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THE LEGAL CONCEPT OF UNSAFE (DANGEROUS) FOOD

Abstract

The purpose of the considerations offered in this article is to determine how the term “dangerous food” should be understood in the light of the applicable law. The food safety system includes general and specific criteria for assessing whether a product is safe or not. Sometimes the concepts of defective product within the meaning of Directive No. 85/374/EEC, and dangerous food within the meaning of Regulation No. 178/2002 coincide. Food safety requirements include both health quality and commercial quality. Responsibility for unsafe food in individual areas must be determined separately, as they are based on divergent legal foundations. The legislation includes sub-categories of unsafe food, such as product harmful to health, adulterated product or spoiled product.

KEYWORDS

food, dangerous product, responsibility, harmful to health

SŁOWA KLUCZOWE

żywność, produkt niebezpieczny, odpowiedzialność, środek szkodliwy dla zdrowia

1. INTRODUCTION

The legislator did not define the term “unsafe food”, even though it appears in the Regulation No. 178/2002¹. The concept of food has a universal dimension, because it is used for the purposes of various legal acts in the field of food law. It has also been the subject of research in both Polish and foreign legal literature². Food as a product also attracts attention of researchers in various perspectives and circumstances³. Similarly, many scientific publications, not only legal ones, concern food safety⁴. However, relatively few works were devoted to the problem of dangerous food⁵.

¹ Regulation (EC) No. 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures for food safety; “Official Journal” L No. 31, 1.02.2002, pp. 1–24, hereinafter Regulation No. 178/2002.

² P. Wojciechowski, *Odpowiedzialność za szkodę wyrządzoną przez produkt niebezpieczny żywnościowy pierwotny i przetworzony. Wybrane problemy*, “Studia Iuridica Agraria” 2011, Vol. 9, p. 328 *et seq*; K. Leśkiewicz, *Legal aspects of the food concept*, (in:) R. Budzinowski, I. Härtel (eds.), *Food security, food safety, food quality: Current developments and challenges in European Union Law*, Baden Baden 2016, pp. 59–70; M. Korzycka, *Definicje żywności w prawie*, (in:) M. Korzycka, P. Wojciechowski, *System prawa żywnościowego*, Warszawa 2017, pp. 175–178; K. Leśkiewicz, *Ustawa o bezpieczeństwie żywności i żywienia. Komentarz*, Warszawa 2022; K. Leśkiewicz, *Prawo żywnościowe*, Warszawa 2020, pp. 34–36; A. Szymecka-Wesołowska (ed.), *Bezpieczeństwo żywności i żywienia. Komentarz*, Warszawa 2013, p. 1057.

³ See E. Fouilleux, N. Bricas, A. Apha, *Feeding 9 billion people: Global food security debates and productionist trap*, “Journal of European Public Policy” 2017, Vol. 24, issue 1, pp. 1658–1677; I. Lipińska, I. Hasińska, D. Puślecki, K. Różański, *Economic and legal determinants of development of agrifood logistics*, Poznań 2022; K. Leśkiewicz, *Produkcja żywności w gospodarce o zamkniętym obiegu – wybrane aspekty prawne*, “Studia Iuridica Lublinensia” 2017, Vol. 26, pp. 503–518.

⁴ A. Kijlstra, A.P. Bos, *Animal welfare and food safety: Danger, risk and the distribution of responsibility*, “Organic Eprints”, orgprints.org (accessed 31.10.2022); J.D.G. McEvoy, *Emerging food safety issues: An EU perspective*, “Drug Testing and Analysis” 22 July 2016, pp. 511–520, www.drugtestinganalysis.com (accessed 31.10.2022); I. Canfora, *Legal instruments of health protection against unsafe food of agriculture origin in Italy*, (in:) K. Leśkiewicz (ed.) *Legal protection of human health against the unsafe agricultural food*, Warszawa 2022, pp. 149–157; J.L. Pomeranz, *Food law for public health*, Oxford 2016; M.S. Schumann, T.D. Schneid, B.R. Schumann, M.J. Fagel, *Food safety law*, New York 1997; I. Härtel, D. Ren, *Agri-food law: Term, development, structures, system and framework*, (in:) I. Härtel (ed.), *Handbook of agrifood law in China, Germany, European Union: Food security, food safety, sustainable use of resources in agriculture*, Frankfurt (Oder) 2018.

⁵ See e.g. I. Trapé, *Odpowiedzialność za produkt niebezpieczny podmiotów dystrybuujących żywność*, “Przegląd Prawa Rolnego” 2008, No. 2, p. 111; Ł.M. Sokołowski, *Liability for damage caused by unsafe innovative food – a legal perspective*, “Przegląd Prawa Rolnego” 2020, No. 1 (26), pp. 47–63; Ł. Bobeł, K. Leśkiewicz, *Odpowiedzialność cywilna za szkodę wyrządzoną przez niebezpieczny środek spożywczy*, “Przemysł Spożywczy” 2007, No. 3, p. 39 *et seq*.

