

# Chapter I

## Preliminary Considerations

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### 1. The Book Concept

The subject of the research is the legal aspects of protecting human health against unsafe food of agricultural origin. The expression food safety has not been defined in European Union (EU) law. However, this regulation sets out general criteria for the assessment of food safety,<sup>1</sup> in addition, there are legal acts regulating detailed production requirements,<sup>2</sup> hygiene,<sup>3</sup> microbiological criteria,<sup>4</sup> levels of acceptable carry-over on the farm<sup>5</sup> and contaminants,<sup>6</sup> which together

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<sup>1</sup> Regulation (EC) No. 178/2002 of the European Parliament and of the Council of January 28, 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures for food safety; OJ L No. 31 of February 1, 2002, pp. 1–24, hereinafter referred to as “Regulation No. 178/2002.”

<sup>2</sup> Council Regulation (EURATOM) 2016/52 of January 15, 2016 determining the maximum permitted levels of radioactive contamination of food and feed after a nuclear accident or other radiation emergency and repealing Regulation (EURATOM) No. 3954/87 and Commission Regulation (EURATOM) No. 944/89 and (EURATOM) No. 770/90, OJ L No. 13, 20 January 2016, pp. 2–11.

<sup>3</sup> Regulation (EC) No. 853/2004 of the European Parliament and of the Council of April 29, 2004 on the hygiene of foodstuffs (OJ L 139, p. 1, as amended); Regulation (EC) No. 853/2004 of the European Parliament and of the Council of April 29, 2004 laying down specific hygiene rules for food of animal origin, OJ L No. 139, April 30, 2004, pp. 1–54, as amended.

<sup>4</sup> Commission Regulation (EC) No. 2073/2005 of November 15, 2005 on microbiological criteria for foodstuffs, OJ L No. 338, December 22, 2005, pp. 1–26, as amended, hereinafter referred to as “Regulation No. 2073/2005.”

<sup>5</sup> Regulation (EC) No. 470/2009 of the European Parliament and of the Council of May 6, 2009 establishing Community procedures for the determination of maximum residue limits of pharmacologically active substances in foodstuffs of animal origin and 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 (Text with EEA relevance), OJ L No. 152, June 16, 2009, pp. 11–22, hereinafter referred to as “Regulation No. 470/2009.”

<sup>6</sup> Regulation (EC) No. 396/2005 of the European Parliament and of the Council of February 23, 2005 on the maximum levels of pesticide residues in and on food and feed of plant and animal origin, and amending Council Directive 91/414/EEC, OJ L No. 70, March 16, 2005, pp. 1–16 as amended, hereinafter referred to as “Regulation No. 396/2005.”

make up a certain “standard” of food safety, and regulations concerning control and supervision.<sup>7</sup> In the light of these regulations, it is possible to determine which food will be hazardous to health according to the legislator. It should be noted that this assessment will not always be the same as the assessment that can be made from the perspective of health sciences, nutrition, etc.

The legal definition of food safety appears in the Polish Act on Food and Nutrition Safety.<sup>8</sup> And the term “food” appears in art. 2 of Regulation No. 178/2002. According to this act, “food” (or “foodstuff”) means “any substance or product, whether processed, partially processed or unprocessed, intended to be, or expected to be ingested by humans”. A foodstuff includes beverages, chewing gum, and any substance, including water, intentionally added to a food during its production, preparation or processing. This definition includes water that complies with the standards set out 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. A foodstuff does not include:

- 1) feed;
- 2) live animals, unless they are to be placed on the market for human consumption;
- 3) plants before harvesting;
- 4) medicinal products within the meaning of Council Directives 65/65/EEC and 92/73/EEC;
- 5) cosmetics within the meaning of Council Directive 76/768/EEC;
- 6) tobacco and tobacco products within the meaning of Council Directive 89/622/EEC;
- 7) drugs or psychotropic substances within the meaning of the Single Convention on Narcotic Drugs of 1961 and the Convention on Psychotropic Substances of 1971;
- 8) residues and impurities;
- 9) medical devices within the meaning of Regulation (EU) 2017/74 of the European Parliament and of the Council.

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<sup>7</sup> Regulation (EU) No. 2017/625 of the European Parliament and of the Council of March 15, 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 of the European Parliament and of the Council (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) 2016/429, and (EU) 2016/2031, 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 of the European Parliament and of the Council (EC) No. 854/2004 and (EC) No. 882/2004, Council Directives 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), OJ L No. 95, April 7, 2017, pp. 1–142, as amended, hereinafter referred to as Regulation No. 2017/625.

<sup>8</sup> The Act of August 25, 2006 on Food and Nutrition Safety, Journal of Laws of 2019, item 1252, as amended, hereinafter referred to as the “Food and Nutrition Safety Act.”

Agricultural products may be considered food within the meaning of art. 2 of Regulation No. 178/2002, however, not always food can be considered an agricultural product in the light of the Treaty on the Functioning of the EU.<sup>9</sup> Regulation No. 178/2002 applies to all stages of the production, processing, and distribution of food and feed, and therefore throughout the food chain, including primary agricultural production. On the other hand, it does not apply to primary production for personal use or for home preparation, processing, or storage for personal consumption.

