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## **1.7. LEGAL ASPECTS OF FOOD SAFETY**

### **Summary**

The aim of the article is to analyze the Polish and EU regulations on food safety. Food is essential to life of every human, so it is important to its safety. Consumers bear all risks associated with the consumption of the food that is why regulations are necessary to ensure protection from the consumption of harmful substances. These regulations shall apply to both methods of food production and the placing on the market. The basic legal act regulating this issue is the Act of 25th August 2006 concerns food safety and nutrition, which is the frame work which regulates in a comprehensive manner the conditions necessary to ensure food safety “from farm to a table”. Poland, like all European Union countries, forming the so-called rules apply “Hygiene package” comprising four regulations laying down rules for the hygiene of foodstuffs and the rules of conduct food sector regulatory authorities. Consumer safety cannot be provided just by the relevant legislation. It is essential to the proper application of the rules.

**Keywords:** food, security, legal regulations, consumer, producer

### **Introduction**

Globalization is “the process of creating the liberalized and integrated world market of goods and services and the international institutional order for the world-wide development of production, trade and financial flows” (Kołodko, 2001, p.26 ). The phenomenon of “the globe shrinking”, apart from numerous advantages, such as: ease of movement, access to the achievements of culture, science and technology brings about some negative consequences in many fields, e.g. organized crime. The emergence of transnational enterprises, which operate in many regions in the world, also contributes to the spread of pollution beyond the borders of a single country or region (Czerny M., 2005).

The pollution may also refer to food. Therefore, the regulations for food safety play such an important role. It should be pinpointed that in the subject literature there are terms: “food security” and “food safety”. “While discussing the complexity of the problem of food safety, there should be identified its elements and their significance with reference to current trends taking place in the contemporary world economy. From among many definitions of this term, the one, formulated by two American sociologists, L. Bush and W.B. Lacey deserves a special attention. They state that “food security has at least three dimensions: the first one is availability, i.e. having enough food available for all the population at all times to sustain human life. The second dimension of food security is accessibility. Food supply should not be limited by what economists call effective demand (...). The third dimension is adequacy (...).

Adequacy can be understood in the category of a balanced food ration while, at the same time, adequate food supply is free from diseases and toxic substances” (Michalczyk, 2012, p.8). “In legal terminology, ‘food security’ can be defined as an optimal state assumed by the legislator that should be achieved in accordance with the relevant provisions of both the international, EU and domestic law.” (Leśkiewicz, 2012)

“The significance of security and quality of foodstuffs is undoubtedly related to the possibility of risks, most of all, micro-biological ones, and also chemical or physical ones, which may adversely affect the product at various stages of its acquisition and processing” (Kielesińska, 2012). The above definitions indicate different approaches to the concept of food safety. In the present paper, food safety is understood as producing, transporting and ultimately providing customers with products free from any contamination.

Food is essential for life of every human being, therefore, its safety is so important. Consumers take the whole risk associated with the consumption of food; therefore, legal regulations providing their safety against the intake of harmful substances are necessary. These regulations must refer to both the ways of manufacturing foodstuffs and introducing them onto the market. However, discussing all these regulations in the paper is not possible. There will be presented the regulations concerning the basic terminology of food law: the concept of food, foodstuff, and food supplements. Poland, like all the Member States of the European Union, is obliged to observe the EU legal regulations. The first legal act of the EU food law is the Regulation (EC) No 178/2002 of the European Parliament and the Council of 28 January 2002 laying down the general principles and requirements of food law, appointing the European Food Safety Authority, and laying down the procedures concerning food safety (Dz. Urz. UE L 31 of 1.02.2002) (hereinafter referred to as the General Food Law - GFL). It specifies, in Article 3, section 1, the food law of the European Union; “food law” amounts to statutory, executive and administrative provisions regulating food in general, and their safety in particular, both at the level of the Community and at the national level; this definition includes all the stages of production, processing and distribution of food and feed manufactured for farm animals or used to feed farm animals”. “The stages of production, processing and distribution” amount to every stage from the production of basic food, through its storage, shipment, sale or supply to consumers, and also carriage, production, manufacturing, storage, shipment, sale and supply of feed. As it results from the preamble to the Regulation, free movement of food and feed in the European Union is possible only when the requirements for food and feed safety within the Member States do not significantly differ from each other. Poland, like all the Member States, is obliged to observe the provisions creating, so called, Hygiene Package, including four regulations laying down the principles of hygiene of foodstuffs and the rules of conduct of the authorities supervising the food sector. These are:

- Regulation (EC) No 853/2004 of the European Parliament and the Council of 29 April 2004 on the hygiene of foodstuffs

