SAFFI
Safe Food for Infants in the EU and China

Policy Brief n.4

Definition of food according to European legislation. 4.1 Definition of foods that pose a risk consumer health. 4.2 European legislative principles for risk assessment of foodstuffs. 4.3 Closing remarks on food safety in the context of the European Union

4. 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.

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4.1 Definition of foods that pose a risk 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].

4.2. 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

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activity of the EU alert system includes the withdrawal of products considered dangerous to human or animal health[25].

Regulation No. 178 of 2002[18] 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[26] 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].

4.3 Closing remarks on food safety in the context of the European Union

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 by 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.

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