Pursuant to art. 38 para. 1 TFEU, the EU defines and implements the common agricultural and fisheries policy. The internal market also covers agriculture, fisheries, and trade in agricultural products. “Agricultural products means the products of the soil, of stockfarming and of fisheries and products of first-stage processing directly related to these products” (article 38(1) TFEU). At the same time, products covered by articles 39–44 TFEU are listed in Annex I. Therefore, the agricultural origin of food should be related to the concept of agricultural products within the meaning of the TFEU.

For these reasons, the safety of food – which also includes agricultural products, will often be determined by meeting food safety requirements regulated precisely in the food law. Therefore, compliance with the hygiene criteria, in particular, not exceeding the levels of contaminants and residues of substances harmful to health in primary agricultural production is a condition of food safety for human health.

An unsafe food should be considered one that is harmful to health or unfit for human consumption. When assessing the hazardous properties of food, you should take into account:

- 1) normal conditions of use of food by the consumer and its use at every stage of production, processing, and distribution;
- 2) information intended for the consumer, including information on the label and other information usually available to the consumer on how to avoid specific negative health effects related to a given food or type of food;
- 3) not only the likely immediate and/or short-term and/or long-term effects of this food on the health of the person consuming it, but also on the next generations;
- 4) possible cumulative toxicity effects;
- 5) particular health sensitivity of a specific category of consumers, if the foodstuff is intended for that category of consumers.

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<sup>9</sup> Treaty on the Functioning of the European Union, Journal of Laws of 2004, No. 90, item 864/2, hereinafter referred to as “TFEU”. See Irene Canfora, “Commento all’art. 2 del reg. 178/02, Definizione di alimento” in *Le Nuove Leggi Civili Commentate* ed. Antonio Jannarelli (Milano: Casa Editrice Dott. Antonio Milani, 2003): 147–157.

However, 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.

The basic instruments for ensuring food safety are control and supervision of the fulfillment of legal requirements for the production and distribution of food and feed under the agricultural practices. Certain model solutions were included in Regulation No. 2017/625, but their implementation and application were left to the EU Member States, where the practice of their application may vary. However, it is important to ensure the effectiveness and efficiency of EU law in the field of food safety, precisely through the correct application of legal provisions.

The literature indicates that “the safety system is built through a set of definitions, rules, institutions, and procedures aimed at achieving the optimal level of food safety in the European Union”.<sup>10</sup> Three factors may determine the safety of food of agricultural origin:

- 1) the quality of the legal regulation with regard to the requirements relating to food production, agricultural practices;
- 2) requirements for control and supervision in the field of compliance and application of production requirements by producers;
- 3) the practice of applying the law by official food control authorities.

In the regulations of third countries, the issues of food contamination will determine the standards of the Codex Alimentarius, e.g. in the field of food contamination, on which the EU regulation is also based.<sup>11</sup> It will also be important if, and if so, how the regulations shape agricultural practices in the indicated perspective.

The area of research in the scope of the indicated topics is determined by the EU legal regulation, in particular the above-mentioned hygiene regulations (in particular EU Regulation No. 853/2004, 853/2004 and others), as well as pesticide residues, pollutants, microorganisms or substances, residues of pharmacologically active substances, as well as radioactive contamination, and official controls (for

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<sup>10</sup> Małgorzata Korzycka, “Bezpieczeństwo żywności,” in *System prawa żywnościowego*, eds Małgorzata Korzycka and Paweł Wojciechowski (Warszawa: Wolters Kluwer, 2017), 248.

<sup>11</sup> Codex general standard for contaminants and toxins in food and feed (codex standard 193-1995), available at [http://www.fao.org/fileadmin/user\\_upload/livestockgov/documents/1\\_CXS\\_193e.pdf](http://www.fao.org/fileadmin/user_upload/livestockgov/documents/1_CXS_193e.pdf), (accessed on September 20, 2020).

example Regulations No. 2017/625, No. 2019/624,<sup>12</sup> 2019/628<sup>13</sup>). It should be added that special control arrangements are also introduced by other provisions, indicated in the second chapter.

In particular, the EU regulation lays down maximum residue levels (MRLs) for products of plant and animal origin, taking into account good agricultural practice in Regulation No. 396/2005.<sup>14</sup> Thus, any exceedance of the MRL in a food product will legally mean that the product may be unsafe. Similar effects will apply to exceeding the maximum levels of other substances or pollutants in food harmful to health as specified by law.

However, these issues may be regulated differently in the regulations of third countries. The Codex Alimentarius standards that have become universal in nature over the years, for example with regard to the aforementioned MRLs, may be a common regulatory ground for certain aspects of food safety for the EU and third countries. The legislation of various orders refers precisely to these norms. For example, according to the Codex Alimentarius standard for contaminants and toxins in food and feed, Good Manufacturing Practice (GMP) and/or Good Agricultural Practice (GAP) should also be aligned with contamination control. Where possible, maximum levels may be based on GMP or GAP solutions to be set at the lowest reasonably achievable and necessary level to protect the consumer.<sup>15</sup> Therefore, the research area also includes legal regulations of selected EU countries (Spain, Italy, Slovak Republic, and Poland), as well as Argentina, Brazil, Uruguay, and the international agreements, particularly, World Trade Organization (WTO) – General Agreement on Tariffs and Trade (GATT) of 1994 concluded in Marrakesh, Sanitary or Phytosanitary Measures (SPS).<sup>16</sup>

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<sup>12</sup> Commission Delegated Regulation (EU) No. 2019/624 of February 8, 2019 concerning specific rules for the performance of official controls on the production of meat and for production and relaying areas of live bivalve molluscs in accordance with Regulation (EU) No. 2017/625 of the European Parliament and of the Council, OJ L No. 131 of May 17, 2019, pp. 1–17, hereinafter referred to as “Regulation No. 2019/624.”