The concept of food is related normatively to various concepts, such as “product” or “agricultural product”. According to the *Dictionary of Polish language*, the word “dangerous” (*niebezpieczny*) means: “1. Likely to cause something bad, 2. capable of causing trouble”⁶. As the legal nature of food is intended for human consumption, the risk may therefore concern human health or life. Consequently, this article is about food that can have negative consequences for people in the light of the applicable legal regulation.

The opposite of “unsafe food” is “safe food”. This expression has not been defined, either. On the other hand, in national legislation, the phrase “food safety” is defined. In the light of the Food and Nutrition Safety Act⁷ it is “a set of conditions that must be met, in particular: additives and flavorings used, levels of contaminants, pesticide residues, conditions of food irradiation, organoleptic characteristics, and actions that must be taken at all stages of food production or handling – in order to ensure human health and life”. As we can see, this definition refers to both the law (“all conditions”) and the practice of its application (actions)⁸. Therefore, determining how to understand them demands taking into account many requirements regulated in various legal acts, both in EU and national law. For these reasons, the normative research area includes in particular Regulation No. 178/2002, Directive No. 85/374/EEC⁹, and other legal acts.

Both practical reasons and the need to protect human health against unsafe (dangerous) food speak for further elaboration of the issue included in the title of the article.

There is no doubt that determining how to understand the phrase “unsafe food” is a problematic issue for the practice of applying the law. In particular, the criminal sanction covers the production and marketing of a commonly consumed food that is harmful to human health or life, and therefore certainly dangerous. These acts are punishable under Art. 96 of the Food and Nutrition Safety Act (the penalty is a fine, restriction of liberty or imprisonment for up to 2 years). Difficulties in interpretation may be caused by the dispersion of regulations regarding the requirements that must be met by food in order to be considered safe. *A contrario* – it is sometimes difficult to determine the characteristics of unsafe food. In addition, the current regulation includes many different terms that may indicate that it is a hazardous food, e.g. spoiled or adulterated food.

⁶ *Słownik języka polskiego PWN*, <https://sjp.pwn.pl/sjp/niebezpieczny;2488342.html> (accessed 20.10.2022); M. Korzycka, *Bezpieczeństwo żywności*, (in:) M. Korzycka, P. Wojciechowski, *System prawa żywnościowego*, Warszawa 2017, p. 248.

⁷ Act of 25 August 2006 on Food and Nutrition Safety, “Journal of Laws” 2019, item 1252, as amended, hereinafter the Food and Nutrition Safety Act.

⁸ See e.g., K. Leśkiewicz, *Ustawa o bezpieczeństwie...*, pp. 36–37.

⁹ Council Directive 85/374/EEC of 25 July 1985 on the approximation of the laws, regulations and administrative provisions of the Member States concerning liability for defective products, “Official Journal” L 210, 7.08.1985, pp. 29–33, hereinafter Directive No. 85/374/EEC.

From a practical point of view, there are still cases of unsafe food on the market. In particular, consumers obtain such information as part of the Early Warning System against Dangerous Food, thanks to the messages of the Chief Sanitary Inspector, which indicate, for example, the presence of *Listeria monocytogenes* or the presence of gluten in food labeled as gluten-free¹⁰. In these communication one can see a huge variety of risks that food provokes to humans.

In addition, food safety is also influenced by the practice of applying law by the producers and official food control authorities¹¹. Sometimes it is lack of control or supervision that contributes to unsafe food being placed on the market. Some of these effects are shown by the report from the audit carried out by the Polish Supreme Audit Office¹². The introduction of unsafe food to the market is connected with legal liability based on various sources, e.g. in the Food Safety Act or in the Code Civil.

In Poland, the system, diversity and multiplicity of control institutions are of significant importance. The official food control bodies in Poland are various inspections under control (Chief Sanitary Inspector, Chief Veterinary Officer, Chief Inspector of Commercial Quality of Agricultural and Food Products) and the State Plant Health and Seed Inspection Authority. The numerous and overlapping competences of these authorities are not conducive to ensuring the effectiveness of official food control. The Supreme Audit Office determined that the food safety and quality assurance systems operating in Poland in 2017–2018 required changes in the area of consumer protection against consumption or purchase of products of insufficient quality. In the event of detection of food which is unsafe for the consumer, all the inspected bodies were equipped with tools to protect the consumer against consuming or purchasing products that are hazardous to health. The Polish food safety model was assessed by the Supreme Audit Office

¹⁰ Warnings – Chief Sanitary Inspectorate, www.gov.pl (accessed 20.10.2022).

