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## HACCP AND QUALITY SYSTEM IN THE FOOD PROCESSING INDUSTRY

*HACCP (Hazard Analysis and Critical Control Points) is an indispensable contemporary system of process control in the food processing industry. In its original meaning this control procedure includes hazard analysis and identification of the points in the production process where the product contamination is reasonably likely to occur resulting in an unsafe product. At the critical points the control of the production process should be severer in order to eliminate or reduce the product safety risks.*

*The aim of implementing a quality management system being quality management, according to the standards of the ISO 9000 series, the formulation of a product that meets "the requirements stated or implied", where the implied requirements refer to the prescribed quality requirements, which, in the food industry, above all, comprises safety, it is necessary to build HACCP into the quality system. The application of HACCP principles when introducing a quality system should be extended to those parts of the production process in which the required quality of the product may be at risk.*

Recent outbreaks of foodborne diseases and heightened public attention to food safety due to microbiological, chemical and radioactive contamination urged health practitioners and the World Health Organisation to call for the intensification of international activity in preventing and controlling foodborne diseases. The character of contagious diseases, the complexity of the contamination problem and the fast expansion of international food trade contribute to the need for a forced international action and cooperation in Europe. Besides, the development of a unified market for EU countries has resulted not only in removing constraints for trade within the Union, but also in the reorganisation of food safety and national inspection service deals within the Union. The World Health Organisation supports the provision of efficient systems for food safety control in the whole European region in which special priority is given to HACCP system as an efficient mechanism for food safety control.

Hazard Analysis and Critical Control Points (HACCP) is a system of steps, based on scientific knowledge, to identify the specific health risks for consumers and establish the measures for their permanent control for food safety assurance in a systematic way.

On the other hand, the system of quality management, according to the JUS ISO 9000 Standard series, organises the management mechanism in a company and ensures that each final product meets the "requirements stated or implied", that is, the required quality.

The central determination of both systems is a preventive action through established control steps in

order to achieve the final goal which is a safe and quality end product, instead of using final control and investigation to determine its safety and the meeting of quality standards.

Starting from the mentioned basic principles of the HACCP system and the quality management system, their complementarity may also be noticed. When emphasising the compatibility of the two discussed systems, one important moment in which they differ should also be pointed out. That is the legal requirement in EU countries and the USA, while the introduction of a quality system according to JUS ISO 9000 system is voluntary.

Apart from EU member countries and the USA, many other countries have also adopted the HACCP concept in their national regulations.

Following the trends in the legislation of developed countries related to quality systems, the Proposal of the Law on the Safety of Food and Commodities (which will soon be passed) indicates that "legal persons and promoters dealing with the exchange of food and consumer goods are obliged to conduct the safety control of raw materials and finished products using Hazard Analysis and Critical Control Points (HACCP)".

That means that all the food producers in our country will very soon have to develop the HACCP concept for their products.

However, those food producers interested in the export of their products to EU countries now have to take into account the fact that one of the preconditions when registering of an exporting plan is to have the HACCP system implemented.

### HACCP CONCEPT IN FOOD CONTROL

Post production inspection or final product inspection was the traditional way of conducting quality control. Too much time, effort and money have been spent, under these conditions, investigating what was

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wrong with the final product or service, without due respect to what might have been wrong with the process of obtaining that product.

The essence of the HACCP concept is not finding and eliminating errors in the course of the technological process of production (and not only in stating errors in the finished product), which may lead to a risk – health hazard for consumers. The current practice includes the control of finished products and, if the analyses show that they are not hygienically or sanitarily safe, it brings about great economic, marketing and moral disadvantages and losses for the producer (6). In order to prevent this, the HACCP concept provides overall, expert control in the total technological production process (control of basic ingredients, production process and handling of the product) with the aim of eliminating the risk for human health during the production process.

This concept may be applied to all the health risks for humans including biological (all species of microorganisms and parasites), chemical (a series of toxic compounds which may be found in the ingredients, additives and supplements, packagings, etc.) and physical (different foreign bodies of inorganic or organic origin).

