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The QRA as Design Criteria for Safety Management Systems. An Application to the Food Safety

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The paper shows how the hazard identification and evaluation phase of a Safety Management System (SMS) is the design criteria for the whole SMS, with its procedures. In particular, the selection of risk analysis methods and their results, in terms of frequency of occurrence and consequences magnitude, set up the sizing criteria for the whole SMS.
The safety in a process plant relies, among other things, on the adopted managing criteria. They affect all the plant life cycle: from plant design and construction, during the production activity, until its possible dismissing. This clearly applies also to the food process plants.
The links between quantitative risk analysis steps and results and SMS procedure are discussed with reference to the food SMS, according to ISO 22000 standard.
In conclusion, it is shown how a correct and careful risk analysis is necessary to design and implement a SMS able to pursue the policy's objectives allowing an effective revision of the policy itself.

1. Introduction

Failures in food supply chain can be dangerous and costly. 48 million food borne disease cases in United State annually and 3,000 die (CDC, 2011), that in terms of monetary lost it ranges from $6.5 to $34.9 billion dollar annually.
ISO standards on food safety management systems aim to complement local and/or European regulatory requirements and to assist in reducing weak links in the food supply chain, in order to minimize the risks food related and the consequent losses.
The paper shows how the hazard identification and evaluation phase of a Food Safety Management System (FSMS) is the design criteria for the whole SMS, with its procedures. In particular, the selection of risk analysis methods and their results, in terms of frequency of occurrence.
The links between quantitative risk analysis steps and results and SMS procedure are shown and discussed with reference to the food SMS, according to ISO 22000 standard, "*ISO 22000:2005 Food Safety Management Systems-Requirements for any Organization in the Food Chain*". (ISO, 2005).
In conclusion, it is shown how a correct and careful risk analysis is necessary to design and implement a SMS able to pursue the policy's objectives allowing an effective revision of the policy itself.

2. Food Safety and ISO 22000

The large number of food safety incidents in recent years and increasing the risk for public health has resulted in increased requirement for food safety and protection globally. EU regulation in these regards has evolved over the last 20 years in order to meet the growing demand of consumers within food safety.
Nevertheless, food safety standards represent significant differences around the world. These standards are in both public level (i.e. Codex Alignments, regional countries, and individual nations) and private level (firms and supply chain demands and customers requirement), which both have different level of protections (Figure 1).
The confusion resulting from the proliferation of standards led the ISO to design a food safety management system (FSMS) standard aimed at harmonizing those already existing designing the ISO

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22000 specifies the requirements for a FSMS when an organization in the food channel needs to demonstrate its ability to control hazards related to food safety, in order to ensure that the food is safe at the time of human consumption (Escanciano & Santos-Vijande, 2014).

FSMS can be adopted for different reasons (Herath & Henson, 2010), as reflected in different studies analyzing the experience of the companies from various sectors of activity. Most of these studies have focused on Hazard Analysis and Critical Control Points (HACCP), with only a few referring wholly or partially to ISO 22000: Bilalis et al. (2009) in Greece, Kök (2009) in Turkey or Vladimirov (2011) in Bulgaria. Since HACCP is an essential part of an FSMS, and is one of the key elements of the standard, it can be considered that many of the reasons that lead to the application of HACCP would also be attributable to the implementation of ISO 22000: the desire to improve the quality and safety of its products, external pressures, improved image, and access to new markets.

Thus food industry adopts now quality and safety systems like HACCP, ISO 9000/2000 and ISO 22000 to control processes, procedures and activities according to these standards (Van der Spiegel et al, 2004)

Food safety deals with food born hazards in food consumption that can occur at any point of the food chain from farm to table. Therefore, food safety is an integrated approach through the combined efforts of all the parties involved (Figure 2).

