013).
Supplier quality-Assurance	The program of actions to ensure the safety and quality of the raw material supply (Wallace, Sperber & Mortimore, 2011).
Food Chain	The sequence of the stages and operations involved in the production, processing, distribution, storage and handling of a food and its ingredients, from primary production to consumption (ISO, 2005).

2. Food Safety Management System Requirement

2.1. General Requirements

The company's documentation should be based on the requirements of ISO 22000:2005 taking into account other relevant statutory and customer requirements. The documentation should also consider the need for the realization of benefits that derives from a well designed and implemented FSMS. This includes customer confidence/satisfaction, objectives for quality, food safety as well as regional and international trade requirements for food and beverage products.

2.2. Documentation Requirements

The food safety policy is documented that the required procedures and records are found within PRPs, OPRPs and HACCP modules. For the purpose of effective development, implementation and maintenance of the standards Modular Approach has been used. Usually the documentation of the system is shown in "Document Management Program" in the company which covers the process of document creation, formatting, numbering revisions, distribution and control. The document management program is designed to ensure that there should be consistency in documentation of quality management system and the personnel are using the most current version in food safety system. The QAM or designated FSMS co-coordinator has the overall administrative responsibility for the program to be effective.

3. Overview for Study

This provides an overview on the process for documenting the creation or modification, formatting, review and approval, obsolescence, change requests, distribution and tracking. Document owner is a person responsible for preparing or modifying the document. And controlled documents are those which are distributed by the QAM such that the list of copyholders is maintained. Since control includes the documentation in the right place and to protect it from the access by the third parties. Process owner start the process by creating new document based on the business need for process monitoring and FSMS requirements. Process owners and Departments Heads will decide if the documents received from external source or portion of it are to be distributed in a controlled manner so as to ensure that recipients have the latest copy. If so, it will be given to FSMS coordinator for stamping controlled copy before distribution.

Usually a unique code is assigned for each document. The document code can be made up of three or more characters separated by hyphens, commas, etc. In numbering Manual, Program, Standard operating procedure or form first two characters shown in the name of the company, the second two can show the plant or department and the last characters shown is the number in series of the programs. So, now all documents listed in the Master control list show the most current versions distributed. When documents become obsolete FSMS coordinator will retain documents from copy holders and shred. One document may be kept for historical purposes up to a period of 2 years, after which it shall be shredded. Changes as a result of typographical errors shall not follow this formalized system.

3.1. Corrective Action

Corrective Action pertaining to document management is basically to estimate the reoccurrence of non-conformance, identified by different sources such as internal or external audit, management review, and any employee request. The company follow the corrective action program procedure.

Equations and formulae should be typed in Mathtype, and numbered consecutively with Arabic numerals in parentheses on the right hand side of the page (if referred to explicitly in the text). They should also be separated from the surrounding text by one space.

4. Management Responsibility

4.1 Commitment

In planning of the FSMS, the management ensures Food Safety is supported in Business Objectives. The communication is done to all employees and other interested parties on issues relating to food safety and their roles in FSMS, with respect to customers, statutory and regulatory requirements. A Food safety policy is established and communicated to all employees. The coordinator will ensure the allocation of resources is done to support the FSMS through management reviews.

4.2. Food Safety Policy

The company defines and documents its Food Safety Policy. As an example the Policy can be “The Management and Staff of the company are committed to consistently produce and distribute safe, high quality drinking water that meets international standards for drinking water for all its customers and consumers”.

To achieve its promised quality, the company will strictly adhere to food safety management system principles based on the requirement of ISO 22000:2005 Food Safety Standards (ISO, 2005) from the receipt of raw materials through processing, bottling and storage of its drinking water and company shall also strive to comply with the other applicable statutory and consumer requirements.

4.3 Emergency Preparedness and Response

Implementing Incident management/ crisis resolution procedure to effectively prevent and manage potential emergency situation/incident in a manner that protects customers, asset and the image.

