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FOOD QUALITY AND SAFETY MANAGEMENT SYSTEMS:A BRIEF ANALYSIS OF THE INDIVIDUAL AND INTEGRATED APPROACHES

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Abstract

The food industry has a number of Quality Assurance (QA) systems available like GMP (Good Manufacturing Practices), HACCP (Hazard Analysis. Critical Control Points), ISO (International Organisation for Standardisation) standards. These systems and their combinations are recommended for food quality and safety assurance. The agri-food production requires a specific approach to achieve the expected quality level. It is important to know to what extent the systems contribute to the total quality of the product and to balance the tools used for achieving the quality and safety objectives.

Keywords: food, quality, safety, quality and safety management systems.

Introduction

Despite the huge efforts paid by the food safety authorities, specialists and industry, food safety still remains critical and often is coming into spotlights attracting media's attention with outbreaks that can bring a stack of multiple negative consequences. Such major events like BSE in 2000, dioxin or PCB crisis in 1999 and others questioned the effectiveness of the food quality assurance systems and food safety management applied and demonstrate that new tools are needed to complement the actual systems in place. When evaluating the negative consequences one have to take into account the medical costs incurred, the economical losses that can badly shake local small industries, and least but not last consumers` trust.

The safety paradigm is that although food is safer, consumers` attitude is dominated by high levels of uncertainty. In this changing climate we however, need to recognise the effort EU authorities make to restore consumers` trust and enforce new regulations and better communicate food safety related issues. An important feature of food industry is that producers, in order to cope with market needs and legal requirements, have to satisfy both safety and quality criteria for their products. Having multiple options in the form of different quality and/or management systems, food producers should decide the most appropriate one for its specific activity and should establish, document and implement effective systems for managing quality and safety (van der Speigel et al., 2003).

Among the available Quality Assurance (QA) systems there are at hand today systems such as: GMPs (Good Manufacturing Practices), GHPs (Good Hygiene Practices), GAPs (Good Agricultural Practices) or other prerequisite systems and HACCP (Hazard Analysis. Critical Control Points) (van der Speigel et al., 2003).

Food quality and safety management systems:a brief analysis of the individual and integrated approaches

Management systems such as ISO 9000, or integrated management systems according to ISO 22000:2005 (*Food safety management systems - Requirements for any organization in the food chain*) are also accessible for producers

This paper discusses the most important theoretical systems and identifies several factors that limits or contribute to the successful implementation of quality, safety or integrated systems applied in the food industry.

Individual quality and/or safety management systems for food industry - A quality management system (QMS) system can be defined as: *a set of co-ordinated activities to direct and control an organization in order to continually improve the effectiveness and efficiency of it performance*.

Food quality is a complex concept that can be assessed only in relation to food safety. To be considered safe for consumption, a food must meet: legislative requirements; technological criteria; hygiene requirements; transport and handling requirements; trading conditions and satisfy its intended use.

The relation between quality and safety is intricate and although safety cannot be viewed as a totally independent aspect from quality, recognising the complexity of both concepts brought the need of managing them separately. In fact the reasoning behind separating food safety from quality was the need to place the concept of safety first and above all the other quality aspects.

The result can be classified in **quality assurance systems** (QA) that includes the prerequisites (GMPs, GHPs, GAPs) and HACCP; **quality management systems** (QMS) that refers to ISO or TQM; and **integrated systems** (IS) such as ISO 22000.

The systems can be classified according to the extent of activities they cover, in:

- **basic** *safety* systems: prerequisites (GAPs, GMPs, GLPs, etc.);
- **advanced** *safety* systems such as HACCP;
- **integrated** food *safety management* – ISO 22000;
- **basic** *quality management* systems - ISO 9001;
- **advanced** *quality management* systems - ISO 9004.

A part of the quality assurance systems and prerequisite programs that are applied by the industry are presented bellow.

Good Manufacturing Practices - GMP. GMPs as defined by the Food and Drug Administration in 21 CFR part 110 are the minimum sanitary and processing requirements for food companies. The basic aim of GMP is concerned with the precautions needed to ensure adherence to all quality and safety basic requirements, like:

- elimination, prevention, minimisation of all product failures in the broadest sense;
- consistently yields safe, ensuring a certain quality uniformity.

Prerequisite programs provide the basic environmental and operating conditions that are necessary for the production of safe, wholesome food.

The Codex Alimentarius General Principles of Food Hygiene describe the basic conditions and practices expected for foods intended for international trade. In addition to the requirements specified in regulations, industry often adopts policies and procedures that are specific to their operations.