- Regulation (EC) No 882/2004 of the European Parliament and the Council of 29 April 2004 on official controls performed to ensure the verification of compliance feed and law, animal health and animal welfare rules.
- Regulation (EC) No 853/2004 of the European Parliament and the Council of 29 April 2004 laying down specific hygiene rules for on the hygiene of foodstuffs
- Regulation (EC) No 854/2004 of the European Parliament and the Council of 29 April 2004 laying down specific rules for the organization of official controls on products of animal origin intended for human consumption

The basic Polish legal act regulating this issue is the framework Act of 25 August 2006 on food and nutrition safety (hereinafter referred to as AFN), which comprehensively regulates the conditions necessary to ensure food safety “from farm to table”. Section 1 of the Art.1 indicates that the law regulates the requirements and procedures necessary to provide food safety in accordance with the regulations of the European Union and, in section 2, it indicates the EU regulations.

Both GFL and AFN are not applicable to primary production for private domestic use or to the domestic preparation, handling or storage of food for private domestic consumption (Art.1 section 3 of GFL, as well as Art. 2 section 2 of AFN). The Polish law also excludes the application of its provisions to the people individually collecting mushrooms growing in natural conditions (Art. 2 section 2 of GFL).

### **The concept of food**

Food is defined differently. Colloquially, the concept of food is understood as food products, food and nourishment. (Polański E. (ed.), 2012 ). "Food is called the edible parts of plant and animal tissues in their natural or processed state that, when eaten and assimilated by the human body, can be a source of different nutrients. In accordance with the terminology, the concept of food does not include:

- animal feed, live animals, if they are not marketed as food intended directly for consumers,
- plants prior to harvesting,
- medicinal products,
- cosmetics, tobacco and tobacco products,
- -narcotic drugs and psychotropic substances,
- feed,
- residues and contaminants.” (Kumirska et.al., 2010)

“Food can be assigned many functions. The basic one is physiological function, conditioning the existence of a human being and their biological development but satisfying hunger and the pleasure of eating is not less important.” There are also other functions of minor importance but clearly present in reality (...) satisfying the need for sharing meals by the family, other social and religious groups, the share of food in liturgical celebrations and mental compensation”( Czechowski, 2011)

For food legislation, the concept of food is of the key importance. AFN, in Art.3 section 1, indicates that food (foodstuff) is any substance or product within the meaning of Art. 2. of GFL. Polish provisions refer straight to the EU Resolution,

according to which food (foodstuff) “means any substances or products, whether processed, partially processed or unprocessed, intended for human consumption or, whose human consumption may be expected”. On the other hand, foodstuff is: soft drinks, chewing gum and any substances, including water, intentionally added to food during its manufacture, preparation or processing. This definition includes water according to the standards specified in accordance with Art. 6 of Directive 98/83/EC and without prejudice to the requirements of Directives 80/778/EEC and 98/83/EC.

Water, in accordance with EU regulations, should be considered as food from the moment of the water outlet from the source, e.g. water intake facilities, cisterns or from the moment of placing water in bottles or containers. Therefore, water is considered as foodstuff from the moment it can be consumed by the man.

The concept of foodstuff does not include:

- a. feed;
- b. live animals unless they are to be marketed for human consumption;
- c. plants prior to harvesting;
- d. medicinal products within the meaning of Council Directives 65/65/EEC (1) and 92/73/EEC (2);
- e. cosmetics within the meaning of Council Directive 76/768/EEC (3);
- f. tobacco and tobacco products within the meaning of Council Directive 89/622/EEC (4);
- g. narcotic or psychotropic substances within the meaning of The Only Convention on Narcotic Drugs of 1961 and The Convention on Psychotropic Substances of 1971;
- h. residues and contaminants” (Art. 2 GFL)

The definition of food in the EU law is modeled on Codex Alimentarius.” For the purposes of the Codex Alimentarius: Food means any substance, whether processed, semi-processed or raw, which is intended for human consumption, including drink, chewing gum and any substance which has been used in the manufacture, preparation or processing of “food” but does not include cosmetics or tobacco or substance used only as drugs” (Code of Ethics for International Trade in Food, CAC/RCP 20-1979 (Rev.1-1985) and includes definitions of food in the legislation of the Member States. In the British law, according to Food Safety Act of 1990: (1) In this Act “food” includes-(a) drink; (b) articles and substances of no nutritional value which are used for human consumption; (c) chewing gum and other products of a like nature and use; and (d) articles and substances used as ingredients in the preparation of food or anything falling within this subsection.(2) In this Act “food” does not include - (a) live animals or birds, or live fish which are not used for human consumption while they are alive; (b) fodder or feeding stuffs for animals, birds or fish; (c) controlled drugs within the meaning of the Misuse of Drugs Act 1971; or (d) subject to such exceptions as may be specified in an order made by the Secretary of State - (and) medicinal products within the meaning of the Medicines Act 1968 in respect of which product licenses within the meaning of the Act are for the time being in force; or (ii) other articles or substances in respect of which such licenses are for the time being in force in pursuance of orders under section 104 or 105 of the Act (the application of Act to other articles and substances).”(Szymecka-Wesołowska, 2013) As it results from the

definition of GFL, a potential possibility of consumption of the product by humans is enough to qualify it as foodstuff and include in the food law regulations. In cases where the specific substance may be used for both human consumption and other industrial purposes, it must meet the conditions required for foodstuffs until proven that is not suitable for human consumption.