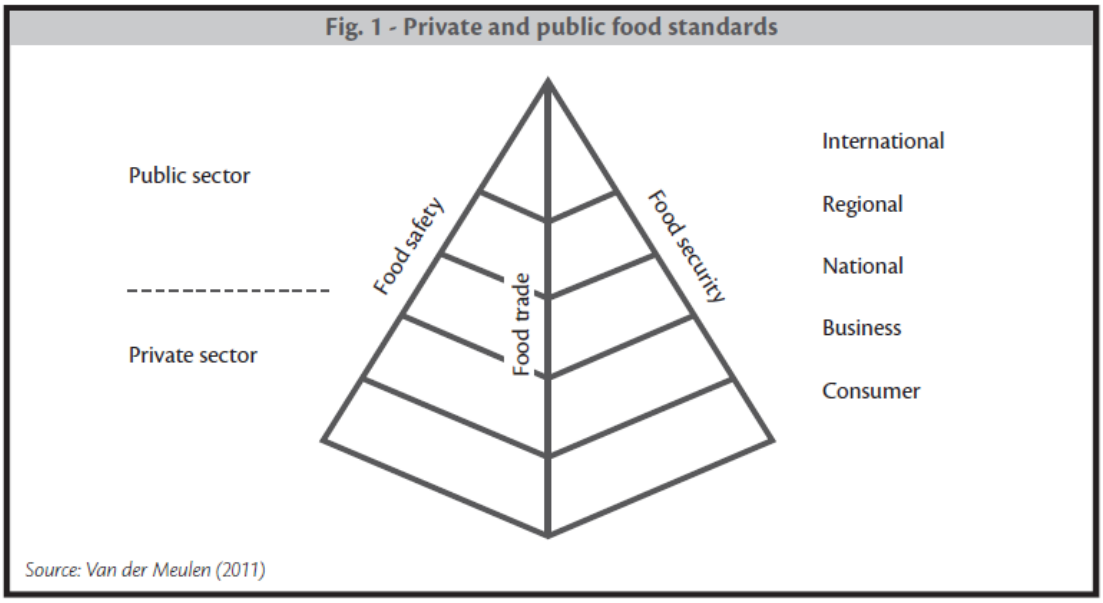

Figure 1. Private and public food standards

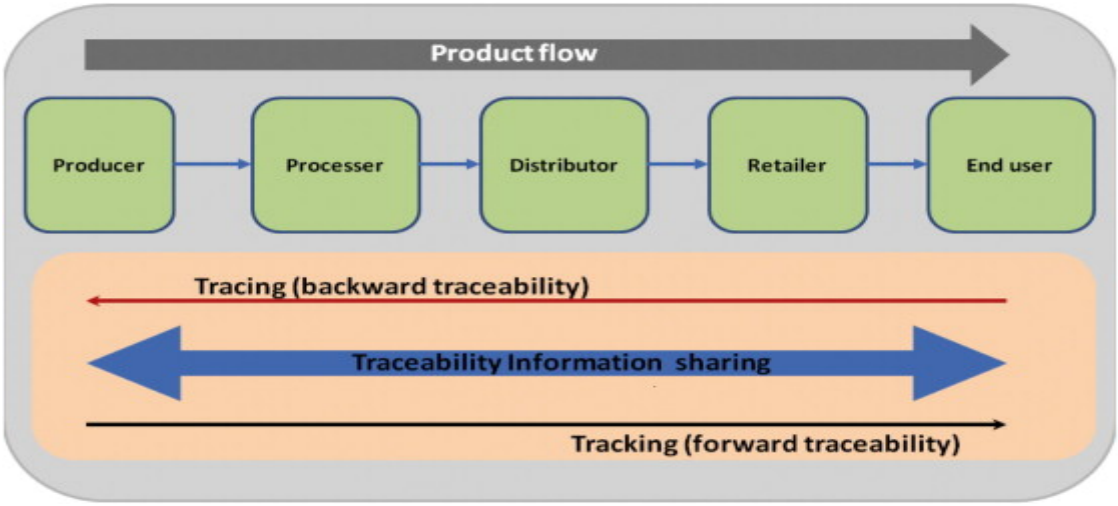

Figure 2. Product flow in food chain

According to (Wallance et al., 2005) food safety management includes the building blocks of designing safe product, prerequisite programmes and HACCP which should be applied accurately.
HACCP is one of the key factors in food safety management and it is broadly accepted that food companies should apply HACCP, therefore, it is essential to understand the factors influence on successful HACCP application.
Using HACCP process help organization in food industry to: (Milunovic, 2012)

- Plan: what need to be done
- DO: what you planed to do to maintain food safety
- Check: that you are doing what you planned to do to maintain food safety
- Act: to revise any food safety issues and problems

The ISO 22000 standard specifies the food safety requirement that combines the following key points to ensure safe food along the food chain (Figure 3).

