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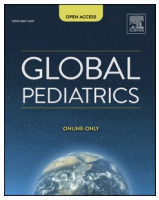

Food safety and public health within the frame of the EU legislation☆

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ABSTRACT

The purpose of this article is to examine some of the issues related to qualitative food safety within the framework of European Union legislation. The development of a multidimensional regulatory system at European level, which has necessarily included international sources, regulations and European Union laws, also relating to national and regional legislations, has rendered finding a balance between the legitimate interests of food producers and consumers problematic. In recent years, the ethical dimension of food has progressively developed, which has led to a greater attention to the way food is produced and consumed, while respecting health protection, food quality and European and international trade dynamics. On the consumer side, however, there has been a growing awareness of the possible risks linked to food and an attention to the issues of food safety. Such awareness is intensified by the use of certain technologies in the food sector. Consumers are increasingly looking to buy commercial products capable of minimizing damage to their health. Consumers consciousness has also influenced the industry, which has increasingly felt the need to pay greater attention to the entire production cycle, thus encouraging production carried out by following the correct methods of supply, processing, up to the final stages of packaging, storage, processing and distribution, in accordance with the "Good Agricultural Practices" (GAP). In conclusion, the important monitoring path of product traceability that has led to a significant increase in the commitment to EU legislative supervision, risk assessment and review of the substances used in food production.

1. Introduction

The various food incidents that took place during the late 1990s draw attention to the need to establish general principles and requirements concerning food and feed law at Union level. In response, the European Commission developed a comprehensive and integrated approach to food safety, 'from farm to fork'[1,2], primarily set out in its White Paper on Food Safety. The approach covers all sectors of the food chain, including feed production, primary production, food processing, storage, transport and retail sale[3].

In 2002, the European Parliament and the Council adopted Regulation (EC) No 178/2002 laying down the general principles and requirements of food law (hereinafter, the "General Food Law Regulation")[3] The General Food Law Regulation is the foundation of food and feed law. It sets out an overarching and coherent framework for the development of food and feed legislation both at Union and national levels. To this end, it lays down general principles, requirements and procedures that underpin decision making in matters of food and feed safety, covering all stages of food and feed production and distribution. The European Parliament also took an important step forward by developing the European Food Safety Authority (EFSA)[4], an independent agency responsible for scientific advice and support. Currently, the General Food Law Regulation ensures a high level of protection of human life and consumers' interests in relation to food, while safeguarding the effective functioning of the internal market[2].

This article seeks to analyze some of the issues related to qualitative

Abbreviations: Good Agricultural Practices", (GAP); Food and Agriculture Organization, (FAO); European Food Safety Authority, (EFSA); Treaty on the European Union, (TEU); Treaty on the Functioning of the European Union, (TFEU); Safety food for infants, (SAFFI); Hazard Analysis and Critical Control Point, (HACCP); Rapid Exchange of Information System, (RAPEX).

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food safety within the framework of EU legislation. Indeed, the development of a multidimensional framework at European level has rendered finding a balance between the rightful interests of food producers and those of consumers complicated. In order to achieve a reasonable balance between the interests of the involved stakeholders, maximum cooperation of the countries involved is deemed essential, especially at EU level, but also between nations, with trade agreements concerning the marketing of food, in order to reduce forms of protectionism and implement the free trade of food products both in the European Union and internationally. Finally, it is necessary to consider the great push of technological innovation in the field of food production, which will have to be increasingly controlled in order to avoid abuses and violations of legislative rules, considering, however, the importance of changes in dietary habits and food traditions[5], without giving in to the often extreme or manipulative positions represented and proposed by pressure groups and opinions.

1.1. Food security. General concepts

According to legal doctrine, the notion of "food safety", includes the concept of both "quantitative food safety", aimed at solving hunger related problems and forms of inequality, and "qualitative food safety", which meets the needs of the market and its marketing of products and involves issues related to health protection[3,5,6]. In less economically advanced societies, the problem relating to food quantity is prevalent, while in economically advanced societies, food quality issues represent a factor of primary importance. According to this conceptual approach, food therefore presents numerous risks to people's health. In fact, as a result of the globalization of markets and the continuous technological progress, there has been a growing push to the development of so-called "unconventional" foods, produced at a lower cost and often with the aim of replacing the "traditional" ones[6].