<sup>13</sup> Commission Implementing Regulation (EU) No. 2019/628 of April 8, 2019 concerning model official certificates for certain animals and goods and amending Regulation (EC) No. 2074/2005 and Implementing Regulation (EU) No. 2016/759 as regards these model certificates, OJ L No. 131, of May 17, 2019, pp. 101–194, hereinafter referred to as “Regulation No. 2019/628.”

<sup>14</sup> Regulation No. 396/2005.

<sup>15</sup> Codex general standard for contaminants and toxins in food and feed (codex standard 193-1995), available at [http://www.fao.org/fileadmin/user\\_upload/livestockgov/documents/1\\_CXS\\_193e.pdf](http://www.fao.org/fileadmin/user_upload/livestockgov/documents/1_CXS_193e.pdf) (accessed on September 20, 2020).

<sup>16</sup> Text is available at [https://www.wto.org/english/tratop\\_e/sps\\_e/spsagr\\_e.htm](https://www.wto.org/english/tratop_e/sps_e/spsagr_e.htm), (accessed on June 5, 2021). See also Technical Barriers to Trade Agreement (TBT), available at [https://www.wto.org/english/thewto\\_e/whatis\\_e/tif\\_e/agrm4\\_e.htm#SPS](https://www.wto.org/english/thewto_e/whatis_e/tif_e/agrm4_e.htm#SPS) (accessed on June 5, 2021).

The research topic has not yet been elaborated on in the legal literature in Poland. Some aspects of food were discussed in both foreign<sup>17</sup> and Polish textbook studies, e.g. by M. Taczanowski,<sup>18</sup> T. Srogosz,<sup>19</sup> K. Leśkiewicz,<sup>20</sup> as well as the studies by M. Korzycka and P. Wojciechowski,<sup>21</sup> and other authors,<sup>22</sup> while discussing other issues in the field of food law. In the international arena, some legal issues have been developed. There are monographic publications in which selected threads concern the issue being the subject of these considerations i.e. by M. Allabrese.<sup>23</sup> There are also some article publications about the Codex Alimentarius standards, the precautionary principle and many different issues connected with the topic.<sup>24</sup> In particular, it is emphasized that in the area of consumer interest in the health protection underlying the Codex Alimentarius, scientific opinion should play the most important role in the decision-making process.<sup>25</sup> Although this approach is analogous to the European model of the Rapid Alert System for Food and Feed Safety, it may in practice compete with the approach based on the policy of interest. Therefore, it can be concluded that

<sup>17</sup> I.e. Alberto Germanò, *Corso di diritto agroalimentare* (Torino: G. Giappichelli Editore, 2007); Ines Härtel and Dapeng Ren, "Agri-Food Law. Term, Development, Structures, System and Framework" in *Handbook of Agri-Food Law on China, Germany, European Union. Food Security, Food Safety, Sustainable Use of Resources in Agriculture*, ed. Ines Härtel (Frankfurt am Oder: Springer, 2018).

<sup>18</sup> Maciej Taczanowski, *Prawo żywnościowe* (Warszawa: C.H.Beck, 2017).

<sup>19</sup> Tomasz Srogosz, *Międzynarodowe prawo żywnościowe* (Warszawa: C.H.Beck, 2020), chapters V, VI.1.

<sup>20</sup> Katarzyna Leśkiewicz, *Prawo żywnościowe* (Warszawa: C.H.Beck, 2020).

<sup>21</sup> Małgorzata Korzycka and Paweł Wojciechowski, *System Prawa Żywnościowego* (Warszawa: Wolters Kluwer, 2017).

<sup>22</sup> E.g. Danuta Kołozyn-Krajewska, ed., *Higiena w produkcji żywności* (Warszawa: Wydawnictwo SGGW, 2019).

<sup>23</sup> Mariagrazia Allabrese, *Il regime della food security nel commercio agricolo internazionale. Dall'Havana Charter al processo di riforma dell' Accordo agricolo WTO* (Torino: G. Giappichelli Editore, 2018).