¹¹ Regulation (EU) No. 2017/625 of the European Parliament and of the Council of 15 March 2017 on official controls and other official activities performed to ensure the application of food and feed law and the rules on animal health and welfare, plant health and plant protection products, amending Regulations (EC) No. 999/2001, (EC) No. 396/2005, (EC) No. 1069/2009, (EC) No. 1107/2009, (EU) No. 1151/2012, (EU) No. 652/2014, (EU) No. 2016/429, and (EU) No. 2016/2031 of the European Parliament and of the Council, Council Regulations (EC) No. 1/2005 and (EC) No. 1099/2009 and Council Directives 98/58/EC, 1999/74/EC, 2007/43/EC, 2008/119/EC and 2008/120/EC, and repealing Regulations (EC) No. 854/2004 and (EC) No. 882/2004 of the European Parliament and of the Council, Council Directives No. 89/608/EEC, 89/662/EEC, 90/425/EEC, 91/496/EEC, 96/23/EC, 96/93/EC and 97/78/EC and Council Decision 92/438/EEC (Official Controls Regulation), “Official Journal” L No. 95, p. 1, as amended, hereinafter Regulation No. 2017/625; See A.F. Hernandez-Jerez *et al.*, EFSA Panel on plant protection products and their residues, 2022; Scientific opinion on toxicity of pyrethroid common metabolites, “EFSA Journal” 2022, No. 20(10), p. 7582, <https://doi.org/10.2903/j.efsa.2022.7582> (accessed 20.10.2022).

¹² Supreme Audit Office, Regional Office in Łódź, Informacja o wynikach kontroli bezpieczeństwa żywności, LLO.430.005.2019, Registry No. 176/2019/P/19/084/LLO, Warszawa, 9 Janu-
ary 2020, 29, <https://www.nik.gov.pl/plik/id,21927,vp,24594.pdf> (accessed 5.10.2022).

as dispersed. Its structure is as follows: food quality includes health quality and commercial quality.

With this in mind, the aim of this paper is to determine how the term “unsafe food” should be understood in the light of the applicable law. In particular, the considerations will indicate the legal criteria for qualifying food as unsafe food, as well as referring this expression to other legal terms, e.g. the concept of a product. Due to the framework of the study, the scope of considerations is not exhaustive, but only indicates some problems.

2. THE CONCEPT OF FOOD AND RELATED TERMINOLOGY

The concept of food is a very broad category, it can cover many products. The definition of food coincides with the concept of agricultural products as understood in the Treaty on the Functioning of the European Union¹³. According to Regulation No. 178/2002 “food” (or “foodstuff”) means any substance or product, whether processed, partially processed or unprocessed, intended to be, or reasonably expected to be, ingested by humans. “Food” includes drink, chewing gum and any substance, including water, intentionally incorporated into the food during its manufacturing, preparation or treatment. It includes water after the point of compliance as defined in Art. 6 of Directive 98/83/EC and without prejudice to the requirements of Directives 80/778/EEC and 98/83/EC.

Regulation No. 178/2002 also lays down exclusion of specific products from the scope of the concept of *ex lege* food. “Food” shall not include: feed; live animals unless they are prepared for placing on the market for human consumption; plants prior to harvesting; medicinal products within the meaning of Council Directives 65/65/EEC(21) and 92/73/EEC(22); cosmetics within the meaning of Council Directive 76/768/EEC(23); tobacco and tobacco products within the meaning of Council Directive 89/622/EEC(24); narcotic or psychotropic substances within the meaning of the United Nations Single Convention on Narcotic Drugs, 1961, and the United Nations Convention on Psychotropic Substances, 1971; residues and contaminants.

It is pointed out as important, *inter alia*, that it is destined for human consumption, if only potential¹⁴. The regularity is that agricultural products will, as a rule, always be food within the meaning of Regulation No. 178/2002. Food, on the other hand, will not always be an agricultural product.

¹³ Consolidated version of the Treaty on the Functioning of the European Union, “Official Journal” C 326, 26.10.2012, pp. 47–390.

¹⁴ K. Leśkiewicz, *Prawo żywnościowe...*, p. 33; K. Leśkiewicz, *Ustawa o bezpieczeństwie żywności...*, pp. 28–31.

Art. 38 sect. 1 TFEU states that agricultural products mean the produce of the land, farming and fishery products, as well as products of first-stage processing directly related to them. Art. 38 TEWG (now Art. 38 (3) TFEU) contains a detailed list of products covered by the agricultural provisions of the Treaty (attached as Annex II to the TEWG, now Annex I to the TFEU). In turn, the Council was authorized to extend this list to other products within two years of the entry into force of the Treaty establishing the European Economic Community¹⁵. The product lists use the nomenclature consistent with the Common Customs Tariff System¹⁶. In the light of this definition, the processed and unprocessed agricultural products will be treated as food.

The food will always be a “product” within the meaning of Directive 85/374/EEC, which has been implemented in the Polish legal system. The binding force of the provisions of Art. 4491–44911 of the Civil Code were granted on 1 July 2000. In the period preceding the implementation of Directive 85/374/EEC into Polish law, the basis of the producer’s liability for placing on the market dangerous goods causing damage was Art. 415 Code Civil.

