ISO 22000:2005 – “Food safety management systems. Requirements for any organization in the food chain”
Implementation in the bottled water industry
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1. Introduction

The need to facilitate international trades, the increasing competitiveness among enterprises and today’s universally accepted maxim “people have the right to expect their food to be safe, to have good quality and to be suitable for consumption”, forced each country and the international organizations to create, adopt and implement efficient tools that could help to produce safe products.

1.1. Codex Alimentarius

With this propose and to ensure fair trade practices in the food trade, FAO and WHO have created in 1963 the Codex Alimentarius Commission. Its mission was to develop food standards, guidelines and related texts (such as codes of practice) under the joint FAO/WHO Food Standards Program.

The Codex Alimentarius Commission promoted the coordination of all food standards, working together with international governments and non-governmental organizations, and became the single most important international reference for developments associated with food standards.

It is fair to say that, through the elaboration of Codex standards and the consideration of all related issues, the Codex Alimentarius Commission has helped significantly to put food as an important element on political agendas. In fact, governments are actually extremely conscious about the political consequences to expect if they fail to heed consumer’s concerns regarding the food they eat. Food-borne illnesses are at least unpleasant but in the worst case they can be fatal. Moreover, there are other consequences. Outbreaks of food-borne illness can damage trade and tourism and can lead to loss of earnings, unemployment and litigation. Poor quality food can destroy the commercial credibility of suppliers, both nationally and internationally, while food spoilage is wasteful, costly and can adversely affect trade and consumer confidence.

The role of the Codex Alimentarius Commission has evolved with the development of the Codex itself. The task of creating a food code is immense and virtually endless, due to the continuing research and product development. The definition of food standards and their compilation into a code that is credible and authoritative requires extensive consultation as well as the collection and evaluation of immense information. This has to be followed up by the confirmation of the final results and sometimes there is a need to achieve an objective compromise in order to satisfy different reliable, scientifically based views.

1.2. HACCP

In order to prevent and control risks throughout the food supply chain the Codex Alimentarius Commission adopted an efficient instrument called HACCP (Hazard Analysis and Critical Control Points).

HACCP was first presented in the 60’s when a company called Pillsbury, the National Aeronautics and Space Administration (NASA) and the US Army Laboratories at Natick decided to
develop a system of managing safe food production for space programs. This concept rapidly became a reference accepted internationally and was adopted and recommended since 1986 by the Codex Alimentarius Commission as “the food safety management tool”.

In EU, this system is mandatory since 1993 (Directive 93/43/EC).

Hazard Analysis and Critical Control Points is a method based on the “risk analysis” and consists on a systematic and structured identification of all potential hazards that may be reasonably expected to occur along the food chain in order to establish preventive measures that can avoid or, at least, control them.

The system refers seven main principles:

First principle – hazard analysis;
Identification of all potential hazards that may occur along the process (since raw materials to manufacture and distribution) and eventual preventive measures that can be taken to control them;

Second principle – from the list of potential hazards, determination of Critical Control Points (CCP);

Third principle – establishment of critical limits for each CCP identified;

Fourth principle – monitoring each CCP to ensure that the process is under control at each of those points;

Fifth principle – corrective measures in order to deal with deviations in CCP, if they occur;

Sixth principle – verification procedures in order to determine if the HACCP system is working properly;

Seventh principle – documentation and record keeping procedures.

In practice, these seven principles can be implemented in 14 sequential steps, as follows:

1. Plan scope;
2. HACCP team;
3. Description of the product;
4. Identification of the intended use of the product;
5. Flow diagram;
6. In loco checking of the flow diagram;
7. Hazard analysis (First principle);
8. Determination of CCPs (Second principle), using the “decision tree” (Figure 1);

9. Establishment of critical limits for each CCP (Third principle);
10. Monitoring each one of the determined CCP to ensure that the process is under control (Fourth principle);
11. Corrective measures, in order to deal with deviations in CCP if they occur (Fifth principle);
12. Verification procedures (Sixth principle);
13. Documentation and record keeping procedures (Seventh principle);

1.3. ISO 22000

ISO 22000:2005 – “Food safety management systems - Requirements for any organization in the food chain”, is a generic safety management system standard that should be matched when
any organization in the food chain needs to demonstrate its ability to control food safety hazards (ensuring that food is safe at the time of human consumption).