New knowledge and technological innovations have diversified food products, but at the same time have increased the risk of consuming the same products[2]. Moreover, in industrial countries there is an exploitation of natural resources and a situation of uncertainty in research methodologies and quality control that makes it difficult to predict, verify and quantify the consequences arising from the proper or improper use of these technologies in food production[7]. In addition, the presence of areas with high environmental impact within national territory as well as the presence of contaminants can determine an additional risk for consumers[7]. It is also important to emphasize that the harmful effects of the use of modern technologies can occur after a long time, following continuous exposure to substances or ingestion of food, which even in small doses could damage the health of the individual in the short, medium or long term.

In recent years, an ethical dimension of food has progressively developed, which has led to a greater attention to the way food is produced and consumed, while respecting health protection, food quality and European and international trade dynamics[8]. On the consumer side, however, there has been a growing awareness of the possible risks linked to food and an attention to the issues of food safety for the consumer, who is increasingly looking to buy commercial products capable of minimizing damage to health and a strong fear of new forms of intervention of technological development in this sector. This greater awareness has also influenced the industry, which has increasingly felt the need to pay more attention to the entire production cycle, thus encouraging the development of production carried out according to Good Agricultural Practices, following the correct methods of supply, processing, up to the final stages of packaging, storage, processing and distribution. Therefore, with an important monitoring path of product traceability[8] that has led to a significant increase in the commitment to supervision, risk assessment and review of the substances used.

In order to obtain a reasonable balance between the interests of the stakeholders involved, maximum cooperation of the countries involved is required, particularly, at EU level, but also between nations with trade agreements concerning food marketing, in order to reduce forms of protectionism and implement the free trade of food products both within the European Union and internationally[9]. Finally, it is necessary to consider the significant push of technological innovation in the field of food production, which will need to be increasingly controlled in order to avoid abuses and violations of legislative rules, while also taking into account the importance of changes in dietary habits and food traditions[10], without succumbing to the frequently extreme or manipulative positions represented and proposed by pressure groups and opinions[10].

1.2. Free circulation of products, food safety and food legislation in the European Union

The main problems to be dealt with in relation to food safety concern the different application of legislation on product safety from one Member State to another. In this regard, legislative requirements related to goods are complex for economic operators, who have to deal with different legislative acts to be applied to a food product. In addition, further inconsistencies have emerged in product legislation, such as the use of different terminologies to describe concepts common to European legislation[11,12]. A further issue concerns the presence of conflicting interests and behaviors of the subjects involved, between the protection of the free movement of food products in the European market and the protection of health[12].

The free movement of goods within the European legislation is one of the founding factors of the single market and represents the core of the establishment of the European Union. Since the 1970s, European Union legislation has guaranteed uniform protection of the consumer, the environment and energy resources through the free movement of goods within the Union. To this end, an integrated strategy has been developed in order to ensure a high level of health protection through consistent measures and adequate controls[2]. In this context, Union action related to health is auxiliary to the action of Member States, therefore the European Union has played a coordinating role, unlike the European harmonization policies implemented in the agricultural sector[1]. Thus, the European action aimed at protecting the right to health, on the one hand, has given rise to direct measures through the provision of secondary legislation and, on the other hand, has determined the adoption of soft law policy documents[13], without, however, ignoring the needs of individual states. Therefore, with reference to consumers, European policy has supported and integrated national policies to protect food safety and health. In this regard, an important element is represented by the EU Charter of Fundamental Human Rights, which, while recognizing in Article 16 the freedom to conduct a business, in accordance with EU law and national laws and practices, protects other interests which primarily include health. In this regard, Article 35 of the Charter indicates that a high level of protection of human health shall be ensured in the definition and implementation of all Union policies and activities, and Article 38 states that *"Union policies shall ensure a high level of consumer protection"*[3].

