FOOD SAFETY ASSURANCE ACCORDING TO CODEX ALIMENTARIUS AND ISO 22000 STANDARD

Tadeusz Sikora, Paweł Nowicki

Quality Management Department, Cracow University of Economics, Cracow

Key words: food safety, HACCP plan, Codex Alimentarius, ISO 2200:2005 standard

Food safety is the most important quality feature for the consumers, hence food law regulates this issue in details, assure the consumer that food he buys fulfill its safety expectations. A Law regulation describes food safety assurance requirements and simultaneously recommends the implementation of specific systems' resolutions that allows gaining this aim.

Considering the food industry as a main link in consumers' food safety assurance, it should be remembered that without using a GAP, GHP/GMP and HACCP plan in all food chain there is no confidence of hazard elimination. It should be stated that beside the food statutory and regulatory requirements and implementation of food safety management system the ethical standards must be complied in all food chain.

The analysis of the attitude placed in Codex Alimentarius and in ISO 22000:2005 standard about efficiency of food safety assurance systems is described in this paper.

INTRODUCTION

"Systems are such as the competences of the people who implement them"

Food safety assurance is realized in its formalized way for past few dozens years, firstly in USA and than the idea of food safety assurance was adopted by international organizations which are engaged in this issue in global range.

In the beginning of the 90's of past century United Europe legislation (93/43/EEC directive) recommended companies to implement HACCP system according to Codex Alimentarius rules. The Regulation 852/2004 *on the hygiene of foodstuffs* also recommends to use HACCP system rules presented in Codex Alimentarius.

The level of reliability of HACCP plans designed by the food branch companies is very differential. It is because of the requirements of HACCP system which gives big latitude in interpretation of its seven rules.

There was a need to define unified requirements and guidelines that could be used for equalizing of the level and reliability of food safety management system implementation.

There was published in 2005 by ISO a new standard *ISO 22000:2005 Food safety management systems – Requirements for any organization in the food chain*, which also refers to Codex Alimentarius rules. However this standard introduces many additional, formal requirements which had not been included in Codex Alimentarius.

While designing this new standard the big attention has been paid on recommendations in WHO Codex Alimentarius Guideline and it has been avoided potential disperancies and inaccuracies to law regulations. This standard was built alike ISO 9001 and ISO 14001 and it is not difficult to successfully integrate food safety management system to quality management systems and environmental management systems. It also harmonizes the requirements of systematic safety management in supply chain and combines HACCP plan to prerequisite programmes (PRP).

This standard is addressed to all organizations in the food chain no matter on size or complexity of production. It covers organizations directly and indirectly connected to one or more stages of food chain.

The aim of this paper is to show the differences between obligatory requirements of HACCP system provided by Codex Alimentarius and voluntary ISO 22000 standard.

SYSTEM HACCP ACCORDING TO CODEX ALIMENTARIUS

Codex Alimentarius gives basic requirements that are needed to implement the food safety system. These requirements are: basic conceptions, definitions, system rules, stages of implementation, decision tree and Critical Control Points data sheets. The idea of HACCP system designing is that the food operator according to its best knowledge leads all stages of system implementation.

Codex Alimentarius also recommends what should be done but not how it should be done. The Codex Alimentarius Commission's documents give also requirements concerning implementation of Good Hygienic Practice. Generally these

requirements are regulated by country legislation as basic requirements, which prelude HACCP system implementation. Therefore the implementation of HACCP system according to Codex Alimentarius requires at first good practices implementation. It should be stated that HACCP system do not undergo the certification, but it is being established by organization's management.

ISO 22000 STANDARD CHARACTERISTIC

The ISO Technical Committee laying down the standard based on specifications connected to Codex Alimentarius and international standards that could be useful in improvement and rising it on the higher level of organizations' food safety systems.

According to ISO 22000 standard the organizations should plan and improve all processes that are needed to realize safe products through effective improvements, planned actions implementing and monitoring as well as keeping going the control measures connected to food safety. This standard came into force on September 1, 2005 and similarly to ISO 9000:2000 is constructed of 8 chapters: (1) Scope, (2) Normative references, (3) Terms and definitions, (4) Food safety management system, (5) Management responsibility, (6) Resource management, (7) Planning and realization of safe products, and (8) Validation, verification and improvement of the food safety management system.

