

## **The transition of the food safety management system to the requirements of the new 2019 edition of the EN ISO 22000 standard**

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*Review*

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### *Abstract*

*The paper presents the activities and results obtained to make the transition of the food safety management system to the requirements of EN ISO 22000 revised in 2019. It presents the importance of food safety for human health and HACCP principles and methods of food safety. The novelties brought by the revision of the reference standard are shown and the activities necessary for their inclusion in the food safety management system are made explicit. The obtained results consist in ensuring the management of risks and opportunities associated with the context and objectives of the organization, establishing prerequisite programs to ensure the conditions and activities for maintaining food safety, establishing the hazard control plan that includes the necessary control measures, procedures for monitoring the limits imposed on technological parameters and the persons responsible for eliminating or reducing to an acceptable level the significant hazards for food safety as well as in reviewing the documentation of the management system.*

**Keywords:** *food, safety, standard, management, system*

## **INTRODUCTION**

By food or food product is meant “any product or substance, whether fully processed, partially processed or unprocessed, intended for human consumption or expected to be used for human consumption” [1]. Food also includes beverages, chewing gum, and any other substance, including water, intentionally incorporated into food during its production, preparation, or treatment.

Food safety means ensuring the quality parameters (microbiological, chemical, and physical) of food throughout the food chain from raw material to the final consumer. Implicitly appeared the notion of safe food, which is that food obtained by classical or modern technological methods during which were taken all measures to prevent the transmission of microorganisms or physical-chemical contaminants. These measures must be ensured at all stages of production, processing, preparation, and marketing. Under the conditions of intended use (preparation or consumption) the safe food product does not harm the consumer.

The intensive production systems, the progressive industrialization of food manufacturing processes, the globalization of the food market, and the development of modern packaging and storage technologies have

contributed to reducing the cost of food and ensuring a sufficient amount of food in Europe and developed countries. However, these new systems, processes, and technologies have not always produced safer food. Because many foods are exported, the effects of non-compliant foods are felt even worldwide. A major concern of the European Union is to ensure that food consumed is all safe for consumption, for all its citizens, whether food is produced within the EU, or imported. Concern for food safety began with the establishment of the EU but has become major in recent decades. This was in response to the great problems of the 1990s: the “mad cow” crisis, the dioxin-contaminated feed crisis and the counterfeiting of olive oils.

The development of modern storage and refrigerated transport processes, the widespread use of freezing since 1950, processes such as freeze-drying, aseptic packaging, heat treatments such as pasteurization or UHT (ultra-high temperature), the use of preservatives, the use of irradiation, etc., have determined considerably prolonging the shelf life of foods and have contributed to their better safety. Despite the existence of these discoveries, there may be a hazard of food contamination by natural contaminants, accidentally introduced contaminants or by improper food treatment.

The quality of food products is given by their specific quality characteristics and depends on a very large number of factors as shown in Figure 1 [2], which shows that a basic characteristic,

product hygiene (hygienic quality), it is influenced (unfortunately negatively and quite frequently) by numerous factors with a potential hazard to the health of consumers.