The Directive 85/374/EEC provides that, for the purposes of the Directive, “product” means all movables, with the exception of primary agricultural products and game, even though incorporated into another movable or into an immovable. The term “primary agricultural products” means the products of the soil, of stock-farming and of fisheries, excluding products which have undergone initial processing. “Product” includes electricity. Food is a movable thing, so it has the status of a product, regardless of whether it is in a natural or processed state. Importantly, when it is placed on the market, it is intended for human consumption. The Food and Nutrition Safety Act in Art. 95 refers precisely to the provisions of the Code Civil regarding liability for damage caused by a dangerous product in the event of damage caused by food. Food is therefore treated by the legislator as a potentially dangerous product.

In the first years of application of Directive 85/374/EEC, it contained a provision allowing the exclusion of unprocessed agricultural products and those derived from farming, hunting or fishing activities from the concept of a product, which in practice eliminated farmers operating farms from the circle of responsible entities. Since the 1999 amendment to the regulations¹⁷ “product” is considered to include all agricultural and livestock products. Therefore, also animals from breeding were considered as a product. In Art. 4491 para 2 of the Code Civil clearly states that animals are also considered products. It is argued that the concept of an “animal” does not include live wild animals, which is not surprising as

¹⁵ Regulation No. 7a of the Council of the European Economic Community of 18 December 1959, “Official Journal” EC 1961, No. 7, p. 71.

¹⁶ A. Jurcewicz, (in:) A. Jurcewicz, B. Kozłowska, E. Tomkiewicz, *Polityka rolna Wspólnoty Europejskiej w świetle ustawodawstwa i orzecznictwa*, Warszawa 1995, p. 22 *et seq.*

¹⁷ “Official Journal” EC L 141, p. 20.

they are not the product of economic activity. Furthermore, it is doubtful whether pets or animals kept for scientific purposes can be included among animals¹⁸.

Meanwhile, the possibility of including animals in the product category within the meaning of Directive 85/374/EEC is of great importance for strengthening the protection of food consumers, because a significant proportion of unsafe (dangerous) food comes from farms and concerns products of animal origin. In this respect, the exclusion of wild animals from the product categories within the meaning of the directive must raise objections. In practice, these products and their derivatives may pose a serious threat in the event of failure to comply with the basic rules of food safety¹⁹. For example, wild game meat that has not undergone post-mortem inspection carries a serious risk of contracting zoonotic disease²⁰. Importantly, the obligation of such research also applies to products obtained for own needs. Therefore, it should be assumed all the more that products of animal origin from wild animals should be included among products within the meaning of Directive No. 85/374/EEC, because even their preparation for sale and processing may and sometimes take place as part of the producer's economic activity.

It should be noted that despite the fact that the Food and Nutrition Safety Act does not apply to food of animal origin within the scope regulated in Regulation No. 853/2004²¹, it is these products that have a number of legal safety requirements. According to Annex to Regulation No. 853/2004, the term "products of animal origin" means food of animal origin, including honey and blood; live bivalve molluscs, live echinoderms, live tunicates and live marine gastropods intended for human consumption; and other animals destined to be prepared with a view to being supplied live to the final consumer.

Another term related to the concept of food and appearing in Polish legislation is "agri-food". Pursuant to the Act on the commercial quality of agri-food products, agri-food products include agricultural products, undergrowth, game, marine and freshwater organisms in the form of raw materials, semi-finished products and finished products obtained from these raw materials and semi-fin-

¹⁸ A. Kubiak-Curył, *Komentarz do art. 449^l KC*, (in:) M. Załucki (ed.), *Kodeks cywilny. Komentarz*, 3rd ed., Warszawa 2023.

¹⁹ See Rozporządzenie Ministra Rolnictwa i Rozwoju Wsi z 21.10.2010 r. w sprawie wymagań weterynaryjnych przy produkcji mięsa przeznaczonego na użytek własny, "Journal of Laws" 2021, item 2059; Judgment of the Court of Justice of 12 September 2019, C-347/17, A *et al.* v. Staatssecretaris van Economische Zaken, ECLI:EU:C:2019:720.

²⁰ If the veterinary requirements for the production of meat for personal use have not been met, including the obligation to subject the meat of shot wild boar to the test on the hair, an appropriate penalty should be imposed (see Judgment of the Provincial Administrative Court in Opole of 19 April 2011, II SA/Op 41/11, Legalis), this judgment is discussed by K. Leśkiewicz, *Ustawa o bezpieczeństwie żywności...*, p. 14.

²¹ Regulation (EC) No. 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin, "Official Journal" L 139, 30.04.2004, pp. 55–205.

ished products, including foodstuffs. As can be seen, within this concept there are things that may have the status of products within the meaning of Directive No. 85/374/EEC, as well as food within the meaning of Regulation No. 178/2002.