The HACCP concept was first developed in the USA by the chemical industry and later implemented to the processes of space flight programmes (NASA). It was introduced into the US food processing industry in 1973, first for the hygienic safety control of food for public places (hospitals, barracks, cafeterias...). According to the US Department of Agriculture all the producers of foodstuffs, as well as retail food stores have been required to start using the HACCP system since January 2000.

The European Union accepted a Council Directive on 14 June 1993 on the hygiene of foodstuffs (93/43/EEC) which imposes food business operators to develop and implement the HACCP system, i.e. to identify any step in their activities which is critical for ensuring food safety and to ensure that adequate safety procedures are identified, implemented, maintained and reviewed (4).

In its basic form the HACCP includes the following principles:

1. Conducting hazard analysis, developing a list of points in those operations where food hazards may occur and identifying appropriate control measures.

2. Determining critical control points (CCPs) within the production process.

3. Establishing critical limits with preventive measures for each CCP.

4. Identifying and implementing effective control and monitoring procedures.

5. Establishing corrective actions in case monitoring show that there are deviations from the established critical limits.

6. Establishing record-keeping and documentation procedures.

7. Establishing verification procedures.

HACCP uses the term hazard to designate any aspect of the food production process, which is unacceptable, being a potential cause of problems connected with food safety. In the beginning the HACCP concept was associated only with microbiological food contaminants and later it included all potential food contaminants.

Hazard Analysis is a procedure used to evaluate the severity or the degree of hazards and the probability their occurrence (risk).

A Critical Control Point (CCP) might be some ingredient, location, practice, procedure or process at which control can be applied in order to prevent or reduce the hazards (NOTE: the expression control means "to have under control" and should not be misinterpreted as examination, safety control or verification). Hazard analysis is used to determine whether some of the points are critical. It is clear that a potential severe hazard with high risk is not acceptable and a point where it is possible to control such a hazard is a CCP. CCP-1 is defined as a point where the hazard can be eliminated and CCP-2 as the point where the hazard can be reduced (to an acceptable level).

The criteria are the limits or characteristics of physical, chemical or biological nature that define points at which anything that is measured and identified becomes unacceptable. A tolerance may be associated with a limit that determines the target values.

Monitoring is the assessment of the control efficiency at critical control points. It includes systematic observations, measurements, records and verification. Verification is a systematic assessment of the total efficiency.

Implementation of the HACCP system of control is a complex, highly professional, completely documented and, therefore, long term process which, despite all our efforts, cannot be finished in a short period of time.

The experiences of the EU in implementing the system of HACCP indicate that only a few plants have trained staff and appropriate equipment to implement this system on their own, and that it is necessary to engage an appropriate expert organisation which possesses expert potentials and appropriate analytical equipment.

Analytical instrumentation, with special emphasis on rapid methods of detection, is of crucial significance for the realisation of the control of critical points. The selection of a control method comprises the definition of measures for the determination of critical control points,

the observation and assessment of work at the control points and establishment of the limit values of the characteristic parameters observed at them. Commonly a continuous observation of the process parameters (monitoring) is conducted. To that purpose, different modern rapid microbiological, chemical, physical and organoleptic methods are used.

It is also necessary that the whole procedure of implementing the system of HACCP be followed by adequate specific documentation, which must be made available for inspection.

HACCP is a dynamic process that changes with every change in the technological process of production or change in the range of products and, therefore, it is necessary to control and supplement the original plan periodically in order to eliminate the influence of new risks.

The implementation of the HACCP concept into plants should not only be seen as an imposed obligation which must be obeyed to receive permission to export foodstuffs to EU countries, the USA and other countries and without which it will soon not be possible to work for the domestic market either. It should be seen as a means which provides the better hygienic and sanitary safety of products, with less samples for laboratory analyses, consumer safety and important savings in production, the elimination of potential errors in the course of the production process.

## QUALITY MANAGEMENT SYSTEM

Implementation of the Quality Management System according to the standards (JUS) ISO 9000 is one of the prerequisites for the free exchange of goods and services in the world market. Standards of the ISO 9000 series are globally accepted in the majority of countries. In our country they were literally translated and issued as standards of the JUS ISO 9000 series. Therefore, it is logically considered that the implementation of the system of quality management is the only project which runs at the same time in all the countries in the world.