The Treaty on the European Union (TEU) states that health is protected in the same way as business and consumers[14]. On this matter, Article 3 of the TEU provides that the European Union must work for the sustainable development of Europe. Therefore, based both on balanced economic growth and price stability and on the awareness that these economic processes are based on a highly competitive social market economy aiming at full employment and social progress, constructed on a high level of protection and improvement of the quality of the environment. Article 6 of the Treaty on the Functioning of the European Union (TFEU) states that the European Union supports, coordinates and supplements the action of Member States both in protecting and improving human health. In particular, Article 168 of the TFEU provides in the first paragraph that in the implementation of the policies and activities of the European Union, a high level of human health protection must be guaranteed, through the prevention of diseases and illnesses and the elimination of sources of danger. According to European legislation,

therefore, the action of the Union must complement national policies and is aimed at improving public health, preventing diseases and eliminating sources of danger to physical and mental health. This action includes the fight against major scourges such as pandemics, promoting research into their causes, their spread and their prevention. Nevertheless, legislation in this area goes further and includes the important activity of health information and education, as well as surveillance, alerting and combating serious cross-border health threats.

1.3. Consumer protection

A large and important legislative chapter of the European Union is dedicated to consumer protection through Article 169 of the TFEU[14]. With this provision, the Union is committed to protecting health, safety and economic interests of consumers as well as promoting their right to information, education and organization to safeguard their interests. In particular, the European Union, through its legislation and regulations, pursues the objective of guaranteeing citizen participation in the single market through greater protection in the purchase of goods and services. Therefore, this explicit involvement of consumers implies the definition of an evolving regulatory framework. That is, one that is capable of identifying the tools and filling the gaps in existing norms and practices in Europe and through a process of education, information and awareness, pursuing the objective of creating an environment in which consumers can choose the best offers for products and services.

Moreover, Article 191 of TFEU[14] completes the European regulatory framework by providing for the precautionary principle to protect not only the environment, but also health. This is a general principle codified at Union level, which compels the competent authorities (including local authorities) to adopt appropriate measures in order to prevent potential risks to public health, safety and the environment (including foodstuffs), by means of providing, in advance, protection of the application of the principle of prevention, in the absence of the verification of a causal link between the harmful event and the resulting prejudicial effects. The application of the precautionary principle, in the case of a situation in which the potentially dangerous effects of a product or of a process have not been identified and in which the preliminary scientific evaluation has not made it possible to determine a potential risk with sufficient certainty, has made it possible to prevent the distribution or to withdraw dangerous food products from the market, thus letting the protection of the right to health or of the environment prevail over economic interests[14]. This principle must be certainly coordinated with those of free competition, freedom of establishment and freedom to provide services provided for by the TFEU.

1.4. Control over the trade of food products within the European Union

Article 36 of the TFEU[14] states that quantitative restrictions on imports and measures having equivalent effect (Article 34 TFEU) and quantitative restrictions on exports and measures having equivalent effect (Article 35 TFEU) may be enforced on imports, exports and goods in transit on grounds of public morality, public order, public security, health protection, life or animal protection or plant preservation. However, it is also indicated that such prohibitions or restrictions must not constitute a means of arbitrary discrimination or a disguised restriction on trade between Member States[26]. In this regard, the Member State, before importing animals or products of animal origin from a country of the European Union, may carry out controls of a non-discriminatory nature. In particular, Article 10 of Regulation No. 1235/2008 of the European Commission[15] provides that a list must be drawn up of the inspection bodies and authorities recognized for the purposes of equivalence that are competent for carrying out controls and issuing certificates in third and public countries. The general requirement for the export of foodstuffs is compliance with the food hygiene regulations in force in the exporting country, and the basic requirement in exporting countries is compliance with the regulations of the European Commission[15]. Therefore, it is indispensable for the producer to guarantee the traceability of food products from their origin to the consumer's table. European legislation foresees that in situations of potential danger for the consumer in the production of a food product, it is necessary to apply procedures capable of identifying the product placed on the market and withdrawing it even when it has been exported to other countries. The safety of exported products requires the observance of conditions of reciprocity with third countries, and initiatives related to this requirement allow for the specific objective of strengthening and improving product safety through effective market surveillance throughout the EU.

