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Risk analysis as a basis for food safety strategy

Introduction

For consumers food health safety is the most important characteristic of food quality. Consumers expect food to be safe [Special Eurobarometr 354, 2010]. According to UE regulations a high level of protection of human life and health should be assured [Regulation (EC) No 178/2002, Special Eurobarometr 354, 2010]. In Poland the meaning of human life and health protection and protection against unfair market practices was highlighted by its inclusion to the Constitution of the Republic of Poland from 1997[1]. The act regulating the issue of health and consumer safety is the Regulation of general products safety from 12 th December 2003 [government gazette, 2003, point 2275]. In addition to the general regulations on products safety legislative solutions for specific industries have been introduced. Main aim of all of these regulations is to protect consumer health. Nowadays food safety is regulated under UE and national regulations. Legal regulations on food safety and quality are regulated by the Act of Food and Feed Safety (25th of August 2006) [government gazette, 2006, point 1225]. This Act defines the requirements for food and feed safety assurance in line with the Regulation No. 178/2002. At Community level there are many other regulations of foodstuffs safety – Regulation 852/2004 on the hygiene of foodstuffs, Regulation 853/2004 regulating principles for hygienic production of food of animal origin, Regulation 854/2004 laying down specific rules for the organisations of official controls on products of animal origin intended for human consumption, and 882/2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules. Based on the abovementioned regulations it can be concluded that the procedures for food safety should be based on scientific risk analysis.

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[1] Article 76: „Public authorities shall protect consumers, users and lessees against activities threatening their health, privacy and safety and against unfair market practices. That protection is defined in the Act".

The aim of this paper is to present the risk analysis as a basic part of the strategy for food safety assurance in the European Union. The paper used an analysis of the literature and the method of synthesis and conclusions.

1. Strategy of European Union for food safety

To deliver higher level of consumer health is the important aim of Community policies as well as one of the tasks of European Parliament and the Council. The pillars of the strategy of UE for food safety are the horizontal regulations on food law and hygiene, European Food Safety Authority and official controls and food authorities.

Assurance of safe food is an essential aspect of the internal market and contributes significantly to the health and well-being of citizens, and to their social and economic interests [Regulation (EC) No. 178/2002]. Nowadays it is necessary to consider all aspects of the food production chain as a continuum including primary production and the production of animal feed, and sale or supply of food to the consumer because each element may have a potential impact on food safety. It is also indicated that all food operators should be involved in food safety assurance [Kwiatek, Wijaszka, 2010, p. 2]. Moreover, dispensed with full control of the final products, because it is assumed that the quality is created throughout the manufacturing process of the product.

The next very important aspect of the strategy of the Community for food safety is to ensure the traceability of food and feed. Traceability system in case of food safety incident enables to withdrawn unsafe foodstuffs from the market and inform consumers and food safety authorities [Regulation (EC) No. 178/2002].

The next pillar of UE food safety strategy is the European Food Safety Authority (EFSA) that was established by the Regulation (EC) No. 178/2002. EFSA should contribute to the high level of protection of human life and health, and in this respect take account of animal health and welfare, plant health and the environment, in the context of operation of the internal market. EFSA is an independent European agency funded by the EU budget that operates separately from the European Commission, European Parliament and EU Member States and has a wide authority to in-depth assessment of food chain compliance with regulations, based on scientific studies and opinions. Scientific opinions are based of food risk analysis. EFSA's role is to assess and communicate on all risks associated

with the food chain. EFSA supports other food authorities in the Community and EEA countries in food and feed risk management in domestic markets.

Food safety authorities and food inspections as well as RASFF are also the elements of food safety management system. RASFF (Rapid Alert System for Food and Feed) was elaborated by the European Commission to immediately inform the Member States about the risk deriving from food or feed that do not meet food safety requirements and are wrongly labeled, and in this way unsafe for consumers [Regulation (EC) No. 178/2002, art. 19][2].

Based on article 17, point 2 of the Regulation (EC) 178/2002 it is required for Member States to enforce food law and monitor and verify that the food law requirements are fulfilled by food and feed business operators at all stages of food chain. In Poland the system of consumer protection in the field of food safety and quality is built of external and internal inspection system [Wiśniewska, 2005, p. 60]. The internal inspection system is held by the food operator[3], and the external system is realized by food authorities, based on the food law requirements [Polish Law, 2006].