There have been defined requirements for food safety management system where organization: needs to demonstrate its ability to control food safety hazards in order to ensure that food is safe at the time of human consumption; follows the law requirements; realizes the food safety policy; effectively communicates food safety issues to their suppliers, customers and relevant interested parties in the food chain; and seeks for certification or registration of its food safety management system

These organizations are aware of raising need of demonstration and providing the evidence for its ability to identify and control the food safety hazards and the conditions influencing the food safety.

The standard describes an example of communication within a food chain that is placed in Figure 1.

ISO 22000 STANDARD'S SCOPE

All requirements of this international standard are generic and are intended to be applicable to all organizations in the food chain regardless of size and complexity. This includes organizations directly or indirectly involved in one or more steps of food chain. Organizations that are directly involved include, but are not limited to. feed producers, harvesters, farmers, producers of ingredients, food manufacturers, retailers, food services, catering services, organizations providing cleaning and sanitation services, transportation, storage and distribution services. Other organizations that are indirectly involved include, but are not limited to, suppliers of equipment, cleaning and sanitizing agents, packaging material, and other food contact materials.
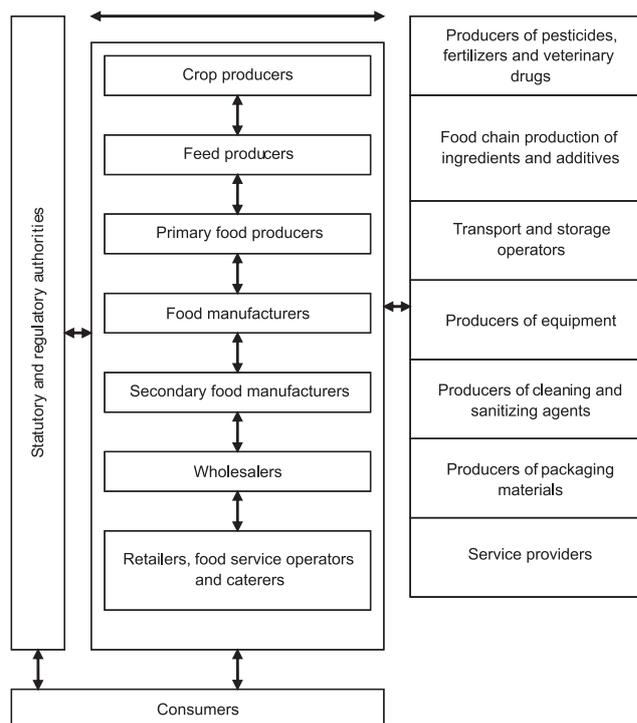

FIGURE 1. Example of communication within the food chain [ISO 22000:2005].

The aims of ISO 22000 standard
• Requirements harmonization in the range of food safety management in a global scale, that allow to use unified requirements by every organization in food chain,
• simplify of the usage of this standard while implementation of integrated management systems,
• improvement of food safety management efficiency in organization through implementation of much more efficient, compact food safety management system,
• improvement of client's satisfaction through efficient control of food safety hazards, including system update processes.

This standard contains the following general requirements:
• the organization shall establish, document, implement and maintain an effective food safety management system and update it when necessary in accordance with the requirements of this standard,
• the organization shall define the scope of the food safety management system. The scope shall specify the products or product categories, processes and production sites that are addressed by the food safety management system,
• the organization shall ensure that food safety hazards that may be reasonably expected to occur in relation to products within the scope of the system are identified, evaluated and controlled in such a manner that the products of the organization do not, directly or indirectly, harm the consumer,
• the organization shall communicate the appropriate information throughout the food chain regarding safety issues related to its products,
• the organization shall be prepared for crisis situations,
• the organization shall identify and place law legislation requirements into its food safety management system.