1.5. Food safety in the European legal system

The regulatory evolution of food safety involves a plurality of players and provides for action plans with different procedures. Initially, the legislation on the safety of products marketed within the European Community[16] (Directive n. 92/59/EEC, and the subsequent Directive n. 2001/95/EC, on industrial products, including foodstuffs) required operators to place on the market products that were safe for human health[16]. However, this regulation evolved in the nineties, and following numerous episodes that involved the public health of the European population, (such as food contaminations and environmental disasters) the community regulation of production and marketing of food and feed was modified. In particular, according to a food strategy pursued by the European Union, both a legislation on the safety of food products and animal feeds and a regulation based on scientific evidences have been foreseen as a legislative support to the formal deliberations and control acts[3]. Therefore, European legislation provides for the control of food at all stages of the food production process, from production, processing, transport, distribution to supply to the consumer[3]. In this context, Union law also specifically provides for preventive and subsequent protection in favor of the consumer, notwithstanding the promotion of free trade of food products. The European Union, however, also protects possible obstacles to trade, disparities in safety standards in Member States and possible distortions caused by competition in the internal market. With regard to the consumer and the protection of his or her health, the precautionary principle provides for safety requirements for every product placed on the market and intended for consumption and establishes that a food product is considered safe when it does not present any risk, or presents reduced and acceptable risks[2,3,4]. The efforts of the European Commission are therefore directed to food safety and to the development of advanced and scientifically useful procedures to minimize the risks of food contamination, starting from foods produced for infants, as it is well evidenced by the project Safety food for infants (SAFFI) financed by the European Commission in the framework of the Horizion 2020 program to monitor risks[6,17].

Regulation No. 178/2002 of the European Parliament and of the European Council of January 28, 2002[18] establishing *"the general principles and requirements of food law"* and laying down *"procedures in the field of food safety*" represented a milestone in European Union food legislation. In fact, this regulation aims to harmonize the free movement of food with the principles of food safety, inspired to the search of a high level of protection of health and animals and to the control of the movement of food and feed along the entire chain of agricultural products, following the principle of protection of food from farm to table[2,18]. Although complex and articulated in a variety of norms that need to be balanced and integrated, the European legislative framework provides that each of its provisions is applied to the extent that there are no specific provisions with the same objective that regulate the safety of the products in question3,18. In particular, the provision of the principles of food legislation in Regulation No. 178 of 2002[18] has allowed for the issuance of further regulations, directives and decisions governing various aspects of food safety. In this regard, when there is specific legislation, it applies to aspects or categories of risks not foreseen by general legislation18. For example, in the case of legislation relating to

genetically modified organisms, the integrating norms refer to various legislative passages[19] that include Regulation (EC) No. 1829/2003, Regulation (EC) No. 1830/2003, Regulation (EC) No. 1333/2008 of the European Parliament and of the Council[19], which established a Union list of food additives, and finally[20], Directives No. 2008/60/EC, No. 2008/84/EC, 2008/128/EC and 2009/10/EC, concerning specific purity requirements for food additives[20]. Therefore, legislation does not always help to clarify the rules to be followed in the field of food safety, whereas simpler and clearer legislative norms would be necessary to apply to such an important area of interest for public health as food safety and its monitoring.

While at the European level, there are various areas of intervention and coordination in the field of research and regulation, at national level there is a sector of discipline and collaboration between operators in the food chain. For example, regarding the attribution of competences, Regulation No. 178 of 2002[21] has appointed the legislative functions to Community institutions. On the other hand, it is foreseen that the Commission, the government bodies of the Member States and the national and European Union authorities with their respective committees and bodies carry out a co-administrative action for the purpose of achieving food safety which seems however not to be always effective. In this regard, Article 23 of Regulation No. 178 of 2002, for example, entrusts the European Food Safety Authority with a different role and different tasks, such as the creation of a system of networks between organizations, and assigns responsibility for the functioning of these structures, thus delegating responsibilities and in some way removing the possibility of a closer, direct and effective control[21].