<sup>24</sup> See for example Silvia Bolognini, "Food security, food safety ed agroenergie," *Rivista Di Diritto Agrario* 2010, No. 1: 308; Irene Canfora, "Le norme igienico-sanitarie per il settore lattiero caseario e la tutela delle produzioni tipiche," *Rivista Di Diritto Agrario* 2001, No. 3: 410–426; Karin Verzijden and Jasmin Buijs, "Meat 3.0 – How Cultured Meat is Making its Way to the Market," *European Food and Feed Law Review* 2020, No. 15, issue 2: 96–107; Bernd Haber, Matthias Rheinheimer, Dietmar Richter and Urilke Zimmer, "VCI-Guide for Good Hygiene Practices in Food Additives Manufacture," *European Food and Feed Law Review* 2019, No. 14, issue 3: 243–247; Abu Noman Mohammad Atahar Ali and S. M. Solaiman, "Dishonest and Excessive Use of Antibiotics in Meat Producing Animals in Bangladesh: A Regulatory Review," *European Food and Feed Law Review* 2020, No. 15, issue 5: 449–466; Corrado Finardi, "Reports Austria. The Austrian Ban of Glyphosate and the Precautionary Principle Paradox: 'The more you wreck it, the more you strengthen it,'" *European Food and Feed Law Review* 2020, No. 15, issue 5: 473–476; Karolina Pruchniewicz and Tomasz Srogosz, "The Codex Alimentarius Standards Decision-Making: Some Critical Remarks on an Ongoing Discussion," *European Food and Feed Law Review* 2020, No. 15, issue 6: pp. 571–578; Bernd van der Meulen, "Impact of the Codex Alimentarius," *European Food and Feed Law Review* 2019, No. 14: 29–50.

<sup>25</sup> Pruchniewicz and Srogosz, "The Codex Alimentarius Standards," 577.

the research topic has not been comprehensively developed. The status of the research can therefore be assessed as insufficient.

Considering the development of the research subject specified in the title of the research project proposal, the reasons for protecting health against unsafe food of agricultural origin, as well as for cognitive reasons, are particularly relevant.

As far as health protection considerations are concerned, it should be noted that there are examples of the health risks posed by food of agricultural origin from the past. This is in particular the case of BSE,<sup>26</sup> or the presence of dioxins in chickens.<sup>27</sup> The first cases of BSE occurred in the UK in 1986 and were associated with a cow disease, Creutzfeldt-Jakob disease which carried a risk for human health.<sup>28</sup> It was then concluded that a number of distinct transmissible forms of spongiform encephalopathies occur separately in humans and animals, and a growing body of evidence suggests that there is a similarity between the BSE causative agent and the causative agent of this new variant of Creutzfeldt-Jakob disease.<sup>29</sup> However, the literature emphasizes that to date the connection between Creutzfeldt-Jakob disease and BSE has not been proven.<sup>30</sup> The Commission obtained scientific advice on measures to reduce the possible risk to humans and animals from contact with products from infected animals.<sup>31</sup>

Providing a high level of health and life protection has become the goal of the food safety regulation in the EU.<sup>32</sup> From then on, dangerous food was not to be marketed, and the systems for identifying and ensuring food safety were to be protecting human health.<sup>33</sup> Meanwhile, after many years, the Rapid Alert

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<sup>26</sup> Anna Szajkowska, "Regulating Food Law. Risk Analysis and the Precautionary Principle as a General Principles of the EU Food Law." *European Institute for Food Law Series Volume 7* (Wageningen: Wageningen Academic Publishers, 2012), 24.

<sup>27</sup> EFSA, "Risk for animal and human health related to the presence of dioxins and dioxin-like PCBs in feed and food. A scientific opinion," <https://doi.org/10.2903/j.efsa.2018.5333> (accessed on July 25, 2021); see also very interesting results of analysis which demonstrates that the most likely contamination source is the soil or soil organisms but that the behavior of the hens determines the extent of the contamination. See the following quote "Restricting outdoor run use on one of the farms resulted in a decrease of the egg dioxin content to a level that was within the EU limits." See Aize Kijlstra, Willem A. Traag and L.A.P. Hoogenboom, "Effect of Flock Size on Dioxin Levels in Eggs from Chickens Kept Outside," *Poultry Science* 2007, No. 86, issue 9: 2042–2048. <https://doi.org/10.1093/ps/86.9.2042> (accessed 25 July 2021).

<sup>28</sup> On the risk of BSE for human health see: Alberto Germanò, *Corso di diritto agroalimentare* (Torino: G. Giappichelli Editore, 2007), 53.

<sup>29</sup> Germanò, *Corso di diritto*, 53.

<sup>30</sup> Kołożyn-Krajewska, *Higiena w produkcji*, 230.

<sup>31</sup> Germanò, *Corso di diritto*, 53.

<sup>32</sup> Points 1 and 2 of the preamble to Regulation No. 178/2002.

<sup>33</sup> Points 9, 10, and 11 of the preamble to Regulation No. 178/2002; see also on the goals of food law Paweł Wojciechowski, *Model odpowiedzialności administracyjnej w prawie żywnościowym* (Warszawa: Wolters Kluwer 2015), 53ff., and the literature cited therein.

System for Food and Feed established in the EU still records cases of unsafe food. For example, in the period from January 1, 2016 to September 30, 2018, via this system, 127 alerts were sent on food originating in Poland, mostly caused by pathogens in non-ready-to-eat food (*Salmonella* in fresh poultry meat and in eggs). These warnings related to foodborne disease outbreaks and were caused by *Salmonella Enteritidis* and *Listeria monocytogenes*, and the *hepatitis A virus*, respectively.<sup>34</sup> Most of them are examples of the health hazards of food of agricultural origin. Recently, *SARS-Cov-2 virus* has been severely affecting public health and the economy. It comes from animals, is dangerous to humans, and is most likely associated with failure to comply with hygiene and sanitary requirements at Chinese food fairs.<sup>35</sup>