The government control of food authorities has the Health Minister in collaboration with the Agriculture Minister. Nowadays the cooperation between Food Authorities is very important as well as informing about inspections results [Ozimek, 2006, p. 94].

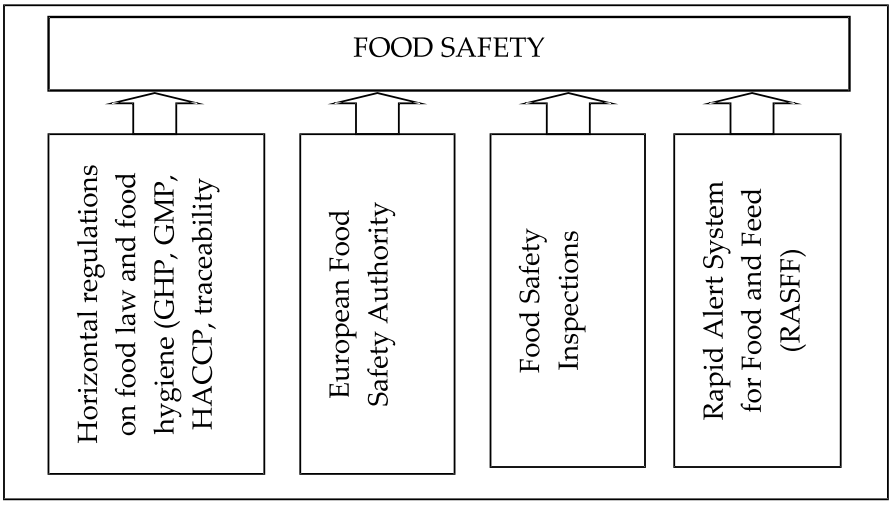
In summary, the basic elements of food safety strategy are based on legal requirements: Good Practice (GAP, GMP, GMP), HACCP system[4], traceability, the European Food Safety Authority, Food Safety Authorities, and system RASFF (see figure 1). Procedures for food safety are based on the scientific risk analysis.

[2] RASFF network is managed by the Chief Sanitary Inspector, who is also responsible for the operation of the national contact point and notify the Commission the cases of unsafe food. Notifications for food products take the form of a warning (Alert notifications) or information (information notification). The product, which is reported as part of the warning must be immediately withdrawn from the market.

[3] Requirements are included in the Regulation of the Ministry of Health from 30th of April 2004 on an internal food health safety control and compliance with the requirements of food hygiene in the food production process (government gazette No. 120, point 1259).

[4] Implemented in the UE in 1996, in Poland in 2001 (the Polish Regulation on health requirements for food and nutrition issued on 11th May 2001). In accordance with the Regulation (EC) No. 852/2004 issued on 1 st of January 2006 system HACCP is obligatory for all sectors of the food industry, excluding the primary production. Certification of HACCP is not obligatory.

Figure 1. Pillars of food safety assurance in UE



Source: Own elaboration.

2. Aspects of risk analysis implementation

The need for risk analysis[5] is denoted in article 6 of the Regulation (EC) 178/2002. Risk analysis is the basic methodology food law should be based on, and results in a high level of protection of human health and life, food law shall be based on. Food law allows an exceptional situations when risk analysis is not recommended to be used due to the circumstances or the characteristics of the substance. Scientific risk analysis[6] that is the foundation of food safety strategy is a three step process. These three steps are (see figure 2):

– risk assessment,
– risk management,
– risk communication.

Risk assessment is a specialized field of applied science, which includes a review of scientific data and research to assess the risks associated with certain hazards. It is a scientifically based process consisting of four steps:

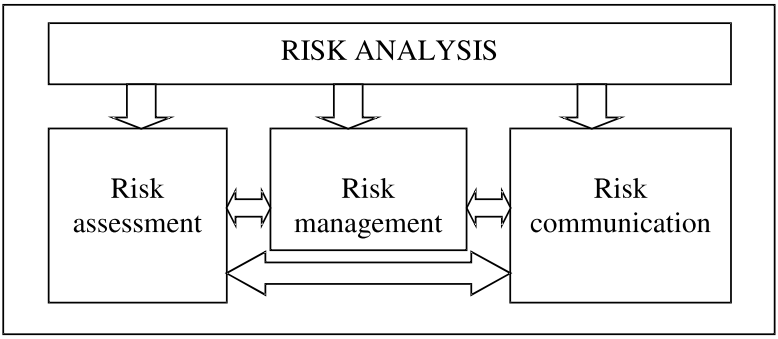
– hazard identification in food or feed,
– hazard characterization (hazard assessment),

[5] Based on the Regulation (EC) 178/2002 risk in defined as a function of the probability of an adverse health effect and the severity of that effect, consequential to a hazard.