- IMCR should be renewed at an interval of three to six months so that efficiency is evaluated.
- Depending on the situation, the assessment of the risk is done with appropriate methodology.
- Implementation of action plans to identify the risk including business, in the event of fire serious injury, disputes, counterfeiting, serious and multiple complaints, etc.
- Training to IMCR coordinator and the alternate person.
- Contact stakeholder in the event of an incident.
- The record of the renewal shall be maintained for future reference.
- Incident that are needed for corrective action are incorporated in the corrective action and preventive action mechanism

5. PLANNING AND REALIZATION OF SAFE PRODUCTS

The company adopted the ISO 22000:2005 standards for a safe drinking water through number of activities.

5.1. PRE- REQUISITE PROGRAMS

Prior to the implementation of the standards, the company needs to implement pre-requisite program (PRPs). This PRPs control generic hazards. That generally account for 80% of the hazards in food processing environment. A pre-assessment is done to identify all the gaps in

- ⇒ Suppliers quality management/assurance(SQA)-inspection on incoming or riots
- ⇒ Employees health and hygiene
- ⇒ Cleaning and sanitation
- ⇒ Design of premise
- ⇒ Maintenance of equipment
- ⇒ Sanitary facilities
- ⇒ Recalls for products-traceability
- ⇒ Pest control
- ⇒ Ingredients storage
- ⇒ Auxiliary materials storage
- ⇒ Warehousing storage of finished products

5.2. PRELIMINARY STEPS TO ENABLE HAZARD ANALYSIS

FSMS team require this steps for hazard analysis

1. Team leader appointment
2. Training of FSMS team on ISO 22000:2005
3. Product descriptions or its characteristics shall be documented
4. Product-contact materials
5. End product characteristics
6. Preparations and verification of process flow diagrams
7. Control measures

5.3 HAZARDS ANALYSIS

5.3.1 SYSTEMATIC APPROACH

A food safety management implements principles of HACCP based on following reference

- ISO 22000:2005 food safety management system standard (ISO, 2005).
- Recommendation of international code of practice-general principles of food hygiene (Wallace & Williams, 2001).
- Code of practice by hygiene in food and drink manufacturing industry.

HACCP-A practical approach (Mortimore & Wallace, 2013). The modular approach which focus on the concept of internal suppliers and internal customers. This approach to FSMS is useful where the internal process is to be carried out. The upstream modules are from internal suppliers to the downstream customers. If FSMS is effectively applied then logically to ensure that output from each module are safe, then the whole value chain shall produce safe finished goods/ products. However this must be supported by properly designed and implemented PRPs. As an example to it is the output of RO water treatment (treated water) is input to the filling operations, resulting in treated drinking water in PET bottles.

The FSMS team develops few tools like

- Hazard Identification for product characteristics
- Hazard Identification for the characteristics of the end product
- Hazard Identification for process flow diagrams with onsite verification
- Hazard Identification for potential hazards identification testing

This gives the material safety data sheets for measuring

- Materials/ Ingredients/ Packaging- inherent hazards
- Personnel activities at each process step
- Equipment
- Production environment
- Build-up due to process delays, store mainly biological or chemical reactions
- PRP related hazards