The Food and Nutrition Safety Act does not apply to this “category”, either. Agricultural and food products are subject to the Act on the commercial quality of agri-food products, which regulates the commercial quality of agricultural and food products as well as the organization and operation of the Commercial Quality Inspection of Agricultural and Food Products. According to these regulations, the agri-food products placed on the market should meet the requirements of commercial quality, if such requirements are specified in the regulations on commercial quality, and additional requirements for these articles, if their compliance has been declared by the producer.

An issue directly related to the concept of a product within the meaning of Directive 85/374/EEC is the term “producer”. The term “producer” means the manufacturer of a finished product, the producer of any raw material or the manufacturer of a component part and any person who, by putting his name, trade mark or other distinguishing feature on the product, presents himself as its producer. Without prejudice to the liability of the producer, any person who imports into the Community a product for sale, hire, leasing or any form of distribution in the course of his business shall be deemed to be a producer within the meaning of this Directive and shall be responsible as a producer.

This group will include farmers introducing agricultural products to the market, processors, and anyone whose company, trademark, etc. appears on the label, in the designation, in the presentation of the foodstuff.

It should be considered whether the category of producer includes a “food business operator” within the meaning of Art. 3 p. 3 of Regulation No. 178/2002. In the Corrigendum of 13 February 2015 to Regulation No. 178/2002²², terminological clarifications were introduced in the text of Regulation No. 178/2002 where “food business operator” should read “food business operator”. By the way, the Polish law still uses this old expression. It is appropriate to use the phrase “food and feed business operators”. Food business operator means the natural or legal persons responsible for ensuring that the requirements of food law are met within the food business under their control. As we can see, a food business operator is not literally the same as a “producer” within the meaning of Directive 85/374/EEC. The group of food business operators includes producers and companies. To a large extent, the concept of “producer” within the meaning of the Directive and the concept of “food business operator” within the meaning of Regulation No. 178/2002 will coincide.

²² “Official Journal of the European Union” L No. 37, p. 24.

3. CRITERIA FOR ASSESSING FOOD SAFETY

The criteria for assessing food safety have been included in various regulations, and they have been widely dispersed. Therefore, it can sometimes be problematic to establish the appropriate legal status to verify the safety properties of a product. So it is important that specific requirements shape a certain level of food safety. The legislation also covers the official food control system and requirements for control and supervision of the production and marketing of food, which already affects the aspect of the activities referred to in the statutory term “food safety” as defined in the Food and Nutrition Safety Act.

The important point is that the food safety assessment criteria in Directive 85/374/EEC differ from those in Regulation No. 178/2002. Pursuant to Art. 6 of the Directive, a product is defective if it does not ensure the safety which a person has a right to expect, taking into account all the circumstances, in particular the appearance of the product, the way in which the product is used which can reasonably be expected and time the product was placed on the market. A product will not be considered defective solely because a better product has subsequently been placed on the market. These are the criteria that apply to a product’s defect. The terminology used in Polish legislation in the Code Civil and the Food and Nutrition Safety Act indicates a certain identity of the concepts of a defective and dangerous product, which is a simplification in the case of food. Food will be a defective product when the conditions of Directive 85/374/EEC are met. Not always, however, a defective product will also be a product that is dangerous to health or life. Criteria included in the provisions of food law and relating to food safety are much more complex and sometimes it will be necessary to refer to more detailed regulations.

Moreover, Directive 85/374/EEC does not constitute the basis for a comprehensive and uniform solution to the problem of liability for a defective product. In some respects, the legal regulations in this field differ in individual Member States. Member States have been given the option to design their domestic law in a way that differs from some of the Directive’s principles, e.g. with regard to claims for damages or the method of implementing the burden of proof. The Court of Justice of the EU explains that the extent of the discretion available to the Member States in regulating liability for a defective product is entirely determined by Directive 85/374/EEC and must be determined on the basis of its content²³.

An issue that gives rise to reflection is the premise for the exclusion of producer liability based on the provisions of the Directive (Art. 7), if he proves that:

²³ See judgments of the Court of Justice: of 25 April 2002 in case C-52/00, *Commission of the European Communities v. France*, EU: C: 2002: 252; of 25 April 2002 in case C-154/00, *Commission of the European Communities v. Greece*, EU: C: 2002: 254; of 25 April 2002 in case C-183/00, *María Victoria González Sánchez v. Medicina Asturiana SA*, EU: C: 2002: 255.

1. he did not place the product on the market or 2. having regard to the circumstances, it is probable that the defect which caused the damage did not exist when he placed the product on the market or that the defect arose later, or 3. he has not produced the product for sale or other form of distribution for a commercial purpose, or has not produced or distributed the product in the course of his business activities, or 4. the defect is due to the product's compliance with mandatory regulations issued by public authorities, or 5. the state of scientific and technical knowledge at the time when he placed the product on the market did not allow the existence of the defect to be detected, or 6. in the case of a component manufacturer, that the defect is due to the product design into which the component is fitted, or from instructions received from the product manufacturer.