The paradox is that food of agricultural origin, as little processed as possible, is considered by doctors and nutritionists as the most desirable in human diets, and that the same food, due to the mentioned roots (agricultural origin), is at the same time the greatest potential source of health risk. This is evidenced by both the scale of risk and its variety (e.g. microbiological hazards, residues of pharmacologically active substances, radioactive contamination), as well as cases of dangerous food occurring in practice (e.g. in Poland, the Sanitary and Epidemiological Station frequently publishes warnings about dangerous food, e.g. detection of *Salmonella Enteritidis* in the environment of a laying hen farm and the associated risk of egg infection from 1.9.2020<sup>36</sup>). The existence of similar risks in other countries is also evidenced by the jurisprudence of the Court of Justice (in one of the cases concerning the submission by the Austrian Health and Food Safety Agency in Innsbruck to microbiological testing of a meat sample which showed a detectable degree of contamination with *Typhimurium Salmonella* according to the food safety criterion set out in Regulation No. 2073/2005).<sup>37</sup>

Thus, in practice, various microorganisms or substances may be present in food, such as bacteria, viruses, yeasts, molds, algae, parasitic protozoa, microscopic parasitic worms and their toxins, respectively, as well as metabolites. Their presence makes food dangerous to health. For these reasons, the legislator

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<sup>34</sup> European Commission Directorate General for Health and Food Safety, "Final report on the audit carried out in Poland on October 8–19, 2018 to assess official controls of ready-to-eat food production," available at [https://ec.europa.eu/food/audits-analysis/audit\\_reports/details.cfm?rep\\_id=4113](https://ec.europa.eu/food/audits-analysis/audit_reports/details.cfm?rep_id=4113) (accessed on January 18, 2022).

<sup>35</sup> About the coronavirus Sars-Cov-2 see <https://www.who.int/emergencies/diseases/novel-coronavirus-2019> (accessed on September 20, 2020).

<sup>36</sup> See for example, <https://www.gov.pl/web/gis/ostrzezenie-publiczne-dotyczace-zywnosci-wykrycie-paleczek-salmonella-enteritidis-w-srodowisku-fermy-kur-niosek-i-zwiazane-z-tym-ryzyko-zakazenia-jaj> (accessed on September 3, 2020).

<sup>37</sup> CJEU judgment C 443/13 Ute Reindl v. Bezirkshauptmannschaft Innsbruck of November 13, 2014, ECLI:EU:C:2014:2370.



lays down, for example, microbiological criteria to assess the safety of products in Regulation No. 2073/2005. It is worth adding that when establishing the microbiological criteria, the Commission followed, *inter alia*, CA guidelines, “Principles for the establishment and application of microbiological criteria for food CAC / GL 21–1997”, which include requirements for powdered milk products, infant and child products, and a histamine criterion for certain fish and fish products. Since the standards are derived from universal norms of the Codex Alimentarius, the level of food safety should be similar in all countries – pages of the Codex, which may be the subject of legal and comparative analyses.

On the other hand, when it comes to the cognitive reasons that justify undertaking the research, it should be noted that it will make it possible to learn about the national regulations of individual countries, both within the EU and outside the EU, as well as experience in applying the law on the examined aspects of health protection against unsafe food of agricultural origin, with particular emphasis on the standards of the Codex Alimentarius. It is about the legal status in third countries, jurisprudence, and legal literature on the subject of research.

EFSA points out that many global health threats have already emerged linked to zoonotic and emerging infectious diseases (e.g. SARS, COVID-19, zika, avian influenza), climate change, and environmental sustainability. The existing challenges such as different crisis of food safety highlights the need to mitigate emerging health risks using a One Health approach.<sup>38</sup> The need for a One Health approach is well recognized by different European and international organizations. The Sustainable Development Goals (SDGs) adopted by the UN General Assembly in 2015 embody a One Health strategy – healthy people living on a habitable planet. The FAO promotes a One Health approach as an integrated way of preventing and mitigating health threats across the Animal–Human–Plant–Environment interface. It was stressed that also the European Commission’s Green Deal is an integral part of its strategy to implement the United Nation’s 2030 Agenda and the SDGs. Some parts of the UE Green Deal such as the Farm-to-Fork and Biodiversity Strategies make explicit reference to One Health.<sup>39</sup> EFSA states in its conclusions that “One Health should be the default approach not only when considering biological hazards and zoonotic agents but is fundamental also to risk assessments in other domains, such as environmental and microbiome assessment. This will mean, *inter alia*, the inclusion of One Health in the education of future scientists and the provision of continuing education to today’s scientists as well as organizing access to

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<sup>38</sup> EFSA’s expertise supports One Health policy needs adopted April 21, 2021 available at <https://doi.org/10.2903/j.efsa.2021.e190501> (accessed June 20, 2021).