KEY ELEMENTS OF FOOD SAFETY MANAGEMENT SYSTEM ACCORDING TO ISO 22000 STANDARD

This international standard specifies the requirements for a food safety management system that combines the following generally recognized key elements to ensure food safety along the food chain, up to the point of final consumption: interactive communication, system management, prerequisite programmes, and HACCP principles.

Extremely important element of the standard is interactive communication. It is basic requirement and it ensure that the hazards are properly identified and controlled on every stage of food chain. Because of that the organization shall establish, implement and maintain effective arrangements for communicating: inside the organization (*i.e.* with personnel, food safety team); outside the organization (*i.e.* suppliers and contractors, customers or consumers, statutory and regulatory authorities and other organizations that have an impact on, or will by affected by, the effectiveness or updating of the food safety management system.

Such communication shall provide information on food safety aspects of the organization's products that may be relevant to other organizations in the food chain. This applies especially to known food safety hazards that need to be controlled by other organizations in the food chain.

Food safety policy should be defined by top management and communicate it. They should also ensure that the food safety policy: is appropriate to the role of the organization in the food chain; conforms with both statutory and regulatory requirements and with mutually agreed food safety requirements of customers; is communicated, implemented and maintained at all levels of the organization; is reviewed for continued suitability; adequately addresses communication; andis supported by measurable objectives.

It is also stated that in order to maintain the effectiveness of the food safety management system, the organization shall ensure that the food safety team is informed in a timely manner of changes, including but not limited to the following: (1) products or new products, (2) raw materials, ingredients and services, (3) production systems and equipment, (4) production premises, location of equipment, surrounding environment, (5) cleaning and sanitation programmes, (6) packaging, storage and distribution systems, (7) personnel qualification levels, (8) statutory and regulatory requirements, (9) knowledge regarding food safety hazards and control measures, (10) customer, sector and other requirements that the organizations observe, and (11) complaints indicating food safety hazards associated with the product.

PLANNING AND REALIZATION OF SAFE PRODUCTS

ISO 22000 standard requires from organization to plan and develop the processes needed for the realization of safe products. The organization shall implement, operate and ensure the effectiveness of the planned activities and any changes to those activities, which should include PRP as well as HACCP plan.

PRP – prerequisite programme – 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 and safe for human consumption.

The PRPs needed depend on the segment of the food chain in which the organization operates and the type of organization. The examples of equivalent terms are:
• Good Agricultural Practice GAP;
• Good Veterinarian Practice GVP;
• Good Manufacturing Practice GMP;
• Good Hygienic Practice GHP;
• Good Production Practice GPP;
• Good Distribution Practice GDP;
• Good Trading Practice GTP;

Prerequisite programmes are designed for supporting infrastructure and for setting the proper level of hygiene in the organization. They are used for basic hygiene requirements establishing and are used in controlling: the likelihood of introducing food safety hazards to the product through the work environment; biological, chemical and physical contamination of the products, including cross contamination between products; and food safety hazard levels in the product and product processing environment.

The PRPs shall: be appropriate to the organizational needs with regard to food safety; be appropriate to the size and type of the operation and the nature of the products being manufactured or handled; be implemented across the entire production system; and be approved by the food safety team.

Operational prerequisite programme is identified by the hazard analysis as essential in order to control the likelihood of introducing food safety hazards to the contamination or proliferation of food safety hazards in the products or in the processing environment.

Operational prerequisite programme should control all hazards that that are not under control of HACCP system. Operational prerequisite programme include: personnel hygiene, cleaning and sanitation processes, vermin population control, cross contamination preventive measures, packaging rules, supplies' management rules, waste management, and product services management,

All issues mentioned above shall be documented and improved. Partition on PRPs and operational PRPs is done because of control measures differences, which may be used and because of its ability to monitor, verification or validation.

Depending on function some prerequisite programmes contain control measures, while some others PRPs establish managing procedures and instructions.

The most important element of the system is Hazard Analysis. The standard requires that all food safety that are reasonably expected to occur in relation to the type of product, type of process and actual processing facilities shall be identified or recorded. The identification shall be based on: preliminary information and collected data; experience; external information including, to the extent possible, epidemiological and other historical data; and information form the food chain on food safety hazards that may be of relevance for the safety of the end products, intermediate products and the food at consumption.