1.6. The relationship between European and national legislations

The relationship between European and national legislation requires that the principle of coordination be applied. Therefore, the above-mentioned European legislation is flanked by the regulations of individual Member States, in order to prevent risks to the health and safety of the consumer. However, as far as food safety is concerned, European legislation has not excluded the regulatory intervention of Member States. Each Member State is required to organize its own system in accordance with the European coordinated system of food safety[3]. Therefore, the current food safety discipline can be found in the coordination between the European system and those of the individual Member States and between the latter and any local legislation. Although it can be further improved, we can consider the European food legislation as complete, since it regulates the actions of the operators involved and it contextualizes and differentiates, through a general legislation applicable to food and feed and a special legislation in those areas where it is necessary, a more specific consumer protection, which includes food hygiene, the use of pesticides, food supplements, colorants, antibiotics, vitamins, minerals and similar substances3.

1.7. Risk management: traceability requirement

Consumer protection is concerned with preventing harm from the circulation of foods that are hazardous to health. This preventive function is identifiable in the regulations that prohibit the marketing of foods that are either harmful to anyone, or to individuals who require specific protection against the intake of certain foods[22]. Aforementioned Regulation No. 178 of 200221 constitutes the foundation in the food sector of a high level of protection of the health and interests of consumers and at the same time of the functioning of the internal market. In addition, the analysis of hazards and critical points in the system of production and distribution of food products is regulated by technical rules taken from the Hazard Analysis and Critical Control Point ("HACCP") system. According to the existing Regulation[22], there is an obligation for producers and distributors of food products to place on the market products that comply with predetermined safety requirements, which include risk analysis (Art. 6), the precautionary principle (Art. 7), protection of consumer interests (Art. 8), transparency in the development of food law (Art. 9), consumer information (Art. 10), safety obligations for food business operators (Art. 11-20), establishment of the European Safety Authority (Art. 22-49), and procedures related to food emergency situations (Art. 50-57)[22,23].

1.8. Definition of food according to European legislation

Article 2 of Regulation (EC) No. 178 of 2002[18] indicates that food is any processed, partially processed or unprocessed substance or product intended to be ingested by humans. However, the rule does not solve the question of the different designations provided in Member States. Therefore, the Court of Justice and part of the doctrine have applied the criterion of mutual recognition, which attributes equivalence to national rules of production and presentation of foodstuffs in intra-community trade[18]. In addition, it is of fundamental importance to distinguish human foodstuffs (food) from medicinal products, which according to Directive 2001/83/EC are products with a therapeutic effect and those which, despite not having such effects, are presented as such[18,24].

A further differentiation and definition concerns feed, which according to Article 3 of the regulation are any substances or products, processed, partially processed or unprocessed, intended for oral nutrition of food. The difference concerns the definition of feed, in which nutrition is foreseen, and of food, which foresees ingestion. However, part of the doctrine does not attribute any legal relevance to this difference, since food and feed, however, are treated in the same way and with the same regulatory provisions.

The current food legislation[3] provides for specific responsibilities and safety obligations to protect the health of the consumer. In fact, the food or feed business operator is defined in Article 3 as the natural or legal person who is responsible for ensuring compliance with the provisions of the legislation in the food or feed business under his control. In particular, producers and distributors have the obligation to place safe products on the market in compliance with food legislation at the stages of production, processing, transport, storage, custody and final distribution. However, there are questions of interpretation, since the food safety obligations provided for by regulations No. 178 of 2002, No. 852 of 2004 and No. 853 of 2004, are different for the various operators in the food chain[18].

For what concerns food safety requirements, risk analysis is a general principle of food legislation for the protection of consumer health. It is characterized by the principle of decision-making, which is divided into different areas, assigned to the responsibility of different subjects. With regard to risk analysis, the European legislator distinguishes between risk assessment, which is based on scientific evidence and must be carried out in an independent, objective and transparent manner, and risk management, which must take into account the results of risk assessment, in particular the opinions of the Food Safety Authority, as well as any additional elements, if relevant but not specifically mentioned, and the precautionary principle.

1.9. Definition of foods that pose a risk to consumer health

Regulation (EC) 178/2002[18] defines the possible risks as a function of the probability and severity of an adverse health effect resulting from the presence of a hazard. In addition, the hazard or hazardous element is defined as the chemical or physical biological agent contained in a food or feed or condition in which a food or feed is found capable of causing an adverse health effect. Thus, food is considered to be unsafe when it is injurious to health or unfit for human consumption according to the probable immediate and/or short-term and/or long-term effects of food on the health of a person consuming it and that of their descendants due to probable toxic or cumulative effects of a food. The same Regulation (No. 178 of 2002) establishes that any food which is considered at risk under the definition set out in the Regulation cannot be placed on the market.