- Interactive communication
- System management
- Prerequisite program

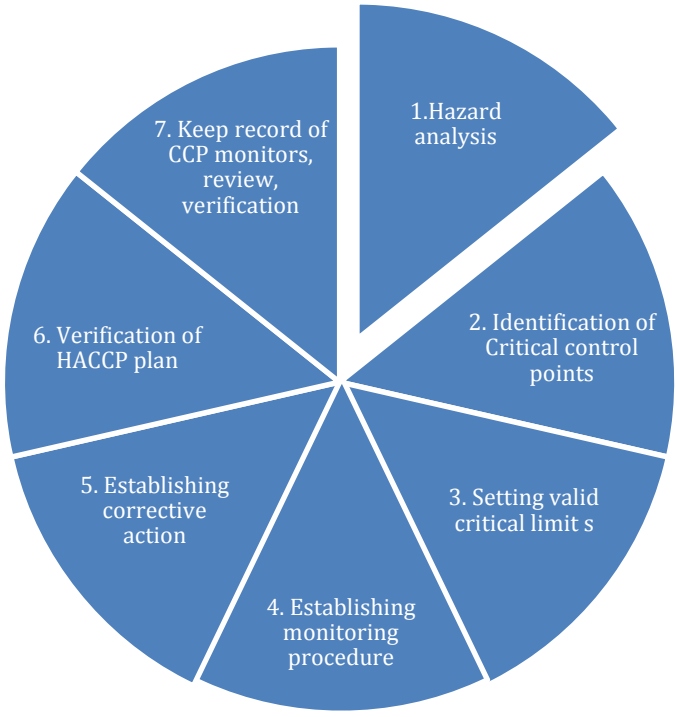

Figure 3. Structure of a Food SMS

3. HACCP and Safety Management System (SMS)

According to National Academy of Science (NAS) “The cornerstone of a science based system of food safety is the incorporation of the results of risk analysis into all decisions regarding resource al location, programmatic priorities, and public education activities.”, as summarized in Figure 4.

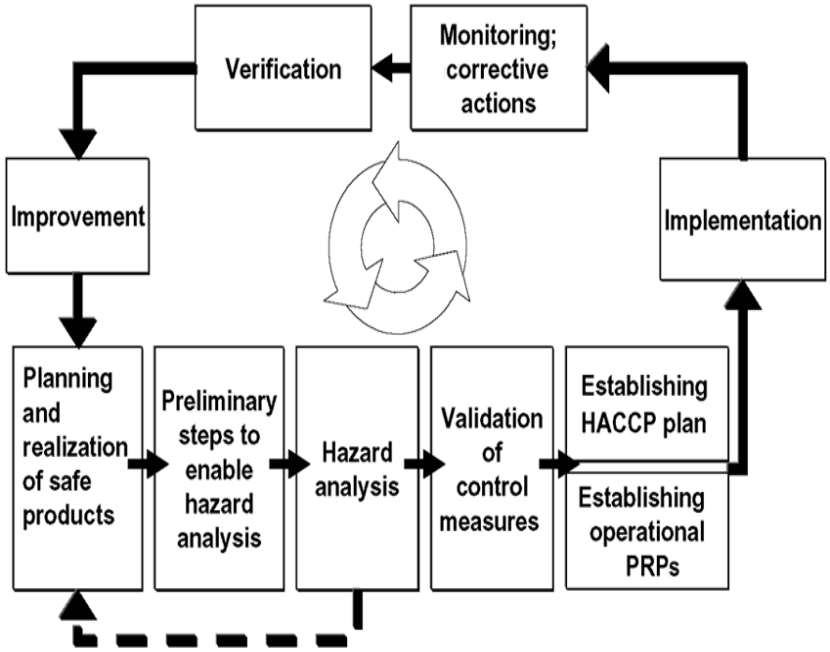

Figure 4. The risk analysis cycle

The Codex (CAC, 2003) represents some brief elements to consider for hazard analysis, where:

- Hazard analysis: The process of collecting and evaluating information on hazard and conditions leading to their presence to decide which are significant for food safety and therefore should be addressed in HACCP plan.
- Hazard: a biological, chemical or physical agent in, or condition of food with the potential to cause an adverse health effect.
- Significant Hazard: Hazard that are of such nature that their elimination or reduction to an acceptable level is essential to the production of safe foods (ILSI,1999).

Therefore, to recognize the significant hazards it is required to investigate the likelihood of occurrence and the severity of the potential effect, and it happens when the incident is likely to happen and cause harm to the customers.

According to Manning and Soon (2013) different risk analysis tools are available to identify significant hazard within food safety, however, the selection of approach is based on preference of Food Company, or influenced by third party auditors, customers or stakeholders. Besides, the all tools for this assessment rely on judgment, experience, and training of the experts using those techniques.

HACCP helps the food industry to have effective controls on plants, products and processing methods to meet the safety and quality requirements. HACCP based on the Codex General Principles of Food Hygiene, improves the food safety by focusing on identifying significant hazards and critical control points, to control, prevent and eliminate a food safety hazard or reduce it to an acceptable level (Van der Spiegel et al., 2004).