These standards make the set of all the acquired experience in developed countries on the internal organisation of business in one company (enterprise, institution) – quality management, in order to meet the stated requirements of a buyer or the implied requirements to ensure the required quality – quality assurance.

When the standards appeared in 1987, they raised doubts because of their pronounced technical character, about the possibility of application in the field of agricultural production and the food processing industry. The doubts were eliminated by the conclusions of the expert committee of the FAO/WHO adopted at the

meeting of Codex Alimentarius, held in Canberra, Australia in 1992 [1]. This expert committee established the important advantages of organising food producers according to the ISO 9000 Standard series compared to the applied systems of control, emphasising, at the same time that the existing systems – HACCP, GMP (Good Manufacture Practice), systems of inspection control, control of the finished product, etc, may successfully be incorporated into a whole system which assures quality and manages the quality.

The required quality systems, established by these standards, are not an alternative to the technical conditions implied for the product, but they are a supplement. That means that the implementation of these standards comprises predominantly the obligatory application of all the regulations addressing a certain product or field of activity of an organisation. The reviewed standards, especially through the "public requirements", indicate the need for assuring health and security in the working place, environmental protection (including the preservation of energy and natural resources), as well as the (of a product).

It may be necessary to explain the term "quality". Quality is defined as "a set of total characteristics of an entity anticipating its ability to fulfil the stated or implied needs".

The term "quality", in the sense of quality system standard, should not be used as a term that designates the degree of product perfection in the comparative sense (qualitatively) or to use it for technical evaluations (quantitatively). "The quality of a product" does not designate products which may be ranked as the best (top quality). Standards require that the realised "quality" of a product should be always the same and, when leaving the control step, to comply to the defined quality characteristics. The "Quality of a product" will be established with subjective or objective procedures of quality control. The "Quality" of a product, if it satisfies the defined characteristics of quality, always has a positive mark [2].

When the characteristics of a product are established – the required quality of a product, the application of a quality system assures the quality in relation to the buyer, while the internal organisation (taking into consideration the economy of the production, expenses, profit) is organised taking into consideration standards related to quality management.

In quality management the detection strategy is replaced by prevention strategy. In this way all the concern is focused on the onset of a process, its input, and emphasis is placed on the fact that the inputs can meet the requirements for product quality, as final outputs. That means that the focus of the battle for product quality is conveyed to inputs – purchase. Purchase control includes the determination of

characteristics of the purchased material (quality specification), the establishment of a list of approved suppliers (from whom the necessary materials may be bought), severer control and examination of the input materials.

The HACCP (Hazard Analysis and Critical Control Points) principles are indispensable in the control of processes. However, in the quality system, these principles should be extended, not only to the critical points where a risk may occur for the safety of a product, as originally implied [3], but also to other points where the quality of a product may be impaired. These principles may also be applied in the control of other processes that are not in direct relationship with the production process.

The system of quality management is based on the documentation of processes and activities, as well as the persistent implementation of the prescribed documents in practice. Implementation of the documented system in practice is proved by records. Standards also anticipate the liability of an organisation to internally review the quality system periodically (according to plan) in order to establish the persistence of its implementation in practice. In case there are some deviations, due to some disturbances in business operations, environment and other circumstances, the prescription of preventive measures has also been anticipated.

#### **CORRELATION BETWEEN THE DISCUSSED SYSTEMS**

It is usually considered that the HACCP system is applied only during the control of a process and, therefore, it has a narrower scope of application compared to the quality management system. However, the final safety of foodstuffs requires the analysis of the effects of raw materials, supplements, production practice and applied technological processes, as well as the influence of the equipment employed and the equipment for control and examination, the methodology of control and examination, storing conditions, training of personnel, etc. Therefore, the HACCP system also includes those elements that are considered specific for the quality management system [5]. Since the HACCP system may be evaluated and certified, the majority of the elements of the quality system must be included (fully or partly). It is obvious that only one element might be excluded and that is contract review, whereas the replacement for internal quality control is obligatory monitoring at critical points and system verification.