The steps from raw materials, processing and distribution at which each food safety hazard may be introduces shall be indicated.

When identifying the hazards consideration shall be given to: the steps preceding and following the specified operation, the process equipment, utilities/services and surroundings, and the preceding and following links in the food chain.

For each of the food safety hazards identified, the acceptable level of the food safety hazard in the end product shall be determined whenever possible. The determined level shall take into account established statutory and regulatory requirements, customer food safety requirements, the intended use by the customer and other relevant data.

A hazard assessment as a part of a hazard analysis shall be conducted to determine, for each food safety hazard identified, whether its elimination or reduction to acceptable levels is essential to the production of e safe food and whether its control is needed to enable the defined acceptable levels to be met. Each food safety hazard shall be evaluated according to the possible severity of adverse health effects and the likelihood of their occurrence. The methodology used shall be described and the results of the food safety hazard assessment shall be recorded.

Based on the hazard assessment, an appropriate combination of control measures shall be selected which capable of preventing, eliminating or reducing these food safety hazards to defined acceptable levels. The effectiveness of these control measures shall be verified regularly. This selected control measures shall be categorized as to whether they need to be managed through operational PRPs or by the HACCP plan. Methodology and parameters used for categorization shall be described in the systems' documentation, and the results should be recorded. The HACCP plan shall be used for critical control points' (CCP) management identified in order to elimination, reduction to acceptable level or preventing from food safety hazards, which are connected to the product and are defined during hazard analysis. During this analysis the organization defines the strategies, that will be followed in order to asses the hazard control through combining prerequisite programs processes and HACCP plan. This standard also requires the organization to identify, monitor, control and periodically update PRPs as well as HACCP plan.

HACCP SYSTEM AND FOOD SAFETY MANAGEMENT

The implementation of HACCP system is obligatory, while implementation of food safety management system according to ISO 22000:2005 standard is voluntary. It should be stated that some of the requirements of ISO 22000 are regulated by law for example point 7.9 of the standard – the traceability system is required by 178/2002 EC regulation. Some of the very detailed records regarding i.e. hazard analysis described in the standard do not solve the problem of its difficulty – point 7.4. It is very difficult to lead especially for small and medium enterprises because of the varied and often not completed theoretical and practical knowledge of the personnel.

In our opinion the implementation of the food safety management system will be possible in large enterprises witch hire well educated personnel and which have a laboratory background. However in SMEs the detailed requirements regarding prerequisite programmes shall be enlarged as well as the improvement of the HACCP plan according to Codex Ali-
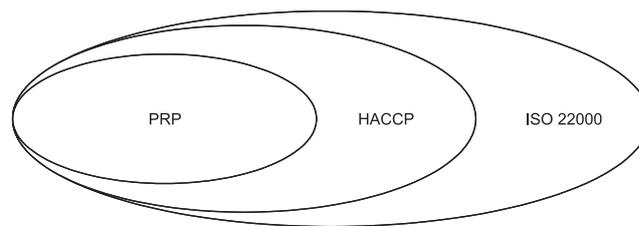

FIGURE 2. Implementation order of food safety systems. Source: Own study

mentarius. Very important are the training programmes lead in these organizations that provide to continuous improvement of functioning systems. Extremely important is ethics of all people working in the food chain.

Figure 2 describes the implementation order of food safety systems.

CONCLUSIONS

The production and raw material sourcing conditions may influence directly or indirectly on safety of the end products. In the obligatory group of food safety systems are Good Manufacturing Practice, Good Hygienic Practice and Hazard Analysis and Critical Control Point (HACCP) system. The basis of the modern food safety assurance systems is conception of designing a specific production and trade conditions that allow gaining optimal quality products. It is necessary to describe the levels of quality indicators, potential hazards and end product's quality in those systems.