Figure 5 summarises the relations between HACCP and Food SMS as defined in ISO 22000.

4. The influence of HOF

There have been major developments in the food industry, including hazard analysis critical control point (HACCP) system, and technologies and analysing methods. In spite of these improvements, the role of human and organization factor (HOF) has not received sufficient attention.

None of the controls or systems which are used in the food safety will be effective without accurate operation of those people who are involved, which includes all sectors, as farmers, workers, managers, inspectors, or legislator. Their profession, knowledge and behaviour as well as their commitment and motivation to overcome their responsibilities, all influence on the food safety. In the same manner, organizational culture will have the major impact on the motivation and attitude of work force by providing the environment and the context for employees to work (Motarjemi et al., 2013).

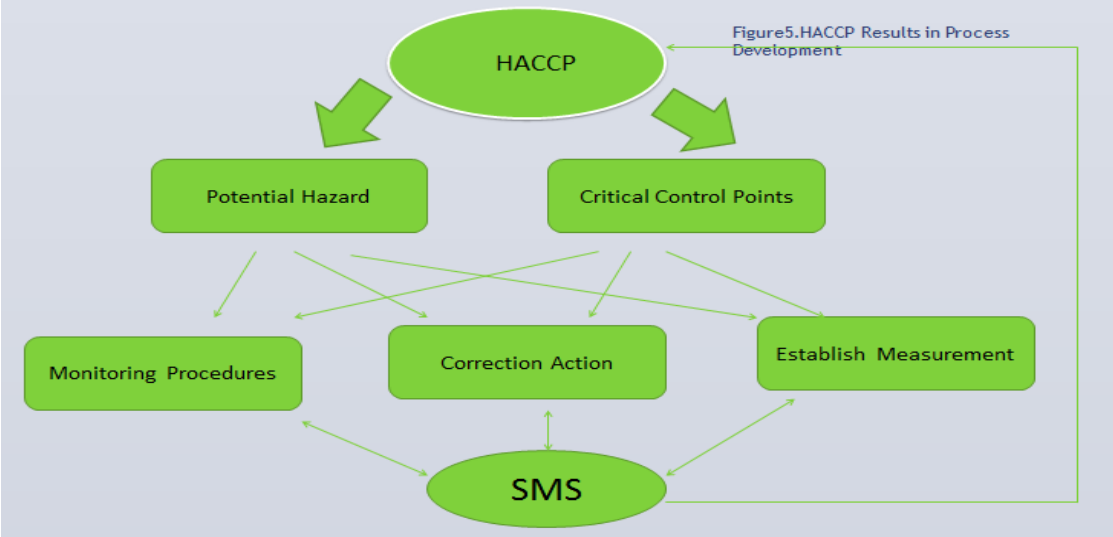

Figure 5. Relation between HACCP and SMS

In many root cause analysis of incidents, the effect of human failures, working condition and working environment are noticeable, which is placed in two different groups by Reason (1995) as conditions leading to an error and condition leading to violation. Violation is deviation from standards or procedures deliberately that may have different reasons as taking a shortcut to not follow the procedure to save time.
According to Motarjemi (2013) the role of technical staff in food production and food safety management is essential, as the intervention of qualified and skilful workers in safety system and control measures are necessary.
Therefore, providing necessary resources, training and education for staff is a need to meet safety criteria. These could be any need from material, equipment, environmental condition, or managerial support, authority or policies. Any failure to consider the HOF as an important factor in food safety could result in human error, and increase the opportunity for incidents.
In further developments of this research work, carried on within the framework of the EC Project InnHF "Innovation through Human Factors in risk analysis and management", the explicit links within Food SMS procedures and Hazard analysis will be identified and discussed with a glance to the shortcomings deriving from the neglecting of Human and Organisational factors, this extended to the whole supply chain.

5. Conclusions

Food safety deals with food born hazards in food consumption that can occur at any point of the food chain from farm to table. Therefore, food safety is an integrated approach through the combined efforts of all the parties involved.
ISO 22000 motivates the adoption of a food chain approach when developing, implementing, and improving the effectiveness and efficiency of a food safety management system. The application of a system of processes within an organization, together with the identification of interactions and the management of these processes can be referred to as the process approach.
The plus point of the process approach is the better control that it provides over the linkage between each process within the system of process, as well as their combination and interaction.
In further developments of this research work the hazard analysis (from the point of view of the methodologies and the results) will be extended to the whole supply chain, identifying the explicit links within Food SMS procedures and Hazard analysis highlighting the shortcomings deriving from the neglecting of Human and Organisational factors, in the analysis and their consequences on the food safety.

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