GMP guidelines are not prescriptive instructions on how to manufacture products. They are a series of general principles that must be followed during manufacturing.

When a company is setting up its quality program and manufacturing process, there may be many ways it can fulfill GMP requirements. It is the company's responsibility to determine the most effective and efficient quality process.

Hazard Analysis. Critical Control Points – HACCP.

HACCP is a preventative, proactive and systematic approach of food safety, which relies on the identification and control of the all the known associated health hazards in the food chain. The system based on seven principles was developed to control the biological, chemical, and physical hazards from the raw material production, through manufacturing, distribution and consumption of the finished product.

According to Codex Alimentarius (Alinorm 97/13A, Appendix III), *the safety of foods is principally assured by control at the source, product design and process control and the application of Good Hygienic Practices during production processing (including labelling), handling, distribution, storage, sale, preparation and use, in conjunction with the application of the HACCP system.*

The production of safe food products requires that the HACCP system be built upon a solid foundation of prerequisite programs. While prerequisite programs may impact upon food safety, they also are concerned with ensuring that foods are wholesome and suitable for consumption. HACCP plans are narrower in scope, being limited to ensuring food is safe to consume (FDA, 1997).

ISO 9000 series of standards had a major revision in the year 2000 when three standards (9001, 9002, and 9003) were combined into one, called 9001. Design and development procedures are required only if a company is in fact engaged in the production and development of new products. ISO 9001 made a radical change in thinking by actually placing the concept of process management front and centre.

The *process management* refers to the monitoring and optimisation of a company's tasks and activities, instead of just relying on *inspection of the final product*. This standard also demanded involvement by upper management in order to integrate quality into the business system and prevent handing over the quality functions to junior administrators.

Another goal of the standard is to improve effectiveness via measuring process performance using statistical tools to assess the effectiveness of tasks and activities.

Expectations of continual process improvement and tracking customer satisfaction are made explicitly in standards` principles.

ISO 9004 goes beyond ISO 9001 and provides guidance on how one can continually improve its business' quality management system. This can benefit not only one`s customers but also: employees; owners; suppliers; society in general.

ISO 22000:2005 is a food safety management standard that is developed based on the ISO 9001 approach. The standard was especially developed to manage food safety. ISO 22000:2005 specifies requirements to enable an organization:

- to **plan, implement, operate, maintain and update** a food safety management system aimed at providing products that, according to their intended use, are safe for the consumer;
- to **demonstrate compliance** with food safety requirements;
- to **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;
- to **effectively communicate** food safety issues to their suppliers, customers and relevant interested parties in the food chain;
- to **ensure that the organization is consistent with** the declaration of food safety policy;
- to **demonstrate such conformity** to relevant interested parties;
- 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 to ISO 22000:2005.

Total Quality Management – TQM is an integrative *philosophy* of management for continuously improving the quality of products and processes *(*Ahire, 1997).

TQM functions on the premise that the quality of products and processes is the responsibility of everyone who is involved with the production or the services offered by an organization (Rotaru et al., 2005).

Integrated approaches for food industry - The agri-food production requires specific approaches to achieve the expected quality level. It is important to know to what extent the systems contribute to the total quality (van der Speigel et al., 2003).

The effective integration of the above mentioned individual systems will improve the performance of the organization. Efstratiadis and Arvanitoyannis (2000) mentioned that HACCP as a part of a quality system not only manages to provide safe food products, but also assure a better and more effective implementation of the entire quality system.

It is important to make distinction between the terms *assurance* and *management*. The term *assurance* relates to a product itself and involves all the safety assurance systems (GMP, GHP and HACCP) and the Quality Assurance Control Points (QACP), the later referring to quality assurance, not safety (Sikora and Strada, 2003). Maintenance and/or introduction of the all the other quality characteristics of the food (nutritional, sensory and convenience values) in quality assurance systems is not requested by law, albeit desirable by customers.

On the other hand, the term *management* corresponds to a company's overall organisation as regards the products' quality (including safety), and involves quality management systems -QMS (ISO-9000, ISO-14000, etc.) as well as TQM. Voluntarily implemented systems, known as quality assurance and management systems include ISO 22000, ISO 9000, ISO14000 and/or ISO 18000.

ISO 9001 can play an important role within TQM, by strengthening systems and procedures, but it is a small part of TQM activities. Thus, the QMS performance would be significantly improved with increasing the level of understanding of the relationship between all the quality and safety systems (Figure 1).To improve the performance of these systems, food manufactures should combine or integrate such systems as to assure that all the safety aspects of food and the necessary quality attributes are covered. For example, HACCP principles are often combined with ISO 9001 so that the technological and management issues regarding food safety and quality are achieved. Thus, ISO 9001 can be helpful for the application of HACCP (Rotaru et al., 2005).