[6] FAO/WHO in 2006–2007 published working principles and method of risk analysis in the process of food safety assurance for official use.

– exposure assessment,
– risk characterization.

Figure 2. The process of the scientific risk analysis



Source: Own elaboration.

These steps require scientific and monitoring studies as well as expert knowledge of scientists. They should be based on the available scientific evidence and undertaken in an independent, objective and transparent manner. However, if the scientific risk assessment cannot provide all the information to make decisions in the field of risk management, other relevant factors that are justified should be taken into account, including societal, economic, ethical and environmental, traditional and the ability to control them.

Hazard identifications refers to already known and potential hazards. Hazard identification requires the interdisciplinary, expert knowledge [Kołożyn-Krajewska, Sikora, 2011, p. 82–94]. It includes biological, chemical and physical agent in foodstuffs with the potential to cause an adverse health effect. Biological agents that may cause food safety hazards are: viruses, bacteria, yeasts, molds, algae, protozoa, parasitic mites, other insects and parasitic microorganisms and their metabolites and toxins. In the biological hazard identification process the data on ecology and epidemiology shall be considered, so it is determined which microorganisms can be present in raw materials, at which food chain stage, and the type and frequency of food poisoning associated with the type of food [Kołożyn-Krajewska, Sikora, 2001, p. 150–161]. To this group of food hazards also GMO can be included as it can cause hazards which are unknown yet. Chemical agents that can cause food safety hazards are natural toxic substances (i.e. amygdalin, saponins), pesticides residues,

fertilizers (nitrates, nitrites) and other chemicals, coming from the industry (heavy metals, PAHs, PCBs, dioxins), technology (micotoxins, heavy metals, PAHs, HCA) and the environment (heavy metals, radioactive elements). Physical agents that may cause adverse health effects are foreign objects entering the raw materials, from raw materials, packaging, processing process, staff negligence and non-compliance with GMP and GHP. The study showed, that women and men link to three potential food hazards: mycotoxins, pesticides and irradiation [Bieberstein, Roosen, 2015, p. 165–176]

Hazard assessment means to make a quantitative and/or qualitative characterization of the hazard that are health adverse effects associated with the indicated biological, chemical and physical agents in foodstuffs. This assessment should be based on experts' opinion.

Exposure assessment is to determine the quantitative and/or qualitative likelihood of exposure to health adverse agents that may occur. For microbiological hazards different types of predictive mathematical models developed for specific groups of products, i.e. Monte Carlo simulation can be applied. This models should take into account variables such as: storage times and the number of micro-organisms, and the start time and the volume of consumption [Kołożyn-Krajewska, Sikora, 2001, p. 150–161]. A series of new risk metrics i.e. The Appropriate Level of Protection (ALOP) and Food Safety Objective (FSO) has been established by Skandamis et al. [2015, p. 310–313].

Risk characterization means to collect data from the previous steps and determine the probability distribution of the assessed exposure. Risk means a function of the probability of an adverse health effect. Risk can be presented as the ratio of the size of food hazard (the severity of its effect) and the probability of its occurrence Kołożyn-Krajewska, Sikora, 2001, p. 150–161]. Quantitative microbiological risk assessment is influenced by the choice of the probability distribution used to describe of closes at exposure. Duart and Nauta [2015, p. 48–57] show the impact of the choice of different probability distributions to describe concentrations at retail on risk estimates is dependent both on concentration and prevalence levels. Achieving the absolute level of safety is not possible, therefore the acceptable risk of a disease caused by a given agent in the population exposed to a hazard shall be defined. To this end, the epidemiological data on the incidence, selected consumer population and the likelihood of uncontrolled health risks shall be considered. An important addition to the risk charac-

terization should be an analysis of the costs associated with its reduction. Keeping the above analysis also needs to take into account the behaviour of other potentially dangerous agents and the risk of being exposed to them [Kołożyn-Krajewska, Sikora, 2011, p. 82–94].