So the hazards are assessed or evaluated on their level of significance

- Biological Hazards
- Chemical Hazards
- Physical Hazards
- OPRP/CCP Hazards

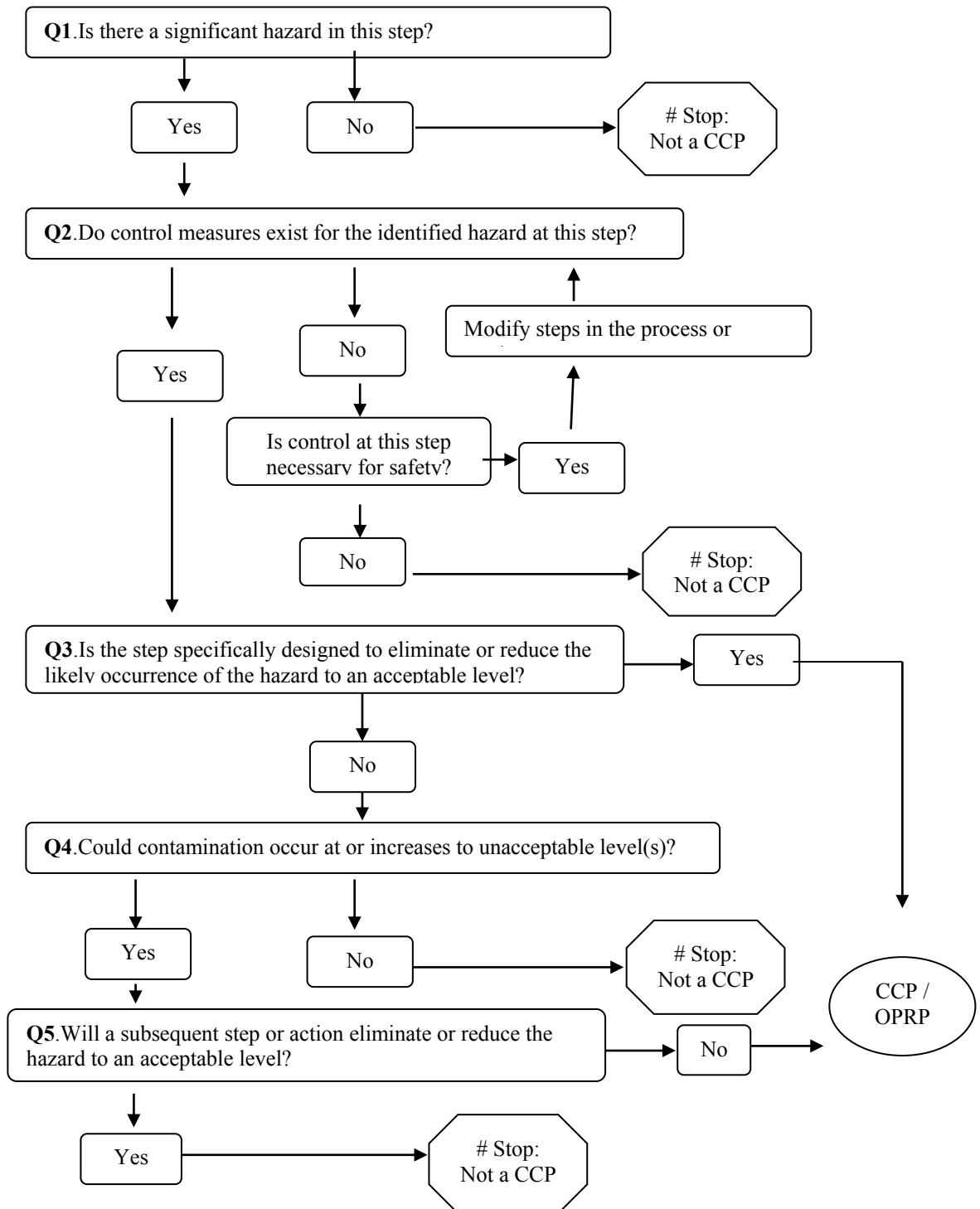


Fig. 1. Establishing the OPRPs and the HACCP plan
 HACCP Decision Tree: Adopted From Mortimore & Wallace (1998).

5.3.2. Control for Non – Conforming Products/Materials

A procedure to prevent the distribution of non-conforming material and products when critical limits exceed there is a control loss of operational PRPs and nonconforming trademark material, product or equipment's. To avoid this it shall include:

- a) Identify and control non-conforming products or materials.
- b) Responsibilities and controlling for nonconforming products as deemed appropriate.
- c) Re-verification.
- d) Disposition of materials – nonconforming.

Records of nature of nonconforming, lot numbers, quantities, causes and consequences, action taken, responsible persons or any other entity is recorded.

5.4. Corrective Action

The documented procedures shall include

- a) Nonconformities Review
- b) Causes of nonconformities
- c) Criteria for entering the corrective action
- d) Determine and implement the action needed
- e) Tracking the action status
- f) Review the corrective action effectiveness
- g) Evaluate the IMCR to manage incidents and crises

6. Control of Monitoring and Measuring Instruments

Laboratory measuring and monitoring instrument used to monitor conformity of product and process to requirement the location of each devices has been identified so as to facilitate traceability of calibration and record keeping. Prior to use the control devices measurement for the first time, the following repair and recalibration and verification should be undertaken before the equipment is put into use. Only trained professionals shall be responsible for adjusting the measuring the test devices to be accurate. This is to avoid invariability in measured results. Measuring equipment shall be protected from deformation due to handling, maintenance and storage. Use of computer for measuring and conforming of specific requirement shall be confirmed to the intended application prior to initial use and shall be reconfirmed as necessary. Calibration records and results of calibration and verification shall be maintained (Sperber, 1998).