<sup>39</sup> Ibid.

transdisciplinary science in a structural manner, particularly for EFSA's Panels and working groups.”<sup>40</sup>

Under EU law, Green Deal key points, and in synergy with other initiatives, by 2030 the EU should reduce: by more than 55% the health impacts (premature deaths) of air pollution; by 30% the share of people chronically disturbed by transport noise; by 25% the EU ecosystems where air pollution threatens biodiversity; by 50% nutrient losses, the use and risk of chemical pesticides, the use of the more hazardous ones, and the sale of antimicrobials for farmed animals and in aquaculture; by 50% plastic litter at sea and by 30% microplastics released into the environment and total waste generation and by 50% residual municipal waste.<sup>41</sup>

Food production is an integral part of the fight for a healthy planet. It is part of the Green Deal, a Strategy of “Farm to Fork”: designing a fair, healthy and environmentally-friendly food system. The aim is to achieve by European food the status of the global standard for sustainability. Food production still results in air, water and soil pollution, contributes to the loss of biodiversity and climate change, and consumes excessive amounts of natural resources.

As indicated in the EU documents, “Climate change, environmental pollution, biodiversity loss and unsustainable use of natural resources pose multiple risks to human, animal, and ecosystem health. They include infectious and non-communicable diseases, antimicrobial resistance, and water scarcity. To build a Healthy Planet for All, the European Green Deal<sup>42</sup> calls for the EU to better monitor, report, prevent, and remedy air, water, soil and consumer products pollution, among other things.”<sup>43</sup> Pollution can cause cancer, ischaemic heart disease, obstructive pulmonary disease, strokes, mental and neurological conditions, diabetes, and more. In the EU, every year, pollution causes 1 in 8 deaths.

At the same time, it is the farm and the production of food from agriculture that are very exposed to pollution. As part of the package of measures, there is a need for a future integrated nutrient management action plan, addressing holistically a long-standing environmental challenge, maximizing synergies

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<sup>40</sup> Ibid.

<sup>41</sup> Communication from the Commission to the European Parliament, the European Council, the Council, the European Economic and Social Committee and the Committee of the Regions the European Green Deal COM(2019/640 final, available at <https://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1588580774040&uri=CELEX%3A52019DC0640> (accessed on June 25, 2021).

<sup>42</sup> Ibid.

<sup>43</sup> Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions Pathway to a Healthy Planet for All EU Action Plan: “Towards Zero Pollution for Air, Water and Soil” {SWD(2021) 140 final} – {SWD(2021) 141 final} Brussels, May 12, 2021 COM(2021) 400 final.

between policies, and making best use of the green architecture of the new common agricultural policy, especially via conditionality and eco-schemes. In the Farm to Fork and Biodiversity Strategies, pollution from pesticides in air, water and soil should be reduced by cutting their overall use and risk by 50% by 2030, including the most hazardous ones. The Commission underlines that this will be achieved through enhanced uptake of integrated pest management, the revision of the Directive on Sustainable Use of Pesticides, the promotion of agro-ecological practices, including organic farming, and avoiding the use of chemicals, pesticides in sensitive areas.<sup>44</sup>

The aim of the research is to answer the question whether, and if so, to what extent, legal regulations in various countries (including EU Member States and third countries of research team members, and legal framework between UE and third countries in the WTO level) regarding especially agricultural practices in agricultural production allow for human health to be protected against unsafe food of agricultural origin in the light of legal safety criteria, including microbiological criteria, residues of pharmacologically active substances. To achieve the goal of the work, it will be necessary, in particular, to answer specific questions:

- 1) how the legislator defines the notion of food;
- 2) what are the legal criteria for assessing food safety, taking into account the microbiological risk, residues of pharmacologically active substances;
- 3) what is the role of health, nutrition, medical and other sciences in the risk analysis process in the legal system(s);
- 4) how to understand the term “unsafe food” in the light of the provisions of law, considering mainly unprocessed food from agriculture;
- 5) what are the requirements of agricultural practices used on the farm from the perspective of food safety;
- 6) what legal solutions are put in place to ensure the protection of human health against unsafe food, especially, what they consist in and how the organization and implementation of official control and supervision are presented;
- 7) how the hygiene requirements in the production of food from agriculture have been regulated; what is the role of good manufacturing practices and HACCP;
- 8) what sanctions have been provided for violating legal requirements in the field of production of food dangerous to health, including criminal, administrative and other, if any.

The implementation of the research goal also requires an assessment of the legal regulation, potentially in terms of the application of law and, importantly, a comparison of legal solutions in force in individual legal orders.

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<sup>44</sup> Ibid.

## 2. Assumptions and Hypotheses

There is no doubt that food safety may be defined in the legal systems of third countries differently from the definitions provided in the EU and national regulations. Thus, the approach in foreign legislation to the subject of food safety regulation and its scope, to risk and its definition, as well as to tools for ensuring food safety for health may differ. It may be debatable whether unsafe food is one that does not meet the legal requirements but this will each time depend on the adopted “threshold” for these products to enter the market in a given legal order. However, **a certain common denominator of legal regulations aimed at ensuring food safety is their goal – protecting people’s health against unsafe food. This goal can be achieved in various ways, such as through the use of official control and supervision solutions, as well as sanctions for violations of law, certain principles of law. The model of legal framework may be based on risk prevention (e.g. in the EU), as well as on the precautionary principle and equivalence on the international level (e.g. regulated by SPS).**

Since food production has strong relationships with agriculture and the environment, which is also reflected in the doctrinal concepts that see the relationship with agriculture and the environment in food law, and place the origin of food law in legal and agricultural regulations and environmental protection (e.g. the so-called agri-food law<sup>45</sup>), that the properties of food are derived from the relationship between the food and the agricultural product and agricultural practice. Thus, the multiplicity and variety of the aforementioned relationships cause a corresponding increase in the risk to human health in the broadly understood food production chain. In particular, the presence of production residues, contaminants, drugs, etc. in food in amounts exceeding the levels permitted by law, may result from improper agricultural practice. Depending on how broad is the approach to risk defined by proper science and reflected in a given legal order and solutions aimed at ensuring food safety, the context of legal research may be so broad.