### **Food supplements**

There are also food supplements available on the market. They are not food but they are consumed by people. Therefore, the EU and Polish law include their definition. Food supplement is foodstuff being the supplement of a regular diet. A regular diet is a balanced and varied diet. “An adequate and varied diet could, under normal circumstances, provide all nutrients necessary for proper development and maintenance of healthy lifestyle in quantities meeting the standards established and recommended by generally accepted scientific data” (item 3 of the preamble of the Directive 2002/46/EC). Food supplement, in accordance with the Polish and EU provisions, is intended only to complement a regular diet.

In accordance with Art. 3 section 3 item 39 of GFL, food supplement is foodstuff which is: the supplement of a regular diet; concentrated source of vitamins, minerals or other substances, single or complex, indicating nourishing or another physiological effect; placed on the market in the form that allows dosage, in the form of: capsules, tablets, pills and other similar forms, sachets of powder, ampoules of liquid, drop dispensing bottles and other similar forms of liquids or powders intended to be consumed in small, measured amounts of units. Lack of fulfillment of any of the above criteria brings about that the substance cannot be considered as food supplement. The supplement may not have the properties of a medicinal product within the meaning of pharmaceutical legislation. In accordance with Art. 2 item 32 of pharmaceutical legislation, a medicinal product is “any substance or combination of substances presented as having properties for preventing or treating disease in human beings or animals or administered with a view to making a medical diagnosis or to restoring, correcting or modifying physiological functions in humans by exerting pharmacological, immunological or metabolic action”. On the other hand, Art. 1 item 2 of the Directive 2001/83/EC indicates that a medicinal product is: a) any substance or combination of substances presented as having properties for treating or preventing disease in human beings; or b) any substance or combination of substance which may be used in or administered to human beings with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis.”

The provisions settle how to classify the supplement which, at the same time, fulfills the criteria of a medicinal product. In such a case it is referred to as a medicinal product.

Disputes on which category a specific product belongs to, i.e. foodstuff or medicinal products, were also resolved by the Supreme Administrative Court before the entry into force of the regulations currently in force. In the judgement of 26 October 1995, Ref. I SA 753/94, OSP 1996, vol.1, item 18, the Court ordered that “The herbalist guide indicates that various herbal blends (...) cure the whole range of diseases such as

cancer, multiple sclerosis, hypertension, duodenal ulcer and others. There must be no doubt that if the discussed herbal blends have medical properties stated by the manufacturer, they should not be ingested freely by healthy individuals. Therefore, these sets cannot be declared, as the plaintiff wish, herbal teas for general use but drugs.” The judgement of the Voivodeship Administrative Court in Lodz of 4 September 2007, Ref. III SA/LD 56/06, LEX, No 914685, is dedicated to the problem of avoiding the regulations of pharmaceutical legislation, even more restrictive than AFN. Among others, the Court declared that the introduction by the manufacturer on the market (...), as a dietary supplement, with identical composition quantities, active substances that occur in the medicinal product (...) would aim at circumventing the provisions of the Act – The Pharmaceutical Law and it would violate the provisions of the Act on health conditions of food and nutrition”. In accordance with Art. 2 p. 32 of the Act – the Pharmaceutical Law, the medicinal product is: a substance or mixture of substances, presented as having properties for preventing or treating diseases in human beings or animals or given to make a diagnosis or to restore, correct or modify physiological functions of a human body by pharmacological, immunological or metabolic impact. To introduce a medicinal product on the market there is required the decision of the President of the Office of Medicinal Products, Medical Devices and Biocides. Launching on the market takes place after the decision has been rendered. The permit is issued with a time limit for the period of five years and can be extended on the basis of the documentation for the period of another five years or without a time limit.

The entity operating on the food market that introduces a food supplement on the market is required to notify the Chief Sanitary Inspector on the planned marketing and present the label model. A food supplement is implemented without the decisions of the Bodies. An easier implementation of food supplements than medicinal products brings about that there may occur the attempts to circumvent the provisions on medicinal products and to implement them as food supplements.