The system of the quality management should be applied to analyse business expenditures, which is not necessary with the HACCP system. In other words the HACCP system is exclusively oriented to satisfy the

safety of the final product, and thus includes all the elements of the system of quality management which are directly associated with this orientation or must be conditionally related (e.g. records).

Considering the quality management system, the principles of HACCP may be applied in process control (not only production), the determination of critical control points which may have an effect either on the hygienic safety of a product, the impairment of the quality of a product or those which may cause significant deviations from the prescribed steps.

It is very important to conclude in this part of the discussion that the application of the HACCP system is indispensable in the food processing industry when establishing an efficient system of quality management [3].

The existing model of food production, until now, has been quantity oriented. When it was established, its purpose was to assure supply of the population with food. However, there is continuous liberalisation of world trade, which sharply increases competition and consumers in developed markets increasingly demand food, that is not only inexpensive, but at the same time hygienically safe, with attractive sensory characteristics. The production process is also expected to respect animal welfare and protect the environment. These factors change the existing production model.

A new model of food market which is quality instead of quantity oriented influences production. In other words, it is market instead of production oriented. We, actually, talk about a new production model in which quality exceeds quantity.

How can industry absorb this change? The food industry has been lax, slow and has shown a limited interest to introduce objective process and product control methods and measurements into manufacturing practice, which has resulted in poor quality control systems (Newman, 2001). Nevertheless, before the meat industry invents something, it is prudent to examine what others have worked on effectively for years. The implementation of management philosophies such as TQM, the HACCP system and ISO 9000 Standards has proved to be a useful tool for improved safety and quality assurance and decreased costs. These management systems have been around for many years. According to Newman (2001), in a recent survey, of 100 major meat company web sites and almost 200 meat based food products, only 5 had vague quality assurance or quality control promises and no guarantees.

The HACCP system replaces ISO 9000 Standards for food safety. Currently there is no international standard, equivalent to ISO 9000 Standards, for the HACCP application. Nevertheless, several national authorities are proceeding with issuing national

standards for HACCP, along the lines and the philosophy of ISO 9000 Standards. Appropriate competent authorities are taking over responsibility for auditing the efficient application of the HACCP system, since its mandatory application has been imposed to nearly all developed economic areas in the world.

At the same time, independent agencies are taking over the responsibility for HACCP certification, again along the lines of ISO 9000 Standards certification. In fact, they are the same quality assurance agencies active in ISO 9000 certifications, demanding equivalent requirements for HACCP certification to those for ISO 9000 Standards certification.

The HACCP system is a control system assuring the hygienic safety of a product. A standard textbook definition could describe HACCP as, "a systematic approach to the identification, assessment and monitoring of the microbiological, chemical and physical hazards and risks associated with a food operation" [3]. The FAO/WHO Codex Alimentarius Commission (CAC) defines HACCP as a "system, which identifies, evaluates and controls hazards which are significant for food safety" (CAC, Basic texts).

The more important point in these cases is the place of the HACCP system within the ISO 9000 Standards description of procedures and the quality manual. There are again two different approaches. One is to fully integrate the HACCP standard requirements to the equivalent clauses of the ISO 9000 Standards system, merging, in fact, quality and food safety plans and procedures. Another is to develop the HACCP plan independently of the ISO 9000 Standards, avoiding overlapping and doubling. The arguments stated below for not merging quality and safety procedures are valid in this case also. Therefore, it is believed that the second of the above options is preferable.

The issue of whether to limit HACCP systems only to safety related concerns or to include quality parameters or non-safety regulations has evenly divided food safety professionals and regulators. The main argument against such an extension is the concern that such an extension and, consequently, the incorporation of quality attributes into a processing plant's HACCP program, would dilute efforts to control attributes associated with public health. It is, therefore, recommended that if quality or non-safety regulatory factors are desired to be controlled by industry, they should be established and operated separately of the HACCP system. In this respect one could suggest that there are two different tools in our hands, HACCP for

assuring the safety of food and ISO 9000 Standards application for quality attributes.