Studies carried out by the EFSA on the risk assessment result in food safety improvement in Europe and improve the public trust. In the first five years of its operations it has issued over 450 scientific advice on inter alia*:* Bovine Spongiform Encephalopathy (BSE), Transmissible Spongiform Encephalopathy (TSE), safety of food additives: aspartame, food additives that cause allergy, genetically modified organisms (GMO), wild and farmed fish, pesticides and animal health problems including Bird Flu. The EFSA also carries out scientific studies on its own initiative, in particular when hazard appears and knowledge and approaches are constantly changing. These studies include the harmonization of risk assessment methods, i.e. has developed a harmonized approach to compare the risks from substances that can cause cancer and biosecurity antibiotics-resistant marker genes. In order to ensure risk assessment at the European level the EFSA collects and analyzes the most complete scientific data available. This is possible thanks to the cooperation of the EU Member States in the collection, sharing and analysis of data from the European Union [http://www.efsa.europa.eu/en/efsawhatriskassessment.htm, accessed 4.01.2015].

The next step of the risk analysis is risk management. Risk management means the process, distinct from risk assessment, of weighing policy alternatives in consultation with interested parties, considering risk assessment and other legitimate factors, and, if needed, selecting appropriate prevention and control options. Risk management process should be characterized by its transparency and consistency. The decisions taken should be documented in order to facilitate a broader understanding of the risk management process by all interested parties. Relevance, effectiveness and impact of decisions and their implementation should be regularly monitored, and if needed improved. Risk management should include in particular the recommendations of the EFSA and other factor, and the precautionary principle. In accordance with this principle, in specific circumstances where, following an assessment of available information, the possibility of harmful effects on health is identified but scientific uncertainty persists, provisional risk management measures necessary to

ensure the high level of health and life, and consumers' interests protection may be adopted.

Effective communications and dialog with the interested parties have a significant impact on public trust to the food safety system in the UE and to the EFSA. Policies related to information could be an important component of improving public health because mobilizing potential demand for food safety. In controlled market experiment confirm that informed consumers are more likely to purchase labeled fruits [Birol et al., 2015, p. 470–491]. Risk communication means the interactive exchange of information and opinions throughout the risk analysis process as regards hazards and risks, the factors that are affecting food safety [Charlebois, Summan, 2015, p. 303–317], risk-related factors and risk perceptions, among risk assessors, risk managers, consumers, feed and food businesses, the academic community and other interested parties, including the explanation of risk assessment findings and the basis of risk management decisions. The goal of risk communication is to provide interested parties and the public with reliable information based on scientific evidence. The result of the proper communication between interested parties is the success of risk management. One of the fundamental tasks of the EFSA is to inform about the risks related to the food chain on the basis of scientific study. It is a difficult and responsible task because scientific results cannot always be easily transformed into simple tips and advice to recipients who are not scientists nor the media, in the way they can easily understand and obey them. This information must be helpful and given to consumers and other interested parties in a clear, understandable and timely way. Should help the fulfill the gap between science and the consumer. This way of risk communication results in the rise of consumers awareness. The EFSA explains its scientific opinions by: analyzing the social perception of risks associated with food, explaining and contextualizing risks, collaborating with the various parties (including with national authorities, the media) to apply the information in the best possible way to different audiences, ensuring consistency with other evaluation and risk management authorities, as the European Commission and the Member States of the EU.

In the process of risk information the EFSA implements various ways, channels and tools of communications, including a website, is present in social networks, participate in conferences and public consultations, issues publications and information materials, organizes press confer-

ences and gives information to media in the form of informational messages and alerts [*When Food Is Cooking Up a Storm*…, p. 20–26]. Shan et al. [2015, p. 104–108] examined the use and impact of social media on 2-way communication between consumers and public organizations in the food safety and nutrition area. Based on in-depth qualitative study in the United Kingdom and Ireland they stated that, social media penetrated and brought new opportunities to food organizations' interactions with the public. In Communication Strategy 2010–2013 Perspective the EFSA defines the following priorities:

– increase relevance and understanding of EFSA communications for key target audiences and informed key audience,
– increase the independence of EFSA's opinion on risk assessment,
– enhance outreach in the EU and beyond, by increasing awareness and recognition of EFSA and its role and work as risk assessor,
– increase the coherence of risk communications across the EU and beyond,
– increase audience interactivity and dialogue with interested parties.

In support of these priorities, EFSA is implementing its communications activities in key thematic areas thereby increasing their impact and effectiveness. The choice of themes both reflects European consumer concerns and public health priorities.