The legal concept of food in EU regulation assumes that **an agricultural product can be considered food**. It is undoubtedly an extremely versatile and embedded in modern sustainable food systems look at the source of health risk, taking into account the aspect of agricultural production. It should be emphasized that the literature distinguishes food systems within the so-called global multi-level system which cover the legal regulation of the relations of agriculture and

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<sup>45</sup> Cf. Ines Härtel and Dapeng Ren, “Agri-Food Law. Term, Development, Structures, System and Framework” in *Handbook of Agri-Food Law on China, Germany, European Union. Food Security, Food Safety, Sustainable Use of Resources in Agriculture*, ed. Ines Härtel (Frankfurt am Oder: Springer, 2018), 2.

the environment, especially the management of environmental resources, and in this context it is necessary to consider the protection of human health against unsafe food. The agricultural production process is therefore an important source of risk to human health.

Another assumption that should be formulated is: **the safety of food of agricultural origin depends on the effectiveness of control and supervision over compliance with legal requirements**, as well as sanctions related to the violation of regulations in a given country and respecting the main rules as principle of precaution and equivalence in the international movements of food. The above-mentioned examples of unsafe food that enter the market, for example in the EU, give rise to concerns about whether the legislator ensures the safety of these products for human health.

The comments made justify the formulation of the preliminary research hypothesis as follows: **the current legal system is diverse in terms of territories (international, EU, and national) and contains appropriate solutions to protect human health against unsafe food of agricultural origin, however, they are not always properly applied.**

The structure of the considerations was subordinated to the purpose of the work. The layout of the content has been divided according to the subject of the analysis. The first chapter is an introduction to the subject of considerations. The starting point is the outline of solutions occurring at the international level within the WTO, such as the Codex Alimentarius, SPS, TBT because they are the ones that influence the food safety solutions adopted in the EU, as well as in relations between the EU and regions (i.e. the future Mercosur).<sup>46</sup>

The first part of the paper includes considerations on detailed regulations in force in the EU and selected Member States, i.e. in Poland, Spain, Slovakia, and Italy, with particular references to the UE food law requirements.

In the second part, the regulations of selected third countries – Brazil and Uruguay – are discussed, and the introductory part is a commentary to the selected Mercosur provisions by L.F. Pastorino.

The last part of the work is a summary of the entirety and contains *de lege ferenda* postulates.

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<sup>46</sup> Mercosur is an international economic organization founded in 1991, South American trading bloc established by the Asunción Treaty in 1991 and the Ouro Preto Protocol in 1994. Its members are full members Argentina, Brazil, Paraguay, Uruguay; Venezuela is a full member but has been suspended since December 1. Associated countries are Bolivia, Chile, Columbia, Ecuador, Guiana, Peru, Suriname See <https://trade.ec.europa.eu/access-to-markets/pl/glossary/mercosur> (accessed on June 20, 2021). At the end of June 2019, the European Union negotiated a Trade Agreement with Mercosur to facilitate exports and imports.

### 3. Introductory Notes to the First and Second Parts of the Book

#### 3.1. The Global Agri-Food Safety Standards

Food production and trade are vulnerable to threats of physical, chemical, or biological origin.<sup>47</sup> The legal regulation on counteracting the risk related to the above-mentioned threats is located at various levels: international, regional (e.g. EU), and local. On the international arena, the regulations related to risk analysis when admitting food to international trade were included from the very beginning in the provisions of the WTO agreements – General Agreement on Agriculture concluded in Marrakesh in 1994.

Based on article 3 para. 1 of the WTO agreement on the application of sanitary and phytosanitary measures, the parties to this agreement are obliged to base their measures on international standards, guidelines, or recommendations, to which Annex A to the agreement includes the standards established by the Codex Alimentarius Commission. They are therefore legally binding in the field of international law. They can be accepted at the international, national, and European level.<sup>48</sup>

There is no doubt today that the Codex Alimentarius has created the foundations for building global standards and instruments of the food safety guaranties. However, at present, an institution such as the Codex Alimentarius Commission is criticized for triggering a crisis of values in the decision-making process, dominated by political and corporate interests at the expense of food quality.<sup>49</sup>

Codex standards are used by its members to protect the health of the consumers and to ensure fair practices in the food trade. We can find many references to the Codex on different levels. Reference to the Codex Alimentarius is made in many bilateral and plurilateral trade agreements. Several trade agreements or its projects, i.e. the Trans-Pacific Partnership (TPP) among twelve