## **Conclusions**

Consumer safety is provided not only by appropriate legal regulations. The provisions of both the EU and Polish law concerning food safety are rather extensive. They, among others, regulate the issues of food labeling, authorized food additives used in its production, the food coming from genetically modified products or organic food. “Despite the attempts to strengthen the EU food safety system and the early warning system, there are still accidents which may have negative impact on consumers’ health. There can be listed the use of counterfeited dried eggs in food production or the use of contaminated sodium chloride for the production of meats in Poland. These situations adversely affect the consumers’ trust in food and the institutions supervising production and the legislation” (Leśkiewicz., 2012, p.181). It is necessary not only to introduce but, most of all, to apply these provisions correctly to make them fulfill their role and secure consumers against the consumption of food posing a threat to human life and health.

Rigorous adherence to the regulations of the food law is one of the factors influencing the improvement in food safety in Poland. According to the latest update of the World Food Security Index (<http://foodsecurityindex.eiu.com>), Poland is one of the four European countries where food safety increased. Poland occupies the 28th position in the world and is in the group of the countries that achieved the best results in the World Food Security Index, developed at the commission of the DuPont company. In 2015, Poland received 74.2 points out of 100, obtaining 0.5 point more, compared to the previous year. The fall from the 26<sup>th</sup> to the 28<sup>th</sup> position was caused by an increase in food safety in other countries that obtained higher score. In the ranking of the European countries, Poland fell from the 16<sup>th</sup> to the 17<sup>th</sup> position. Ireland, with 85.4 points, and Austria, with 85.1 points, achieved the best results. Poland mostly improved its score in the area of the access to food. The score in here increased from 66.3 points last year to 70 points at present, by means of which the country occupies the 25<sup>th</sup> position in the world in this category. Referring to the food price accessibility, Poland fell from the 27<sup>th</sup> to the 28<sup>th</sup> position in spite of the fact that the value of the ratio changed slightly and it amounted to 78.4 compared to 78.6 points last year.

In case of food quality and safety, the score of Poland is stable. It remained at a similar level for four years, although, now, it is slightly lower and it amounts to 75 points (less than last year by 0.7 point). In this category, Poland occupies the 27<sup>th</sup> position in the world. The highest scores (100 out of 100) were obtained by Poland in such areas as: programs supporting food security, farmers' access to finance, nutrition standards and food safety. The country also obtained high scoring for low proportion of people below the world poverty line in the country's population (99.9 points) and a small loss of food (90 points) which, when compared to the previous year, received the score better by 8.1 points.

Poland also maintained the last year improvement in scoring in the field of the share of expenditure on food in household budgets, receiving 81.8 points out of 100. Food consumption amounts to 18.5 % of the share in household expenses, as in Greece (16.2%), Slovakia (17.4%) and Hungary (17.6%). For comparison in Germany it is 11.7% and in Great Britain 9.2%.

The level of expenses for research and development in agriculture, measured by the percentage share of expenses for research and development in GDP received the lowest scoring. Poland obtained in here only 12.5 points out of 100 and the result is the same as in the last three years and twice lower than in 2012.

As far as the neighboring countries of Poland are concerned, Germany obtained 83.9 points in this year edition of the Index, which amounts to a minimum increase compared to the previous year, and maintaining the 8<sup>th</sup> position in the index. Czech Republic obtained the score of 74.9 points, which is by 0.3 point more compared to 2014 and fell from the 23<sup>rd</sup> to the 25<sup>th</sup> position. Slovakia ended in the slightly worse position since it took the 32<sup>nd</sup> place with the score of 70.7 points. (<http://www.pir.home.pl/>)

The accession of Poland to the European Union significantly affected the improvement in food safety that can be acquired in our country. This results from the duty to apply, both by food producers and distributors, and sellers, the rigorous EU standards concerning food safety. On the other hand, the common market brings about some

risks as well. The constituent of the common market – the freedom of flow of goods enables rapid movement of food between the Member States. There should be also indicated the necessity of detailed inspections of food or generally foodstuffs before allowing them on the common market in case of import from the outside of the European Union. Obviously, in case of the occurrence of threat to life and health of humans or animals there are provided the procedures restricting the free movement of food. The European Union developed the principles of close cooperation of the States in matters of food safety and the notification system for existing or possible hazards that may occur and also how to respond in the event of threats. However, the presentation of these regulations goes beyond the scope of the present paper. It should be underlined that the most perfect regulations of both the national and the EU legislation will not be sufficient unless there is awareness of the absolute necessity to follow them among all entities participating in the process of food production and distribution and also consumers.

Generally speaking, to discuss food safety, first of all, it should be established if, in the specific case, we deal with foodstuff or food supplement. Therefore, in the paper, there are presented only the definitions without the knowledge of which one cannot discuss the application of the rules of food law. The other issues ought to be the subject of further considerations.

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