7. Validation, verification and improvement of the Food Safety Management System

To ensure the continued and suitability of effectiveness, the FSMS team shall carry out the activities like

- Validate the control measures.
- Carryout internal audit by FSMS team for OPRPs and HACCP plans.
- Review on PRPs audit to ensure continued effectiveness.
- FSMS team meeting half monthly and monthly to review performance of the system.
- Refer, if any issue to the management.
- Carry out investigative audit for CCP.
- Review the result by external auditors of this surveillance audit.
- Customer complaint data and analysis (trending of CCP and OPRPs performance data).
- Communicate through HOD's (coordinator all the issues of FSMS).

- Gauge improvement based on system performance.
- By Gap analysis looking for emerging hazards and to provide training accordingly.

8. Conclusion

In order to successfully implement FSMS by overcoming the challenges faced by an organization it is necessary to impart awareness and training to its employee. The company has to provide training on food safety for FSMS team members through competent personnel who also will facilitate the implementation. The company ensures that all employees involved in food handling activities have adequate training to entrench a culture of good manufacturing/hygiene practices and effective communication. The FSMS Team leader in collaboration with Plant Manager and Supervisor will train the operators on general food safety and hygiene concepts. The core Team members will be responsible for general food safety awareness and training of operators and shop floor personnel. For operators responsible for OPRP and CCP, specific training shall be conducted with focus on their role on FSMS with emphasis on their assigned stations. The importance of CCP monitoring, record keeping and use of deformation procedure is emphasized to all managers managing CCPs. Top management will ensure that the FSMS is renewed at least bi-annually and updated if necessary as per management reviews. Any updates will be recorded and reported by group QAM.

References

- Alimentarius, C. (2003). Hazard analysis and critical control point (HACCP) system and guidelines for its application. *Annex to CAC/RCP*, 1-1969.
- Alimentarius, C. (2003). Hazard analysis and critical control point (HACCP) system and guidelines for its application. *Annex to CAC/RCP*, 1-1969
- Codex, (1997). Codex Committee on Food Hygiene. (1997). Recommended international code of practice general principles of food hygiene. In *Food hygiene basic texts*. Rome: Food and Agriculture Organisation of the United Nations, World Health Organisation
- Davids, S. (2011). An evaluation of the impact of food safety management systems within the wine industry in the Western Cape, South Africa (Doctoral dissertation, Cape Peninsula University of Technology).
- Echols, M. A. (2001). Food safety and the WTO: the interplay of culture, science and technology. Kluwer Law International.
- ISO (2005). ISO 22000:2005. Food safety management systems-Requirements for any organization in the food chain. Switzerland: International Standard Organization.
- Mortimore, S., & Wallace, C. (2013). HACCP: A practical approach. Springer.
- Mortimore, S., & Wallace, C. (2013). Prerequisites for Food Safety: PRPs and Operational PRPs. In HACCP (pp. 113-154). Springer US.
- NAC (1992) National Advisory Committee on Microbiological Criteria for Foods. (1992). Hazard analysis and critical control point System. *International Journal of Food Microbiology*, 16(1), 1-23.
- Sperber, W. H. (1998). Auditing and verification of food safety and HACCP Food Control, 9(2), 157-162.
- Wallace, C., Sperber, W., & Mortimore, S. E. (2011). Food safety for the 21st century: Managing HACCP and food safety throughout the global Supply chain. John Wiley & Sons.
- Wallace, C., & Williams, T. (2001). Pre-requisites: a help or a hindrance to HACCP. *Food control*, 12(4), 235-240.
- WHO. (2009). A report on " ".retrieved from www.fao.org/docrep/012/a1552e/a1552e00.pdf. Accessed on December 5, 2014.