This standard provides international harmonization in the field of food safety standards, offering a tool to implement HACCP throughout the food supply chain.

This ISO was first published in 2005 and specifies the requirements for a food safety management system (FSMS) that involves the following elements:

- Prerequisite programs (PPRs);
- Operational PPRs (OPPRs) and HACCP (according to the principles of the Codex Alimentarius);
- Managing the system;
- Interactive communication (between suppliers, customers, and regulatory authorities).

Hazard analysis is the key to an effective FSMS, since conducting a hazard analysis assists in organizing the knowledge required to establish an effective combination of control measures. ISO 22000 requires that all hazards that may be reasonably expected to occur in the food chain (including hazards that may be associated with the type of process and facilities used) are identified and assessed. Thus it provides the means to determine and document why certain identified hazards need to be controlled by a particular organization and why others do not. During hazard analysis, the organization determines the strategy to be used to ensure hazard control by combining the prerequisite programs and the HACCP plan.

By means of auditable requirements, ISO 22000 was designed to be used for Audit and Certification purposes and it specifies the requirements that enable an organization to:

- plan, implement, operate, maintain and update a FSMS with the objective of providing products that, according to their intended use, are safe for the consumer,
- demonstrate compliance with applicable statutory and regulatory food safety requirements,
- evaluate and assess customer requirements and demonstrate conformity with those mutually agreed customer requirements that relate to food safety, in order to enhance customer satisfaction,
- effectively communicate food safety issues to their suppliers, customers and relevant interested parties in the food chain,
- ensure that the organization conforms to its stated food safety policy,
- demonstrate such conformity to relevant interested parties, and
- seek certification or registration of its FSMS by an external organization, or make a self-assessment or self-declaration of conformity to ISO 22000:2005.

2. Case study – Bottling Water Company

2.1 The company

The company employs about 20 workers. The plant occupies near 5,000 m² and it includes the main building (with two floors), water tanks, silos for the storage of empty PET bottles, warehouses and the microbiology lab.

The production unit has two “filling lines” prepared for capacities of 5Lts, 1,5Lts, 1,0Lts, 0,5Lts and 0,33Lts.

The plant has a maximum production capacity of about 30,000,000Lt/year.

2.2 The FSMS

The main reason to implement a Food Safety Management System in a water plant is to control all chemical, physical and microbiological hazards related with all the steps of production (from the water collection and supply until the final product storage) and assure that the consumer gets safe products.
As it was mentioned before, to implement an operational FSMS, there is the need for the following elements:

- Prerequisite programs (PPRs);
- OPPRs and HACCP;
- Managing the system;
- Interactive communication.

2.2.1 Prerequisites Programs (PRPs)

PRPs can be considered as “basic conditions or activities that are necessary to maintain a hygienic environment throughout the food chain suitable for the production, handling and provision of safe products”.

PPRs must be adopted and implemented before HACCP. The most important to be considered in this case are:

1. **Installations and lay-outs**
   Good hygiene and manufacturing practices must be facilitated by internal lay-outs. Equipments, workers and material circuits should avoid sources of potential cross contamination.

2. **Production process and equipments**
   Risks of potential contaminations in utilities, equipments and the containers coming into contact with food should be minimized.

3. **Management (reception and storage) of purchased raw materials**
   Suppliers of raw materials must meet all requirements for the materials supplied and it is important to verify the compliance of those incoming raw materials with their specifications.