From the point of view of the producer's responsibility for unsafe food, two situations are particularly interesting: when the defect results from the product's compliance with mandatory provisions issued by public authorities, and when the state of scientific and technical knowledge at the time of placing the product on the market did not allow for detection of the defect.

This first premise has to be confronted with the provisions of Regulation No. 178/2002. According to Regulation No. 178/2002, food that complies with the specific Community provisions regulating food safety is considered safe in terms of factors covered by specific Community provisions. Compliance of a food with the specific rules applicable to it should not prevent the competent authority from taking appropriate measures to impose restrictions on the placing on the market or require it to be withdrawn from the market where there are grounds for suspecting that, despite such compliance, the food is dangerous.

Conversely, in the absence of specific Community provisions, food is considered safe if it complies with the specific provisions of the national food law of the Member State on whose territory it is placed on the market, if such provisions have been drawn up and applied without prejudice to the provisions of the Treaty, in particular its Art. 28 and 30. According to the Food and Nutrition Safety Act, non-compliant foodstuffs are allowed to be marketed in the territory of the Republic of Poland, provided that they were produced or marketed in another Member State of the European Union, in accordance with the law of that country, or produced in a Member State of the European Agreement on Free Trade (EFTA), which is a party to the Agreement on the European Economic Area, or produced or marketed in the Republic of Turkey, in accordance with the laws of these countries, to the extent that they enjoy the free movement of goods under agreements concluded with the European Community – provided that they do not pose a threat to human health or life. Therefore, against the background of these regulations, the legality of a food is a premise which makes it possible to release from risk-based liability for a defective product. Regarding the food safety criteria of Regulation No. 178/2002, the principle is that unsafe food must not be placed on the market. These provisions distinguish between the categories of “unsafe food” and “harmful food”.

This issue remains problematic, therefore, when the product does not comply with national law, but has been legally manufactured or marketed in another Member State of the European Union, in accordance with the law of that country, or produced in a Member State of the European Free Trade Association (EFTA), because in these situations there is a non-compliance of the product with the legal provisions within the meaning of Directive No. 85/374/EEC. In such cases, the producer will always be able to invoke the food law regulations mentioned here as an excuse from liability. In the event of non-compliance with national law, when the food was authorized in another Member State, the food may be placed on the market.

At the same time, a foodstuff is considered dangerous if it is harmful to health, not fit for human consumption. When assessing these characteristics, one should take into account the normal conditions of use of the food by the consumer and its use at every stage of production, processing and distribution, as well as information intended for the consumer, including information on the label, and other information usually available to the consumer about avoiding specific negative effects. health effects related to the food or type of food in question. Undoubtedly, it is up to the entity that places the food on the market to assess the suitability for consumption of a product.

It should be added that the Polish legislator decided to define the expression “food harmful to human health or life”. A food harmful to human health or life is a food which, if consumed under normal conditions and as intended, may cause negative effects on human health or life, in particular if:

1. it does not meet the health requirements specified in section II of the Food and Nutrition Safety Act,
2. it includes:
 - a. pollutants or microbiological contaminants in amounts exceeding the permissible levels specified in the regulations of the European Union and other pollutants,
 - b. residues of radioactive contamination in amounts exceeding the levels specified in European Union regulations,
 - c. veterinary medicinal products in quantities exceeding the permissible levels or prohibited specified in the regulations of the European Union,
 - d. other substances harmful to human health or life defined in the regulations of the European Union²⁴.

The term “in particular” used in the Polish definition of an agent harmful to health contained in the Food and Nutrition Safety Act means that in order for a food to be considered harmful to health, no violation of the law is required. This solution significantly differs from the provisions of Directive No. 85/374/EEC and the solutions implemented in the Polish Civil Code in the indicated scope. The

²⁴ K. Leśkiewicz, *Ustawa o bezpieczeństwie żywności...*, pp. 90–92.

directive makes it possible to discharge from liability when there is a prerequisite for the compliance of the product with the law. In the light of the Polish Food and Nutrition Safety Act, food that is harmful to health and does not infringe the law (although it is difficult to imagine it) may result in criminal liability (see Art. 96 of the Food and Nutrition Safety Act). An example of a dangerous food will also be “spoiled food” within the meaning of the Polish Food and Nutrition Safety Act. It is a food whose composition or properties have changed as a result of irregularities in the production, marketing or natural factors such as humidity, time, temperature or light, or due to the presence of microorganisms and impurities, preventing them from it is fit for consumption for its intended purpose within the meaning of Art. 14 sect. 2 b and para 5 of Regulation No. 178/2002.