In addition, the notion of food at risk is foreseen by the Regulation in the categories of food harmful to health and food unfit for human consumption of European legislation[4,20]. It provides that the safety of the food is assessed according to the normal conditions of use of the food at each stage of production, processing and distribution and according to the information shown on the label or other information related to the harmful effects resulting from the food[4].

1.10. European legislative principles for risk assessment of foodstuffs

European Union legislation provides that the risk is identified by evaluating the probability and severity of the harmful effect of the food or feed on health, resulting from the presence of a hazard. The risk assessment is carried out through a scientifically based procedure, which evaluates the exposure to the hazard and the risk, the probability and the severity of the harmful effect on health. This control is carried out by the European Food Safety Authority, which collects communications from Member States or national authorities, consumers, food businesses, the academic community and those interested in food safety[25].

After the risk assessment, the European Commission establishes the procedures for a correct risk management according to the precautionary principle and a careful evaluation of the available information and of the possible harmful effects on health, through the analysis between the alternatives of intervention and the adoption of restrictive measures and appropriate preventive and control choices to protect health[25].

Finally, the European Union foresees the important step of risk communication, through the exchange of information and opinions between managers, consumers, food companies and other interested parties, regarding the elements of danger and the risks detected. In order to facilitate coordination between businesses and the competent authorities of Member States, the European Union has set up the Rapid Exchange of Information System (RAPEX), which is the European Union's rapid alert system for unsafe consumer products and consumer protection[26]. In addition, rapid notifications are an additional tool for assessing possible risks. In order to notify, in real time, direct or indirect risks to health deriving from the consumption of food or feed, the Rapid Alert System of the European Union (RASFF)[27] has been established. This newly created alert system is a form of network in which the European Commission, the EFSA (Food Safety Authority)[25] and the Member States of the Union participate. The activity of the EU alert system includes the withdrawal of products considered dangerous to human or animal health[25].

Regulation No. 178 of 200218 also provides for additional safety obligations, such as the traceability obligation[18], which was developed for the control of beef, in relation to the emergency related to the spread in Europe of Creutzfeldt-Jakob disease, commonly referred to as "mad cow disease". Regulation No. 178/2002 has provided for this obligation of traceability for professional operators in various sectors, as a tool of food safety, in order to proceed with "withdrawals" aimed at informing consumers or those responsible for controls. According to the approach defined as one step back, one step forward it is therefore necessary to set up control systems and procedures in order to identify who supplied what and the companies to whom the products were supplied. The traceability provided for in Regulation No. 178/2002 concerns the flow of raw materials and components within the production process of an individual food business. This regulation facilitates the identification of the operator who is obliged to comply with the regulatory provisions for the protection of the safety of the food product and the obligation to communicate any dangerous situation to consumers or to those responsible for withdrawing it from the market. In particular, the traceability system foreseen by the regulations in question allows for the identification of the person responsible for the danger produced and the damage caused[66] and, with reference to food imported from third countries, foresees the possibility of adopting, for the protection of public health, animal health and the environment, appropriate emergency measures at Union level for food and feed imported from a third country, should the risk not be adequately dealt with by measures adopted by Member States[18].

Conclusions

In the context of the European Union, there is a clear intention of the legislator to balance the interests of food producers with the interests of consumers with the aim of guaranteeing healthy and safe food to people, through the regulation of individual production phases and the behavior of individual operators involved in the food production sector. All this through the use of control mechanisms and an information network capable of involving individual Member States in the implementation of this food safety.