If the industry is not ISO 9000 certified, it again may or may not certify its HACCP plan. If, however it is to be certified, the particular part of the certification system concerned with the technicalities of certification and implementation of the system, as described in all certification standards, must be developed.

## CONCLUSIONS

The HACCP system and quality management system are two complementary systems. In the food industry quality requirements predominantly address safety, for which HACCP is indispensable at implementing a system of quality management.

The implementation and development of a HACCP system in the food industry is a legal obligation in the EU, USA and many other countries, while the implementation of a system of quality management is a voluntary category. The new law on the hygienic safety of foodstuffs and commodities in public use will also impose a legal obligation in our country to implement the HACCP system.

The possibility of implementing the HACCP system in the control of processes by establishing critical points where the diminishment of product quality may occur, should be reviewed.

The HACCP system and quality management system are driving forces for increasing the level of safety and quality of foodstuffs, necessary especially at this moment when the image of the food industry is somewhat disturbed by excessive happenings over the past few years.

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## IZVOD

### HACCP I SISTEM KVALITETA U PREHRAMBENOJ INDUSTRIJI

(Stručni rad)

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Analiza rizika i kontrola kritičnih tačaka (HACCP, Hazard Analysis and Critical Control Points) predstavlja nezamenljiv savremeni sistem kontrole procesa u prehrambenoj industriji. U svom izvornom značenju ovim postupkom kontrole analiziraju se rizici i utvrđuju mesta u procesu proizvodnje u kojima može da nastane kontaminacija proizvoda, što bi imalo kao posledicu gotov proizvod koji nije zdravstveno bezbedan. U kritičnim tačkama pooštrava se kontrola procesa proizvodnje da bi se otklonili ili umanjili rizici po zdravstvenu bezbednost proizvoda.

S obzirom da je cilj uvođenja sistema upravljanje kvalitetom, prema standardima serije ISO 9000, izrada proizvoda koji zadovoljava "iskazane potrebe ili potrebe koje se podrazumevaju", a potrebe koje se podrazumevaju odnose se na propisane zahteve kvaliteta, što se u prehrambenoj industriji, pre svega, odnosi na zdravstvenu bezbednost, to je neophodno da se HACCP ugradi u sistem kvaliteta. Primenu principa HACCP prilikom uvođenja sistema kvaliteta, treba proširiti i na one delove procesa proizvodnje u kojima može da se ugrozi zahtevani kvalitet proizvoda.

HACCP sistem i sistem upravljanja kvalitetom su dva komplementarna sistema. U prehrambenoj industriji zahtevi kvaliteta se, pre svega, odnose na zdravstvenu ispravnost, za šta je prilikom uspostavljanja sistema upravljanja kvalitetom HACCP nezamenljiv.

Uvođenje i primena HACCP sistema u prehrambenoj industriji je u EU, SAD i mnogim drugim zemljama zakonska obaveza, dok je uvođenje sistema upravljanja kvalitetom dobrovoljna kategorija. Donošenjem novog Zakona o higijenskoj ispravnosti namirnica i predmeta opšte upotrebe, uvođenje HACCP sistema biće i za našu prehrambenu industriju zakonska obaveza.

Treba preispitati mogućnost primene principa HACCP u kontroli procesa određivanjem kritičnih tačaka u kojima može da dođe do umanjenja kvaliteta proizvoda.

HACCP sistem i sistem upravljanja kvalitetom predstavljaju pokretače za podizanje nivoa zdravstvene ispravnosti i kvaliteta prehrambenih proizvoda, neophodne pogotovu u ovom trenutku, kada je ugled prehrambene industrije donekle poljuljan ekscesnim događajima tokom proteklih nekoliko godina.

Ključne reči: Analiza rizika • Prehrambena industrija • Kontrola kritičnih mesta • Kontrola procesa • Rizici •

Key words: Hazard analysis • Food processing industry • Critical control points • Control • Production process • Risks •