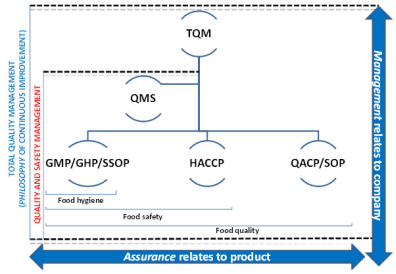

Figure 1. *Relationship between the quality systems in food industry*

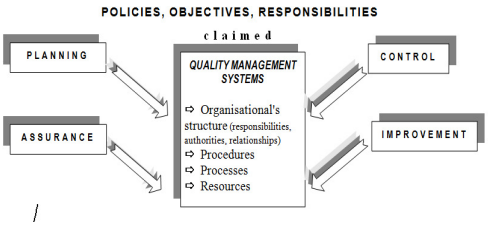

Figure 2. *Implementing QMS (*Teodoru, 1993*)*

Furthermore, food manufactures are obliged by legislation to apply HACCP principles, while the other systems are applied voluntarily in the food industry.In **Table 1,** an integrated model of the essential requirements for food industry is presented.

Since the assurance of safe production and safe food products are mandatory requirements for food industry, these can be attained by adopting a systematic and organizational structure, controlling activities, processes, procedures and resources according to the standards which constitute the basis for the quality and hygiene systems, including HACCP, ISO 9001 and 14000 series (Early, 1995).

The standard ISO 22000:2005 offers an alternative to food organizations which do not implement ISO 9001 and want to have an effective food safety management system.

Implementing QMS - Implementing a fully documented QMS will ensure that two important requirements will be met:

- ✓ *customers' requirements* – confidence in the ability of the organisation to deliver the desired product and service consistently meeting their needs and expectations.

- ✓ *the organisation's requirements* – both internally and externally, and at an optimum cost with an efficient use of the available resources – materials, working force, technology and information.

Table 1. *Essential requirements for quality and safety assurance in the food industry*

Features	General requirements
1. Quality management	Top management commitment; Plan and share responsibilities; Assign proper human and material resources; Ensure an effective quality system
2. Staff	Create an appropriate organizational framework; Describe the key positions; Train the workers; Develop behavioral and attitude competencies Supervise personal hygiene and health.
3. Production areas and equipment	Ensure proper facilities and equipment – constructions, installation; maintenance, environmental conditions, sanitizing, cleaning, validation of cleaning.
4. Documentation	Document, develop, approve, update, distribute, and archive documentation.
5. Processing	Validate the processes; Prevent cross-contamination during manufacture; Purchase good raw materials; Ensure the quality of the process, for intermediate, bulk or end products; Comply legal labeling requirements; Ensure good quality of the end products (quarantine, storage, handling, delivery); Track the products rejected recovered and returned (tracking and identification).
6. Quality control	Apply good practices in the laboratory; Apply sampling techniques; Validate the analytical method; Inspect the process; Maintain, check and calibrate the measuring and monitoring devices.
7. Regulations	Apply mandatory requirements; Follow contractual requirements.
8. Consumer complaints	Handle the complaints; Document the Withdrawals / Recalls; Analyze the decisions.
9. Self-inspection	Perform internal audit. Check compliance and corrective action
10. Supplier relationships	Identify and select key suppliers. Communicate clear and open. Share information and future plans. Establish joint development and improvement activities. Inspire, encourage and recognize improvements and achievements.

A QMS have four main components: quality planning, quality control, quality assurance and quality improvement (Figure 2):

When implementing an advanced/integrated food quality and safety management system, the lack of financial and human resources conflicting with high costs, the low personnel and time restrictions side by side with a general lack of knowledge and experience are important constraints. A brief analysis of the decisive factors that influence the application of advanced and/or integrated systems helps in understanding the relationship between certain specific elements such as: *internal* (staff involvement, communications, leadership), *external* (level of competition, relationships with suppliers, customers and authorities), *structural* (size, ownership structure) and the degree to which the *management practices* are applied (Figure 3). Only if all these elements are well addressed an organizations have the preparedness to implement an advanced management system.

The organizations that implement TQM understand that customers will only be satisfied if they consistently receive products and services that meet their needs, are delivered when expected, and are priced for value. TQM organizations use the techniques of process management to develop cost-controlled processes that are stable and capable of meeting customer expectations.