3. Risk analysis in HACCP

System HACCP (Hazard Analysis and Critical Control Point) also is based on risk analysis. Nowadays HACCP is used worldwide in food processing. In UE countries it has been obligatory since 1996 based on the Directive 93/43/EEC. In Latin America and the Caribbean region implementation of risk analysis among the different sectors is relatively low (46%). In countries such as Mexico and Brasil with a long history of trade with the United States and the European Union, implementation of risk analysis is higher (56 and 50% respectively). It suggests that commerce may be a driver for achieving higher food safety standards [Cherry et al., 2014, p. 2098–2105]. Risk analysis in HACCP means hazard analysis and identification of critical control points (CCPs) based on the decision tree [Tyszkiewicz, 2000, p. 5–17]. Hazard analysis is the process of collecting and evaluating information on hazards and conditions leading to their formation. So it can be described as hazard identification. It aims to determine which of the identified risks are significant for food safety and should be

included in the HACCP plan. The next stage in the risk analysis in HACCP system involves specifying CCPs, and therefore an assessing the food risks. CCP is the stage at which control can be used to prevent or eliminate food safety hazards or reduce these risks to an acceptable level. Risks identified as critical control points need to be monitored and if there is not compliance with the critical limit, actions should be taken. Before the applying the decision tree a simple method of quantitative risk assessment elaborated by the French organization Certiviande [Tyszkiewicz, 2000, p. 5–17][7] can be used. It involves calculating the so-called priority index, which is the product of three-stage indices of validity threats and the frequency of their occurrence. This method has been included by the Institute of Meat and Fat in the guides for the implementation of HACCP systems in the meat and fat industry [Tyszkiewicz, 2000, p. 5–17][8]. We should also notice that risk analysis is an important element of the other systems of food safety management which are based on system HACCP, like standard ISO 22000 (Chapter 7.4) [EN ISO 22000].

Conclusion

In today's world food safety and consumers' interests safety are the main objects of interests of the society, NGOs, international organizations and professional and trade associations. The main elements of the strategy for food safety in the UE are the horizontal regulations within the principles of food law and hygiene that require to implement best practices, HACCP system, traceability, the European Food Safety Authority (EFSA) and food safety authorities, and system RASFF too. Based on legal requirements the risk analysis is the fundamental methodology for food safety and consumers' health protection in UE. Scientific risk analysis is built of a three stage process including: risk assessment, risk management and risk communication. Risk assessment is specialized field of applied science, which includes scientific research and expert knowledge. Risk management is a process that involves the examination of the alternatives of policies and considering the results of the risk assessment and other significant factors, and if necessary selecting the proper ways of prevention and inspection. A significant influence on the confidence in food safety sy-

[7] According to the Guide of Assocoation for the development of the meat industry certification in France Certiviande.

[8] According to the practical Guide for implementation of occupational hazard analysis system of health quality based on the control of critical points in the meat industry according to the principles of HACCP.

stem in UE has an interactive information and opinions exchange while risk analysis and the dialogue between various interested parties, so the effective communication. In the whole process of risk analysis the EFSA participates and plays an important role. Risk analysis is an important element of food safety assurance and management systems, including system HACCP and the other systems which are based on system HACCP, like standard ISO 22000. The ethics is over the food law and the obligation to use food safety and quality management systems. Practice has shown that without their implementation the abovementioned elements of the strategy for food safety assurance will be not very effective [Sikora, 2005, p. 41–48].

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Risk analysis as a basis for food safety strategy (Summary)

Food health safety is the most important characteristic of food quality for consumers. They expect food should be safe. Food safety is regulated by the UE food law and Polish food law. Based on legal requirements it can be concluded that the fundamental principles of the food safety strategy are: best practices, HACCP system, traceability, the European Food Safety Authority (EFSA), food safety inspections and authorities, and the Rapid Alert System for Food and Feed (RASFF). Procedures for food safety are based on the scientific food risk analysis. The main aim of this paper is to characterize the food risk analysis as the fundamental element of the strategy for food safety assurance in the UE. The scientific risk analysis is built of a three stage process: risk assessment, risk management, and risk information. EFSA actively participates in the whole process of the risk analysis. System HACCP and other systems of food safety management i.e. system according to ISO 22000 standard, are also based on risk analysis.

Keywords

risk analysis, food, safety, law requirements, EFSA