It was underlined that EU law uses the expression “health quality” of food. This expression is referred to e.g. in Regulation 2017/625 in Polish version there is “health quality” in the Art. 1 sect. 2 a. According to Art. 1 sect. 2 a, the Regulation No. 2017/625 shall apply to the official controls performed for the verification of compliance with the rules, whether established at Union level or by the Member States, to apply Union legislation, in the areas of food and food safety, integrity and wholesomeness at any stage of production, processing and distribution of food, including rules aimed at ensuring fair practices in trade and protecting consumer interests and information, and the manufacture and use of materials and articles intended to come into contact with food. Health quality of food is marked with the “health mark” in accordance with the requirements set out in the regulations in relation to products of animal origin (e.g. Art. 48 of Regulation No. 2019/627)²⁵.

When assessing that a food is harmful to health, consideration should be given not only to the likely immediate and/or short-term and/or long-term effects of the food on the health of the person consuming it, but also on future generations, possible cumulative toxicity effects; the particular health sensitivities of a certain category of consumers, if the food is intended for that category of consumers. In this regard, the assessment of the harmfulness of food to health is based on the state of scientific and technical knowledge – at the time when the product was placed on the market it did not allow for the detection of the defect. In the light of Directive No. 85/374/EEC, it is this state of scientific and technical knowledge that will determine the possible exclusion of liability for defective food within the meaning of the Directive, but will not determine the exclusion of liability in general, as liability is possible on a general basis. With regard to food, the state of scientific knowledge is an important point in the scientific risk assessment on which law-making and enforcement is based, and what is called development risk in the doctrine. In this regard, the precautionary principle should be followed.

²⁵ See more: K. Leśkiewicz, *Legal aspects of the health quality of food in terms of soil quality*, (in:) P. Massányi, A. Bandlerová, L. Palšová, M. Capcarová (eds.), *Quality soil as a pathway to healthy food in the EU: Challenges to 2030: FOODIE*, Nitra 2021, pp. 44–54.

On the other hand, when assessing whether a foodstuff is unfit for human consumption, it should be taken into account that the foodstuff cannot be consumed by humans for its intended purpose due to contamination, both by foreign and other factors, or due to rotting, deterioration or decay. Importantly, the legal status of pollution in detailed regulations²⁶ means that they are not food ingredients but are an undesirable superfluum in food. Some area of regulation regarding residues and contaminants in food²⁷, including pesticides fall into a category that can be defined as the health quality of food²⁸.

The food information is also important in determining whether a food is unsafe. Relevant requirements in this regard are regulated by Regulation No. 1169/2011²⁹, as well as other acts regulating the requirements for providing information on food, e.g. Regulation No. 2018/848³⁰.

²⁶ Commission Regulation (EC) No. 2073/2005 of 15 November 2005 on microbiological criteria for foodstuffs, "Official Journal" L No. 338, p. 1 as amended, hereinafter Regulation No. 2073/2005; Commission Regulation (EC) No. 1441/2007 of 5 December 2007, amending Regulation (EC) No. 2073/2005 on microbiological criteria for foodstuffs, "Official Journal" L No. 322, p. 12; Regulation (EC) No. 470/2009 of the European Parliament and of the Council of 6 May 2009 laying down Community procedures for the establishment of residue limits of pharmacologically active substances in foodstuffs of animal origin, repealing Council Regulation (EEC) No. 2377/90 and amending Directive 2001/82/EC of the European Parliament and of the Council and Regulation (EC) No. 726/2004 of the European Parliament and of the Council, "Official Journal" L No. 152, p. 11, hereinafter Regulation No. 470/2009; Regulation (EC) No. 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin, and amending Council Directive 91/414/EEC, "Official Journal" L No. 70, p. 1, as amended, hereinafter Regulation No. 396/2005; Council Regulation (EURATOM) 2016/52 of 15 January 2016 laying down maximum permitted levels of radioactive contamination of food and feed following a nuclear accident or any other case of radiological emergency, and repealing Regulation (EURATOM) No. 3954/87 and Commission Regulations (EURATOM) No. 944/89 and (EURATOM) No. 770/90, "Official Journal" L No. 13, p. 2.

²⁷ Commission Regulation (EC) No. 1881/2006 of 19 December 2006 setting maximum levels for certain contaminants in foodstuffs (Text with EEA relevance), "Official Journal" L 364, 20.12.2006, pp. 5–24, hereinafter Regulation No. 1881/2006.

²⁸ K. Leśkiewicz, *Legal aspects of the health quality...*, pp. 44–54.

²⁹ Regulation (EU) No. 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers, amending Regulations (EC) No. 1924/2006 and (EC) No. 1925/2006 of the European Parliament and of the Council, and repealing Commission Directive 87/250/EEC, Council Directive 90/496/EEC, Commission Directive 1999/10/EC, Directive 2000/13/EC of the European Parliament and of the Council, Commission Directives 2002/67/EC and 2008/5/EC and Commission Regulation (EC) No. 608/2004 Text with EEA relevance, "Official Journal" L 304, 22.11.2011, pp. 18–63, hereinafter Regulation No. 1169/2011.