In recent years there has been a significant effort to update legislation that reflects the growing sensitivity of the European Parliament and the Commission toward the issue of Food Safety. In this regard, it is important to point out that the original Regulations No. 854/2004 and No. 882/2004 have been replaced by the subsequent EU Regulation No. 625/2017. Finally, after 15 years also EU Regulation No. 382/2021[28] has updated the (EC) Regulation No. 852/2004. The new regulation now incorporates the update of the Codex Alimentarius guidelines published in September 2020[29] on both Food Hygiene and the new Policy for the Prevention and Management of Allergenic Cross-Contact. In the new regulations, the basic prerequisites are in fact updated and new requirements for the reduction of food waste are introduced. The fundamental concepts of Food Safety Culture are therefore introduced in the European legislative framework, demonstrating an attention to public health issues that may have been lacking in the early years of the legislative life of the Union, thus contributing to further bring the European population closer to its institutions, increasingly perceived as an element of guarantee of their rights, including the fundamental right to health.

Statement

The corresponding author states on behalf of the co-authors that all Authors have no conflict or competing of interests to declare.

References

1 European Union. From Farm to fork. Controlling the safety of agri food chan. Laws and regulations. 2020, https://ec.europa.eu/food/system/files/2016-12/fs_infograph_from-farm-to-fork_en.pdf (Accessed, 12 February, 2022).
2 European Commission. White Paper on food safety. 2020, https://op.europa.eu/en/publication-detail/-/publication/6d4b523b-dad8-4449-b2b4-9fa9b0d6e2be. (Accessed, 10, February, 2022).
3 European Union. Eur-Lex. European Union Laws, 2020. https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:32002R0178 (Accessed, 12 February, 2022).
4 European Union. European Food Safety Authority (EFSA). 2020, https://www.efsa.europa.eu/en (Accessed, 12 February, 2022).
5 Pettoello-Mantovani M, Ehrich J, Sacco M, Ferrara P, Giardino I. Pop food insecurity and children's rights to adequate nutrition in Europe. TL. *J Pediatr*. 2018;198:329–330.
6 Pettoello-Mantovani M, Mestrovic J, Namazova-Baranova L, Giardino I, Somekh E, Vural M. Ensuring safe food for infants: the importance of an integrated approach to monitor and reduce the risks of biological, chemical, and physical hazards. *J Pediatr*. 2021;229:315–316. Febe2.
7 European Union. Transparency and sustainability of the EU risk assessment in the food chain. 2020, https://ec.europa.eu/food/horizontal-topics/general-food-law/transparency-and-sustainability-eu-risk-assessment-food-chain_en (Accessed, 12 February, 2022).
8 Fusco G, Coluccia B, De Leo F. Effect of Trade Openness on food security in the EU: a dynamic panel analysis. *Int J Environ Res Public Health*. 2020;17(12):4311. https://doi.org/10.3390/ijerph17124311. PMID: 32560272; PMCID: PMC7344940.
9 Mo C. Product traceability requirements in the european union: an overview. 2020, https://www.compliancegate.com/product-traceability-requirements-european-union/ (Accessed, 12 February, 2022).
10 Ferrara P, Corsello G, Quattrocchi E, Dell'Aquila L, Ehrich J, Giardino I. Pettoello-Mantovani M. Caring for Infants and Children Following Alternative Dietary Patterns. *J Pediatr*. 2017;187:339–340.
11 van der Meulen B. *EU Food Law Handbook*. Wageningen Academic Publisher; 2014. European Institute for Food Law series, Volume 9.
12 El Gemayel M. Food quality in the european union: does the consumer have free choice? *Eur J Risk Regulation*. 2021:1–18. https://doi.org/10.1017/err.2021.39.