Beside the obligatory systems, the voluntary food safety management systems may by implement on basis the ISO 22000 standard. There are a lot of very detailed requirements in this standard, much more than in Codex Alimentarius. This fact does not guarantee that the results will be more perfect than in case of usage the Codex Alimentarius requirements. The basis is knowledge and competence of the employees.

Considering food industry as a main link in consumers' food safety assurance, it should be remembered that without using a GAP, GHP/GMP and HACCP plan in all food chain there is no confidence of hazard elimination. It should be stated that beside the food statutory and regulatory requirements and implementation of food safety management system the ethical standards must be complied in all food chain.

REFERENCES

1. Codex Alimentarius Recommended International Code of Practice, General Principles of Food Hygiene, CAC/RCP 1-1969, rev. 4-2003.
2. PN-EN ISO 22000:2005 Food safety management systems – requirements for any organization in the food chain.
3. Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety.
4. Regulation (EC) No 852/2004 of The European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs.

ZAPEWNIENIE BEZPIECZEŃSTWA ŻYWNOŚCI WEDŁUG KODEKSU ŻYWNOŚCIOWEGO I NORMY ISO 22000:2005

Tadeusz Sikora, Paweł Nowicki

Katedra Zarządzania Jakością, Akademia Ekonomiczna, Kraków

„Systemy są takie, jak kompetencje osób, które je wdrażają"

Zapewnienie bezpieczeństwa żywności w sposób sformalizowany (systemowy) jest realizowane od kilkudziesięciu lat, najpierw w USA, a następnie w idea zapewnienia bezpieczeństwa żywności została przejęta przez organizacje międzynarodowe zajmujące się tą problematyką w skali globalnej.

Początkiem lat 90. XX w. ustawodawstwo Unii Europejskiej (dyrektywa 93/43/EEC) zaleciło wdrażanie systemu HACCP zgodnie z zasadami zawartymi w Kodeksie Żywnościowym. Także rozporządzenie 852/2004 *w sprawie higieny środków spożywczych* zawiera zalecenie stosowania zasad dotyczących systemu HACCP zawartych w Codex Alimentarius.

Poziom rzetelności opracowywanych zakładowych planów HACCP jest w bardzo zróżnicowany. Spowodowane jest to tym, że wymagania systemu HACCP pozostawiają dużą swobodę interpretacyjną siedmiu zasad.

Zaistniała więc konieczność określenia ujednoliconych wymagań i wytycznych, za pomocą których wyrównany zostałby poziom i wiarygodność wdrażania systemu zarządzania bezpieczeństwem w produkcji żywności.

W 2005 r. została opublikowana przez ISO norma ISO 22000:2005 dotycząca zarządzania bezpieczeństwem żywności *ISO 22000:2005 System Zarządzania Bezpieczeństwem Żywności – Wymagania dla każdej organizacji uczestniczącej w łańcuchu żywnościowym*, która również odwołuje się do zasad zawartych w Codex Alimentarius. Norma jednak wprowadza wiele dodatkowych formalnych wymagań, których nie ma w Codex Alimentarius.

Przy pracy nad nową normą szczególną uwagę zwrócono na zalecenia zawarte w przewodniku Kodeksu Żywnościowego WHO, aby w ten sposób uniknąć ewentualnych rozbieżności i nieścisłości z przepisami. Norma ta zbudowana została analogicznie do ISO 9001 i ISO 14001, dzięki czemu jest możliwa skuteczna integracja systemu zarządzania bezpieczeństwem żywności z systemami zarządzania jakością i zarządzania środowiskowego. Harmonizuje ona wymagania systematycznego zarządzania bezpieczeństwem w łańcuchu dostaw oraz łączy plan HACCP z programami wstępnymi PRP.

Norma ma charakter ogólny i adresowana jest do wszystkich organizacji uczestniczących w łańcuchu żywnościowym, bez względu na wielkość i złożoność produkcji. Obejmuje organizacje bezpośrednio i pośrednio włączone w jeden lub więcej etapów łańcucha żywnościowego,

W publikacji jest przedstawiona analiza podejścia zawartego w Codex Alimentarius i w normie ISO 22000:2005 odnośnie skuteczności zapewnienia bezpieczeństwa żywności.