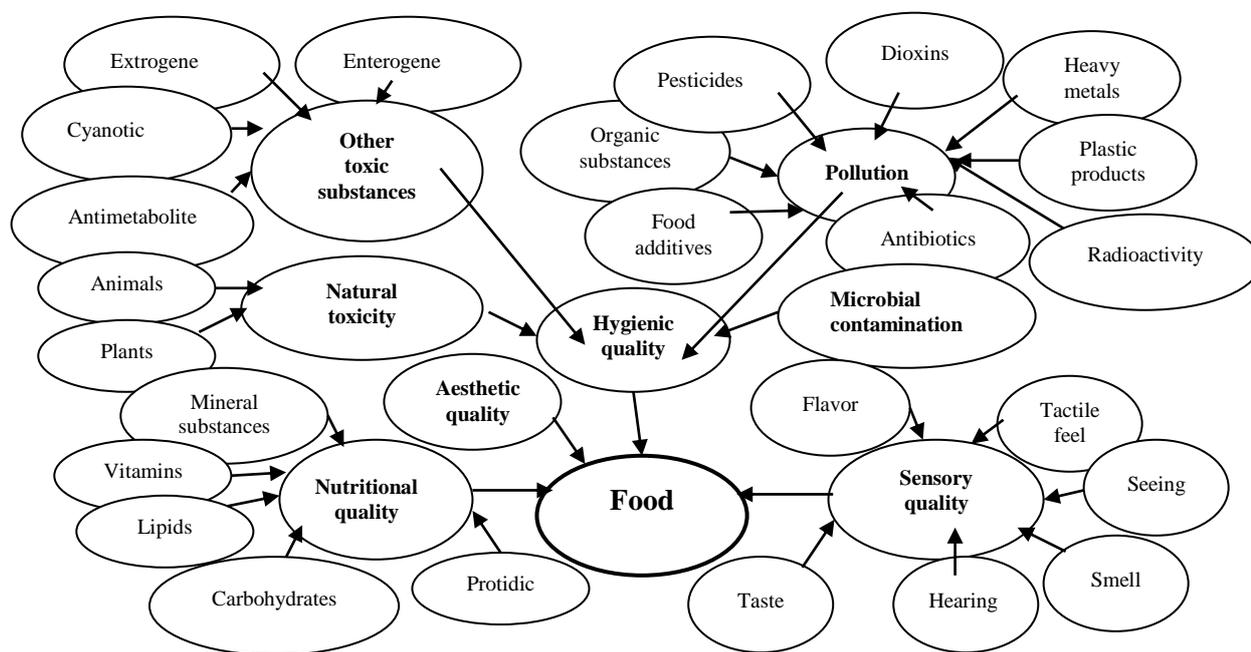


Fig. 1. Food quality characteristics

The European Commission, to maintain a high level of public health, proposes an approach whose specific rules for food hygiene include responsibilities for producers and competent authorities and a specific framework for regulating animal health. The new approach to ensuring food safety is based on the identification, assessment, and control of food contamination hazards (physical, chemical, and biological) at every stage of the food chain. Hazards must be prevented, eliminated, or reduced to an acceptable level by procedures for the effective implementation of the measures established before the product is available for consumption.

The European Commission has proposed normative acts underlying the new approach to food safety, including "Regulation (EC) No. 178/2002 of the European Parliament and of the Council 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", known as the General Food Law. The requirements of Regulation no. 178 was transposed in our country by Law no. 150/2004

on food safety amended and supplemented by Law 412/2004.

According to the law, "food and feed business operators must ensure the implementation of the food safety management system according to the Hazard Analysis and Critical Control Point (HACCP) principles at all stages: production, processing, and distribution, within the businesses under its control" [1].

"The HACCP system, which is science-based and systematic, identifies specific hazards and measures for their control to ensure the safety of food. HACCP is a tool to assess hazards and establish control systems that focus on prevention rather than relying mainly on end-product testing" [3].

Created in the 1960s by Pillsbury and NASA to ensure food safety for astronauts, the HACCP method was later adopted by international food safety bodies such as The Food and Agriculture Organization of the United Nations (FAO) and The World Health Organization (WHO).

The Codex Alimentarius Commission has transformed it into food quality and safety system by setting out the following seven principles:

1. Performing hazard analysis (identification of potential hazards associated with a food product at all stages of the technological flow, risk assessment compared to harmful to the consumer, establishing control or prevention measures),
  2. Determining the critical control points (CCP) which can prevent, eliminate, or reduce the hazard to acceptable limits,
  3. Establishing critical limits (in which the CCP is kept under control),
  4. Establishing the control monitoring system of each critical control point,
  5. Establishing corrective actions, if a certain CCP is outside the critical limits,
  6. Establishing the verification procedures of the HACCP system to confirm its conformity and effectiveness,
  7. Establishing documentation and keeping records appropriate to these principles application [3].
- The HACCP method is not "standardized", so an international standard had to be created, on the

model of ISO 9001 standard and based on HACCP principles. In 2005 was developed and approved by the International Organization for Standardization the international standard ISO 22000: 2005 "Food safety management systems. Requirements for any organization in the food chain" which establishes the requirements for a food safety management system, throughout a food chain organization controls its food safety hazards to ensure food safety for human consumption. The standard was taken over by ASRO with the code EN ISO 22000:2005 as reference for the development, implementation, and evaluation of the food safety management system.

To align with the new ISO requirements for management systems standards: common framework structure, identical basic text, and common terms with identical definitions, the international standard ISO 22000 was revised in 2018, and 2019 ASRO took over the standard in Romania.

## MATERIALS AND METHODS

The Codex Alimentarius Commission has established 12 steps for the practical application of the HACCP principles. These steps have been

taken over by the reference standard as requirements for the implementation of the food safety management system.