13 Wendler F. The European Food Safety Authority as a Source of „Soft Law“: Towards more Effective and Legitimate EU food safety governance?CONNEX Workshop: „Soft Governance and the Private Sector: The EU and Global Experience. Darmstadt, 1-3 November 2005. http://www.mzes.uni-mannheim.de/projekte/typo3/site/fileadmin/research%20groups/6/Papers_Soft%20Mode/Wendler.pdf (Accessed, 12 February, 2022).
14 European Union. Eur-Lex. The treaty on the functioning of the european union. 2020, https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:12012E/TXT:en:PDF (Accessed, 12 February, 2022).
15 Eco.Lex. Commission Regulation (EC) No. 1235/2008 laying down detailed rules for implementation of Council Regulation (EC) No. 834/2007 as regards the arrangements for imports of organic products from third countries. 2020, https://www.ecolex.org/details/legislation/commission-regulation-ec-no-12352008-laying-down-detailed-rules-for-implementation-of-council-regulation-ec-no-8342007-as-regards-the-arrangements-for-imports-of-organic-products-from-third-countries-lex-faoc086651/#:~:text=(EC)%20No.-,1235%2F2008%20laying%20down%20detailed%20rules%20for%20implementation,Council%20Regulation%20(EC)%20No.&text=This%20Regulation%20lays%20down%20detailed,and%20labelling%20of%20organic%20products. (Accessed, 12 February, 2022).
16 United Kingdom. Council Directive 92/59/EEC of 29 June 1992 on general product safety. 2020, https://www.legislation.gov.uk/eudr/1992/59/adopted# (Accessed, 12 February, 2022).
17 Safe Food for Infants in the EU and China, 2020. www.saffi.eu. (Accessed, 12 February, 2022).
18 INFO Mea Treaties. Regulation (EC) No. 178/2002 of the European Parliament and of the Council laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety. 2020, https://www.informea.org/en/legislation/regulation-ec-no-1782002-european-parliament-and-council-laying-down-general-principles#:~:text=(EC)%20No.-,178%2F2002%20of%20the%20European%20Parliament%20and%20of%20the%20Council,in%20matters%20of%20food%20safety. (Accessed, 12 February, 2022).
19 Official Journal of the European Union. Regulation (Ec) No 1830/2003 Of The European Parliament And Of The Council of 22 September 2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modorganisms and amending Directive 2001 /18/EC. https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2003:268:0024:0028:EN:PDF (Accessed, 12 February, 2022).
20 Food Standards Agency. Food Standards Agency Consultation. Enforcement of European Parliament and Council Regulations on Additives and Enzymes. Laws and Regulations collection. 2020, https://www.foodlaw.rdg.ac.uk/pdf/uk-09016-draft-additive-enforcement-regs.pdf (Accessed, 12 February, 2022).
21 Eur.Lex Regulation (Ec) No 178/2002 Of The European Parliament And Of The Council. 28 January 2002. General principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety. 2020, https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:02002R0178-20140630&rid=1 (Accessed, 12 February, 2022).
22 European Commission. Consumer rights directive. https://ec.europa.eu/info/law/law-topic/consumer-protection-law/consumer-contract-law/consumer-rights-directive_en (Accessed, 12 February, 2022).
23 European Commission. Review of EU consumer law. 2020, https://ec.europa.eu/info/law/law-topic/consumer-protection-law/review-eu-consumer-law_en (Accessed, 12 February, 2022).
24 European Union. Directive 2001/83/Ec of The European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use, 2020. https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:02001L0083-20121116&qid=1472567249742&from=EN (Accessed, 12 February, 2022).
25 European Food Safety Authority. 2020, https://www.efsa.europa.eu/en (Accessed, 12 February, 2022).
26 European Commission. About European Rapid Alert system for dangerous products (RAPEX), 2020. https://joinup.ec.europa.eu/collection/rapex/about (Accessed, 12 February, 2022).
27 Food Standards Scotland. The Rapid Alert System for Food and Feed (RASFF), 2020. https://www.foodstandards.gov.scot/consumers/food-crime/report-a-problem/european-commission-food-alerts-rapid-alert-system-for-food-and-feed-rasff#:~:text=The%20Rapid%20Alert%20System%20for,contact%20materials%20and%20animal%20feed. (Accessed, 12 February, 2022).
28 Daenen M. New EU Regulation Enforces A Food Safety Culture For Food Operators. 2020, https://diversey.com/en/blog/new-eu-regulation-enforces-food-safety-culture-food-operators#:~:text=New%20EU%20Regulation%20Enforces%20A%20Food%20Safety%20Culture%20For%20Food%20Operators,-AUTHOR&text=The%20European%20Union%20(EU)%20recently,of%20appropriate%20Food%20Safety%20culture. (Accessed, 12 February, 2022).
29 Food and Agriculture organization of the United Nations. Codex Alimentarius Commission: 24-26 September 2020 and 12 October 2020. https://www.fao.org/news/story/en/item/1308515/icode/ (Accessed, 12 February, 2022).