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<sup>47</sup> See Sławomir Sitarz and Małgorzata Janczar-Smuga, “Współczesne zagrożenia bezpieczeństwa żywności, możliwości ich kontroli oraz eliminacji,” *Nauki Inżynierskie i Technologie* 2012, No. 2(5): 68–93, available at [https://www.dbc.wroc.pl/Content/16059/Sitarz\\_Wspolczesne\\_Zagrozenia\\_Bezpieczenstwa\\_Zywnosci\\_Mozliwosci\\_2012.pdf](https://www.dbc.wroc.pl/Content/16059/Sitarz_Wspolczesne_Zagrozenia_Bezpieczenstwa_Zywnosci_Mozliwosci_2012.pdf) (accessed on June 6, 2021); See also Agata Lasik, Tomasz Szablewski, Renata Cegielska-Radziejewska, Łukasz Tomczyk and Jan Zabielski, “Zastosowanie mikrobiologii prognostycznej do oceny bezpieczeństwa żywności,” in *Bezpieczeństwo żywności w łańcuchu żywnościowym*, eds Grażyna Lewandowicz and Agnieszka Makowska (Poznań: Uniwersytet Przyrodniczy w Poznaniu, 2016), 41.

<sup>48</sup> Srogosz, *Międzynarodowe prawo*, 86.

<sup>49</sup> See more Pruchniewicz and Srogosz, “The Codex Alimentarius Standards,” 571.

Pacific Rim countries; the Comprehensive Economic and Trade Agreement (CETA) between Canada and Europe, and the Transatlantic Trade and Investment Partnership (TTIP) between the European Union and the United States. These agreements typically contain provisions related to SPS measures and invariably reference the standards adopted by the Codex Alimentarius Commission.<sup>50</sup>

As mentioned, the Codex Alimentarius consists of various norms, guides, rules, and codes of practice, e. g. Codes of Practice<sup>51</sup> or General Methods of Analysis For Contaminants CXS 228-2001 adopted in 2001<sup>52</sup> and standards.<sup>53</sup> To the extent covered by the subject of this paper, the standards for maximum levels of Codex Alimentarius substances include (without limitation) contaminants in food and feed,<sup>54</sup> pesticides.<sup>55</sup>

Contaminants in food are substances that have entered the food unintentionally. The risk of food contamination always occurs during production, at various stages, and some even naturally. The maximum level of contamination (ML) for Codex Alimentarius or feed is the maximum

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<sup>50</sup> More information is available at <http://www.fao.org/fao-who-codexalimentarius/about-codex/faq/faq-detail/en/c/454751/> (accessed on June 15, 2021).

<sup>51</sup> For example: General Principles of Food Hygiene CCFH 2020, CXC 1-1969; CCASIA Regional Code of Hygienic Practice for Street-Vended Foods in Asia CXC 76R-2017 available at <http://www.fao.org/fao-who-codexalimentarius/codex-texts/codes-of-practice/en/> (accessed on June 20, 2021).

<sup>52</sup> See [http://www.fao.org/fao-who-codexalimentarius/shproxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252Fstandards%252FCXS%2B228-2001%252FCXS\\_228e.pdf](http://www.fao.org/fao-who-codexalimentarius/shproxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252Fstandards%252FCXS%2B228-2001%252FCXS_228e.pdf) (accessed on June 15, 2021).

<sup>53</sup> E.g. Standard for Honey CCS 2019, CXS 12-1981, available at <http://www.fao.org/fao-who-codexalimentarius/codex-texts/list-standards/en/> (accessed on June 20, 2021).

<sup>54</sup> CCCF Code of Practice Concerning Source Directed Measures to Reduce Contamination of Food with Chemicals, 2001, CXC 49-2001; CCCF Code of Practice for the Prevention and Reduction of Arsenic Contamination in Rice, 2017, CXC 77-2017; CCCF Code of Practice for the Prevention and Reduction of Mycotoxins in Spices, CXC 78-2017; CCCF Code of Practice for the Reduction of 3-Monochloropropane-1,2- Diol Esters (3-MCPDEs) and Glycidyl Esters (GEs) in Refined Oils and Food Products Made with Refined Oils 2019, CXC 79-2019; CCCF Guidelines for Rapid Risk Analysis Following Instances of Detection of Contaminants in Food where there is No Regulatory Level 2019, CXG 92-2019; CCCF General Standard for Contaminants and Toxins in Food and Feed, 2019, CXS 193-1995; CCMAS General Methods of Analysis for Contaminants 2004, CXS 228-2001, available at <http://www.fao.org/fao-who-codexalimentarius/thematic-areas/contaminants/en/> (accessed on June 20, 2021).

<sup>55</sup> CCPR Recommended Methods of Sampling for the Determination of Pesticide Residues for Compliance with MRLs, 1999, CXG 33-1999; CCPR Guidelines on Good Laboratory Practice in Pesticide Residue Analysis 2010, CXG 40-1993; CCPR Portion of Commodities to which Maximum Residues Limits Apply and which is Analyzed 2010, CXG 41-1993; CCPR Guidelines on the Use of Mass Spectrometry (MS) for Identification, Confirmation and Quantitative Determination of Residues 2005, CXG 56-2005; CCPR Principles and Guidance on the Selection of Representative Commodities for the Extrapolation of Maximum Residue Limits for Pesticides to Commodity Groups 2017, CXG 84-2012; CCPR Guidelines on Performance Criteria for Methods of Analysis for the Determination of Pesticide Residues in Food and Feed 2017, CXG 90-2017, available at <http://www.fao.org/fao-who-codexalimentarius/thematic-areas/pesticides/en/> (accessed on June 20, 2021).