**Table 1.** Stages of HACCP application and standard requirements [4]

Codex HACCP stage		EN ISO 22000:2019 requirements	
Stage 1	Formation of HACCP team	5.3	Food safety team
Stage 2	Product description	8.5.1.2	Characteristics of raw materials, ingredients and materials in contact with the product
		8.5.1.3	Characteristics of finished products
Stage 3	Identification of intended use	8.5.1.4	Intended use
Stage 4	Construction of the flow chart	8.5.1.5	Flowchart and process description
Stage 5	Confirmation of the flow chart on the spot		
Stage 6	Enumeration of all potential hazards	8.5.2	Hazard analysis
	Performing a hazard analysis	8.5.3	Validation of control measures and combinations of control measures
	Consideration of control measures		
Stage 7	Determination of critical control points (CCP)	8.5.4	Hazard control plan
Stage 8	Establishing critical limits for each CCP		
Stage 9	Establish a monitoring system for each CCP	8.5.4.3	Monitoring systems at CCP level and for OPRP
Stage 10	Establishing corrective actions	8.5.4	Hazard control plan
		8.9.2	Corrections
		8.9.3	Corrective actions
Stage 11	Establishing verification procedures	8.7	Monitoring and measurement control
		8.8	Checking on PRP and hazard control plan
		9.2	Internal audit
Stage 12	Establishing documentation and keeping records	7.5	Documented information

In addition to the new structure organized in ten chapters, this revision of the standard brings as

main novelty elements: a. the concept of risk-based thinking, b. the requirement for actions to

treat risks and opportunities, c. pays special attention to the establishment of prerequisite programs, d. introduce the hazard control plan.

a. Risk-based thinking means taking into account the risks and opportunities associated with the context and objectives of the organization. These risks are risks at the organizational level and should not be confused with food safety hazards.

Risk is the "effect of uncertainty" [4]. The risk is the possibility of an event that will have an impact on the achievement of processes and objectives. In the case of a negative impact, the risk is a threat, and in the case of a positive impact, the risk is an opportunity. Risk is the uncertainty in achieving the desired results and should be seen as a combination of probability and impact.

b. The risks related to the accomplishment of the processes and the achievement of the established objectives must be identified and evaluated and measures to treat the risks and opportunities must be established and put into practice.

Risks are identified and defined for the processes and objectives which can be influenced by the materialization of risks. The threats and opportunities for each process/objective are identified. The risks must be identified at any level where consequences on the achievement of the processes or of the objectives may occur and specific measures can be taken to solve the problems, raised by the respective risks.

c. Prerequisite Program (PRP): "basic conditions and activities that are necessary within the organization and throughout the food chain to maintain food safety" [4]. PRPs are known as good practices on manufacturing (GMP) / hygiene (GHP) / production (GPP) / distribution (GDP) / commercial (GTP) etc.

Prerequisite Operational Program (OPRP): "the control measure or combination of control measures applied to prevent a significant hazard to food safety or to reduce it to an acceptable level and within which the criterion of action and measurement or observation allow effective control of the process and/ or product" [4].

Hazard for food safety means any "biological, chemical, or physical agent present in the food with the potential to cause an adverse health effect" to the consumer [4].

A significant food safety hazard is a "food safety hazard identified during the hazard assessment that needs to be controlled by control measures" [4].

To establish the prerequisite programs, under the analysis of the hygiene system proposed by the Codex Alimentarius Commission, the following are taken into account [4]: construction, location plan of buildings and related utilities; location plan of the spaces, including zoning, workspaces, and facilities for employees; supply of water, electricity, and heat, compressed air, natural gas, etc.; pest control, waste and wastewater disposal and related services; the appropriate construction of the equipment and the accessibility offered by them for cleaning and maintenance; supplier approval and monitoring processes (for example raw materials, ingredients, chemicals, and packaging materials); reception of incoming materials, storage, shipping, transport and handling of products; measures to prevent cross-contamination; cleaning and disinfection; personal hygiene; product information/consumer awareness.

d. According to the old reference standard EN ISO 22000: 2005 the food safety hazards were managed through prerequisite operational programs and the HACCP plan. The revised standard combines the prerequisite operational programs with the HACCP plan in the hazard control plan.

The hazard control plan shall be drawn up for the management of the control points and critical control points identified by the hazard analysis. The hazard analysis is the process that identifies potential hazards of product contamination, assesses the risks posed by these hazards, and establishes measures to keep them under control (prevention, elimination, or reduction).

A critical control point is that "stage in the process in which one or more control measures are applied to prevent a significant food safety hazard or reduce it to an acceptable level and in which the defined critical limit and measurement allow corrections to be applied". The critical limit is "the measurable value that separates acceptability from unacceptability" [4].

## RESULTS AND DISCUSSION

### 1. Actions to treat risks and opportunities

Organizational risk management is ensured following the NRDI ECOIND procedure *Risk management* code PL-23 developed and approved for the implementation of the internal management control system and used for the transition of the integrated quality and environmental management system to the requirements of EN ISO 9001 and EN ISO 14001 standards revision 2015.

Risk management is "the process of identifying, evaluating, managing (including treating) and establishing a plan of risk mitigation measures, periodic review, monitoring and establishment of responsibilities" [5].