4. **Cleaning and sanitization**
   The established cleaning and sanitization programs should be suitable for each area or equipment. The purpose of these programs is to remove foreign bodies and reduce microorganisms to a level considered acceptable (throughout physical or chemical methods).

5. **Pest control**
   An efficient program for pest control is most important.

This program should guarantee that this kind of risks is reduced to minimum.

6. **Suppliers selection**
   All suppliers must be referenced and included in the database. At least an alternative supplier for each material should be ensured to the leading provider.

7. **Waste disposal**
   Defined areas must be prepared for the removal and storage of waste materials preventing contaminations that could affect other areas or the final product.

8. **Transportation**
   Transportation must take place in road vehicles properly cleaned and prepared for this purpose. “Shipping containers” can also be used for exportation.

9. **Personal Health and Hygiene**
   Personal health and hygiene is most important. Works must be sensitized for their behaviors and the risk they represent.

10. **Training**
    All employees, with no exception, must receive basic training in food hygiene and should be aware about their responsibilities on the safety of the final product. Tasks in specific equipment must have proper training before operation.

11. **Packaging and labeling**
    Packaging and labeling are most important. Package will be in direct contact with the product and label will transmit all information to the consumer.

12. **Traceability**
    Most important now a days is to be able to trace all suppliers used to produce any batch (or the consumers that received the final product). In case of any contamination or risk, this is the only way to identify the source or the next step of the chain that received it.

2.2.2 Operational PRPs and HACCP

To implement HACCP in this FSMS, all the 14 steps referred before were followed sequentially. However, first a Food Safety Team (FST) was
created. Composed by 4 elements the team was led by the Responsible of the Quality Department and helped by elements from the Production, the Maintenance and the Microbiology Lab.

The scope was then carefully defined. It included the plant and all range of products (from 0.33L bottles to the 5Lts and the water spray). Also all physical, chemical and microbiological hazards were considered.

It was made a detailed description of the product (including types of packaging, detailed physicochemical parameters and lifetime), as well as, it was defined its intended use.

The process flow was summarized in an easy to read diagram, providing an outline of the process which was checked in loco.

The sources of danger considered were:
- The water (raw material);
- CIP (Cleaning in place) processes and procedures;
- Workers;
- Materials (equipments and packaging);
- Environment.

In this plant, 23 areas of “high risk” were listed and 52 potential hazards were found.

After significance analyses and with the help of decision tree, 8 CCPs were identified (as listed):

<table>
<thead>
<tr>
<th>CCPs</th>
<th>Step</th>
<th>Hazard</th>
</tr>
</thead>
<tbody>
<tr>
<td>CCP 1</td>
<td>Reception and storage of purchased raw materials</td>
<td>Pre-forms</td>
</tr>
<tr>
<td>CCP 2</td>
<td>Reception and storage of purchased raw materials</td>
<td>Caps</td>
</tr>
<tr>
<td>CCP 3</td>
<td>Capture and adduction</td>
<td>Aquifer contamination</td>
</tr>
<tr>
<td>CCP 4</td>
<td>Water storing (in tanks)</td>
<td>Air</td>
</tr>
<tr>
<td>CCP 5</td>
<td>Bottles rinse</td>
<td>Rinse machine</td>
</tr>
<tr>
<td>CCP 6</td>
<td>Bottles filling</td>
<td>Filling machine</td>
</tr>
<tr>
<td>CCP 7</td>
<td>Capping</td>
<td>Capping machine</td>
</tr>
<tr>
<td>CCP 8</td>
<td>CIP</td>
<td>Insufficient rinse</td>
</tr>
</tbody>
</table>

The first seven CCP were managed by the HACCP plan and the last one, as an OPRP.

In these points, it was established control targets (critical limits) in order to evaluate if the CCP was under control.

Those limits were based on guidelines and regulation, experimental results and literature.