TQM can be initiated by implementing ISO 9004 and this would be a step further that implies changing in the organizational culture and a dedication for quality and improvement.The principles of TQM are shown in Figure 4.

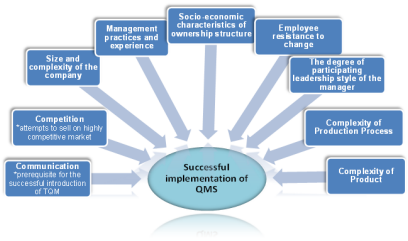

Figure 3. *Factors affecting the implementation of advanced/integrated QMS*

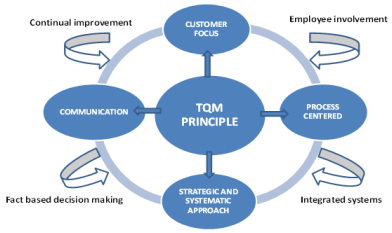

Figure 4. *The TQM principles*

The success of TQM approach is achieved if the system is treated as a strategic key business issue.

Additionally, we need to recognise that ISO and TQM focus more on the managerial aspects, whereas GMP and HACCP focus on the technological aspects (Hoogland et al., 1998). HACCP is the only quality assurance systems that consists of a plan with 14 steps, in contrast with the checklist of ISO. GMP includes guidelines and TQM uses awards or self-assessments (van der Speigel et al., 2003).

One of the key points to successful implementation of an advanced/integrated management system is to recognize the need for continuous improvement. Clause 8.5 ISO 9001 or 22000 urges a company to plan for corrective and preventive action, and continuous improvement.

Application of this principle guarantees the company's efficiency and competitiveness. In other words, a company that has been effectively implementing a QMS will make continuous improvements. Hence, the effort to meet the standards` requirements will bring the benefit of increasing the capability and the performance of the organisation.

Conclusions

Successful implementation of food quality and safety management systems is a necessity today.

In this paper, a brief analysis of the individual and integrated/advanced food quality and safety management systems was made, together with the identification and analysis of the factors that can influence the implementation process.

The effectiveness of the integrated system is based on the relationship between internal, external and structural factors. Besides these factors, food industry have to balance the quality assurance and safety management systems, select the proper ones according to its resources and needs and implement adequate tools for continuously measuring and evaluating the performance of the individual or advanced/integrated management systems.

References:

1. Ahire, S. L. (1997). Management Science- Total Quality Management interfaces: An integrative framework. *Interfaces 27 (6)* 91-105.
2. Bolton, A. (1997). *Quality management systems for the food industry: A guide to ISO 9001/2*. London: Blackie.
3. Early, R. (1995). *Guide to quality management systems for the food industry*. London: Blackie.
4. Efstratiadis, M. M., & Arvanitoyannis, I. S. (2000). Implementation of
5. HACCP to large scale production line of Greek ouzo and brandy: a case study. *Food Control, 11*, 19–30.
6. Hoogland, J.P, Jellema, A, Jorgen, M.T.G., (1998), *Quality Assurance Systems,* In W.M.F. Jongen and M.T.G. Meulenberg Eds., *Innovative of Food productions systems: product quality and consumer acceptance,* Wageningen: Wageningen Pers.;
7. National advisory Committee on Microbiological Criteria for Foods/FDA (1997), Hazard Analysis and Critical Control Point Principles and Application Guidelines (http://www.fda.gov/Food/FoodSafety/HazardAnalysisCriticalControlPointsHACCP/HACCPPrinciplesApplicationGuidelines/default.htm#app-a);
8. Luning, P.A., Marcelis, W.J., Jorgen, W.M.F., (2002), *Food Quality Management: a techno-managerial approach,* Wageningen: Wageningen Pers.;
9. Rotaru, G., Borda, D, Sava, N., Stanciu, S. (2005), *Quality Management in Food Industry,* Ed. Academica, Galati, Romania;
10. Van der Spiegel, M, Luning, P.A., Yiggers, G.W., Jongen, W.M.F. (2003), Towards a conceptual model to measure effectiveness of food quality systems, *Trends in Food Science and Technology*, *14*, 424-431.
11. Sikora, T., Strada, A. (2003). *Safety and Quality Assurance and Management Systems in Food Industry: An Overview*, available on line at http://www.ip.aua.gr/Studies/Sikora-Strada_final.pdf.
12. Teodoru, T. (1993), Asigurarea calităţii. îndrumar metodologic, Ed. Tribuna Economica, Bucureşti.