Risk assessment involves assessing the probability of risks materialization (P) and the impact (consequences) (I) on the objectives. The combination between the estimated level of

probability and the estimated level of impact is risk exposure:  $E = P \times I$  [6].

Both for the probability and the impact, the evaluators use evaluation grids from 1 to 5. The attitude (strategy) towards risk is established taking into account the level of risk tolerance:

Risk tolerance level: tolerable: 1-4 - does not require control measures; high tolerance: 5-8 - requires medium / long term control measures; low tolerance: 9-12 - requires short-term control measures; intolerable: 13-25 - requires urgent control measures [6].

The identified and evaluated risks are registered in the risk register. The control measures for the risks that require control measures, the implementation deadlines, and the responsible persons are established in the plan for implementing the control measures.

**Table 2.** The risk register [5]

Objective/ Activities	Risk	Causes that favor the occurrence of risk	Inherent risk			Strategy adopted	Date of last revision	Residual risk			Obs.
			Probabi- lity	Impact	Expo- sure			Probabi- lity	Impact	Expo- sure	

**Table 3.** The plan for implementing the control measures [7]

No.	Risk name	Control measures	Implementation deadlines	Responsible persons	Monitoring
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### 2. Establishing prerequisite programs

The food safety team, established at the implementation of the food safety management system, following the analysis of the hygiene system, establishes the basic conditions and activities that are necessary within the organization to maintain food safety.

The conditions refer to the provision of workspaces, facilities for employees (locker rooms, toilets, showers, dining area), provision of utilities necessary for the manufacturing process (electricity, natural gas, water, compressed air, etc.), provision of storage spaces for raw materials, materials, and finished

products, avoidance of cross-contamination, provision of waste and wastewater disposal services.

The activities refer to ensuring and maintaining staff hygiene, cleaning, and disinfection of equipment, installations, and workspaces, pest control, reception of raw materials and materials, handling, storage, and transport of products, ensuring product information and consumer awareness. These activities and the corresponding responsibilities are established in operational procedures.

### 3. Hazard control plan

For each stage of the technological flow, is performed the analysis of potential biological, chemical, and physical hazards. The assessment of the risk associated with potential hazards consists of the analysis of the probability

(frequency) of manifestation of each identified hazard and the severity (gravity) of their manifestations, on three levels: high, medium and low.

Depending on the severity and frequency of the analysed risk, the resulting risk class (1, 2, 3, or 4) is established at the intersection of these two elements, using the table for establishing the risk class.

**Table 4.** Table for establishing the risk class [6]

Severity	Frequency of occurrence (consumption)		
High	3	4	4
Medium	2	3	4
Low	1	2	3
	Low	Medium	High

The significant risks usually arise from risk classes 3 and 4. For each of these stages (which can be PCC or OPRP) is established a control measure or a combination of control measures. To keep under control of the technological parameters of these stages, the hazard control plan is drawn up. The hazard control plan

contains for each important hazard of the stage: the necessary control measures, the established critical limits, the monitoring mode, the established corrections when exceeding the critical limits, the monitoring records, and the responsible person.

**Table 5.** The hazard control plan

Stage	Important hazard	Control measure	Critical limits	Process/product monitoring			Correction	Records	Responsible
				Method	Frequency	Responsible			

#### 4. The revised documentation of the food safety management system

The transition of the food safety management system to the requirements of the EN ISO 22000: 2019 standard is reflected in: 1. Food safety management manual developed under the new structure of the reference standard; 2. Revised system procedures following the new standard revision; 3. Operational procedures

developed following the established prerequisite programs as well as for risk management; 4. New records: the risk register, the plan for implementing the control measures, the approved list of prerequisite programs, the hazard control plan.

## CONCLUSIONS

The complex transition process of the food safety management system described in the paper can be interpreted as a methodology. The Department of the Management Systems, which has in its services portfolio providing technical consultation for the implementation of this management system, will use the results obtained in this study in the consulting activity to implement the systems by the new standard or their transition to the new standard requirements.

By integrating modern risk analysis procedures and the concept of prevention for consumer health protection, specific to the HACCP method, the food safety management system, defined by EN ISO 22000:2019, ensures greater

product safety, low-risk recording to guarantee the product and the guarantee that the food that reaches the consumer's table is adequate from a hygienic-sanitary point of view and will not cause diseases.

From this perspective, the development, implementation, maintenance, continuous improvement and certification of a food safety management system is of particular importance, firstly for the organization, because it ensures its ability to consistently provide safe food, secondly, for the authorities, because it is proof of compliance with legal requirements, and thirdly for customers, because the efforts made by the organization for their safety give them confidence in the products and services offered.

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