³⁰ Regulation (EU) 2018/848 of the European Parliament and of the Council of 30 May 2018 on organic production and labelling of organic products and repealing Council Regulation (EC) No. 834/2007 PE/62/2017/REV/1, "Official Journal" L 150, 14.6.2018, pp. 1–92; Act on organic farming and agricultural production of 23 June 2022, "Journal of Laws" 2022, item 1370, hereinafter Act on Organic Agriculture.

In the light of EU law, information on food is an element of food safety, as well as commercial quality within the meaning of the Polish Act on the commercial quality of agri-food products. Commercial quality means the characteristics of an agri-food product related to its organoleptic, physicochemical, and microbiological properties in terms of production technology, size or weight, and requirements resulting from the method of production, packaging, presentation and labeling, not covered by sanitary, veterinary or phytosanitary requirements. As we can see, some of these requirements are the same as food safety requirements in terms of food information, such as presentation, labeling. In practice, information on the use-by date has been considered a requirement for both commercial quality and food safety³¹.

The Polish legislator introduced in the Food and Nutrition Safety Act, also some subcategories of unsafe food: the definition of “adulterated substance”. Adulterated food is a food whose composition or other properties have been changed without the consumer being informed in the manner specified in Regulation No. 1169/2011, or a food in which changes have been made to hide its actual composition or other properties; the food is adulterated food, in particular if:

1. Substances have been added to it that change its composition or reduce its nutritional value.
2. An ingredient has been subtracted or the content of one or more nutritional ingredients or other properties of the food has been reduced.
3. Procedures have been carried out that conceal its actual composition or give it the appearance of a foodstuff of appropriate quality.
4. Its name, composition, date or place of production, use-by date or date of minimum durability were stated incorrectly, or otherwise incorrectly labeled by affecting the safety of the foodstuff by these actions.

Adulterated food is an example of confusion about its composition or other properties. There are also other examples of food adulteration in the legal system, which can also be assessed in the light of other legal acts than the Food and Nutrition Safety Act or Regulation No. 1169/2011. For example, Art. 3 p. 10 of the Act on the commercial quality of agri-food products defines the expression adulterated agri-food product as a product whose composition is inconsistent with the provisions on the commercial quality of individual agri-food products, or a product in which changes have been introduced, including changes to labeling, aimed at concealing its actual composition or other properties, if these non-conformities or changes significantly infringe the interests of end consumers, in particular if:

1. Operations have been carried out that changed or concealed its actual composition or made it look like a product that complies with the provisions on commercial quality.
2. The labeling contains a name that is either inconsistent with the provisions on the commercial quality of individual agri-food products or is untrue.

³¹ Judgment of the Supreme Administrative Court of 28 April 2022, II GSK 1923/18, *Legalis*.

3. The labeling contains incorrect information regarding the composition, origin, use-by date or date of minimum durability, net content or commercial quality class.

4. CONCLUSIONS

The food safety system includes general and specific criteria for assessing whether a product is safe. Among the former, there are the basic requirements included in Regulation No. 178/2002. This scope includes formal criteria related to the presumption of safety and material – related to the actual characteristics of the product. Among the formal criteria, there is the requirement to comply with the law. The legality of a food product carries a legal presumption that the product is safe. However, the said presumption should be treated as rebuttable (*praesumptio iuris tantum*), because formal food safety cannot be more important than actual food safety for health.

The food safety requirements of a material nature include the following requirements: that the product is not harmful to health, as well as that the product is suitable for consumption. These are basically requirements related to the health quality of food, including specific food production conditions, requirements for contaminants and pesticide residues and other undesirable substances, and finally production and processing requirements in organic farming, GMO food, food for particular nutritional uses. Among other specific material requirements there are aspects related to commercial quality.

At the same time, in terms of terminology, the legislator mistakenly considers a defective product within the meaning of Directive 85/374/EEC and a dangerous food under Regulation No. 178/2002 to be the same. This can be seen, for example, in the reference contained in Art. 95 the Food and Nutrition Safety Act, to the provisions of the Code Civil implementing the Directive on liability for unsafe food. However, that coincidence is only apparent, since a defective product within the meaning of that directive does not have to be a hazardous food within the meaning of Regulation No. 178/2002 at the same time. The evaluation criteria used in the two legal acts are different. And so, in fact, food that is harmful to health within the meaning of the Food and Nutrition Safety Act, does not have to violate the law in order to give rise to liability. On the other hand, food which is harmful to health, which does not infringe the law, will not incur liability for a dangerous product within the meaning of Directive No. 85/374/EEC.

Certain legal subcategories of unsafe food are distinguished by EU law in Regulation No. 178/2002, and in national law (which concerns a product that is harmful to health, adulterated product, or spoiled product).

In the regulations discussed here, there is a certain accumulation of solutions in the field of food safety and commercial quality assessment regarding the aspects of food safety. The legal system is therefore opaque and complex, and the responsibility for unsafe food may be spread across different sources.

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