In order to ensure that the defined limits were being respected a sequence of measurements and observations were taken (on those CCP). When the monitorization attested a loss of control, a set of necessary actions was implemented with the purpose of bring the process back into control (if possible). If a critical limit is exceeded, specific procedures must be operated to perform.

It is still necessary to verify that the HACCP is implemented in accordance with plan and if it is effective. This check should be carried out in defined situations or dates.

2.2.3 Documents

FSMS (as HACCP) is a documented system. Records are the evidence of the achievement of activities and they are an important source of information to support proper implementation of the system and ensure its review when necessary.

In this company, documents were properly archived, indexed and available for consultation on places where necessary. The documentation is liable to be updated/changed and is kept for pre-defined periods, indicating the update status. In this case, documentation files are indexed as follows:

1. Legislation 2. Standards
5. Good practice guide 6. Hazard analysis
7. Procedures 8. Flowcharts
17. Pest Control 18. Waste disposal
23. Raw materials 24. RM Cert and Safety
25. Samples  Data Sheets
26. Testing 27. Claims to suppliers
28. Costumer complaints 29. Evaluation costumer satisfaction
30. Training 31. Internal Audits
32. Nonconformity 33. Meetings FST
34. Improvement opport 35. Documentary Check
36. Evidence of implem. Monitoring of the system
38. Obsolete 39. Calibrations

2.2.4 Interactive Communication

It is most important to ensure in a FSMS interactive communication with the food chain. Such communication should provide information on aspects related to food security that may be relevant to other organizations in the chain, thus ensuring that the relevant hazards are controlled at some point along the way.

Records about all communications involving elements identified in the chain must be kept. It is also important that there are predetermined channels of communication so when any danger occurs, this information is promptly transmitted to other interested parties in order to control the problem.

It is also important to ensure that issues and data relevant to food safety are communicated to all employees involved in activities with an impact on food security. It should also be ensured that the FST and top management have ready access to information in order to update and revise the FSMS.

3. Internal Audit

After the review and updating of the FSMS, an Internal Audit took place with a result of 72% of compliance with the requirements of ISO (by detecting 12 non-conformities).

The requirements used for Audit are listed in sections 4 to 8 of ISO and the results obtained are summarized on table 2.

In the Audit report, were made suggestions that should be examined by the FST and top management.

4. Conclusions

Based on the existing Codes of Best Practices and HACCP, with this work, it was possible to analyze, review, update and modify procedures, methods and documentation in order to implemented a Food Safety Management System fully operational and prepare this company for a possible certification under the NP EN ISO 22000:2005 - "Management Systems Food Safety" standard.

During this project the entire manufacturing process and all procedures and information (legislation, lay-outs and plants, flow sheets, forms, etc.) were evaluated, checked, and improved. It was stipulated a “Responsibilities Matrix” and a new OPRP was implemented (to control the CIP process). It also took place an exhaustive reevaluation of CCPs.

Regarding buildings and facilities some repairs were made and others were identifies. Those were essential to implement the FSMS. Unfortunately there were some works impossible to complete because of insufficient budget and the fact that some improvements need high investment.

At the operational level and with the inclusion of “pre-packaged control”, “laser coding” and “pallet labeling” it was possible to create better traceability and safety of the final product.
Procedures were also created to streamline communication, internally and externally (along the food chain and with consumers and regulators).

It was also developed a form for Internal Audit based on ISO 22000 specifications. The Audit took place in the end of this project.

In my point of view most of the work that will allow a future ISO 22000 certification is done and with some investment in identified areas these goal can be easily reached.

The possible implementation of ISO 22000:2005 is above all seen as an opportunity because it allows harmonizing on a global level, requirements for food safety management. Therefore, given the increase in exports, especially to Asian countries (like Taiwan, Singapore, Hong Kong or Macao), the standardization of methodologies, the optimization of procedures, the improvements in image and the prestige associated with these measures become a very important competitive advantage.

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