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Review

## Food safety and product withdrawal: Regulations and control mechanisms

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## **ABSTRACT**

The withdrawal of food products is regulated by Polish and European law. In order to remain in circulation, a food product must meet the necessary regulations. This publication presents the definition of a food product, the rules and forms of placing a product on the market, the food categorization system, product labeling rules, current legal standards, and indicates the institutions that conduct audits among food producers. It analyzes the individual steps taken when any irregularities are detected and the penalties imposed on producers under current law. The RASFF system was also described - a rapid alert system for food and feed potentially dangerous to human health, animals, or the environment, and follow-up actions, used to exchange information between control authorities within the European Union. Reference was made to analyses, supplementing the article with specific figures. The following overview is an attempt to systematize the available information on issues focusing on food safety.

## **KEYWORDS**

foodstuff, food safety, food categorisation, official control, RASFF

## **Introduction**

The purpose of the article is to provide a synthetic overview of food safety regulations, the functioning of the RASFF system, and the responsibilities of Polish control authorities in the context of product withdrawal.

The study is based on a narrative literature review of European Union and Polish legal acts, official reports, and selected scientific publications related to food safety and official food control. The analysis included EU regulations, national implementing acts, and RASFF reports. Sources were selected on the basis of their relevance to food law compliance and official control mechanisms.

## **Rules and forms of placing a product on the market**

According to the definition, a foodstuff, i.e. food, is any substance or product (processed, partially processed or unprocessed) that is intended for human consumption or can be expected to be consumed by humans [1,2]. The cornerstone of EU food law is Regulation (EC) No 178/2002, which establishes the general principles and requirements of food law, including consumer protection and the functioning of the internal market. Building on this foundation, Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 lays down general rules on food hygiene applicable throughout the EU. It covers the 'farm to fork' principle – i.e. all stages of the food chain, including primary production, processing, distribution, retail and catering services. It is a directly applicable EU law and has been in force since 1 January 2006 [1]. The key

principle is the primary responsibility for overall food safety, which rests with the food business operator (FBO). Operators must ensure that all stages in their establishment meet hygiene requirements. In Poland, these EU provisions are complemented by the Act of 25 August 2006 on food and nutrition safety, which specifies detailed requirements and responsibilities for food business operators at the national level. In accordance with Article 3, the FBO must ensure that all stages of production, processing and distribution are under its control and meet hygiene requirements [1]. Article 4 – general and specific hygiene requirements: sets out rules on sanitary conditions, temperatures, cleanliness, packaging, etc. [1]. Article 5 – HACCP (Hazard Analysis and Critical Control Points): FBOs must implement, apply and maintain a permanent system of procedures based on HACCP principles. In practice, this means conducting a hazard analysis, identifying CCPs (critical control points), implementing monitoring procedures, corrective actions, records and reviews [1,3]. However, the law allows for a flexible approach – e.g. small businesses may use simplified procedures or industry guidelines [3]. Article 6 – cooperation with authorities: businesses must cooperate with the competent control authorities [1].

Before being approved for sale, every food product must be classified into one of two main categories [2,4,5]:

- Products of animal origin – including not only meat, fish and seafood, but also products obtained in connection with animal husbandry, such as milk, eggs and honey.
- Products of plant origin – i.e. all foodstuffs produced using plant raw materials: vegetables, fruit, cereals, herbs and mushrooms.

In addition, the EU food categorisation system divides foodstuffs into 18 main groups and subgroups, which serve as a reference point for the use of food additives, labelling requirements and product safety assessment before it is placed on the market. This categorisation is applied across different areas of food law. For example, one of the most crucial regulation before placing the product on the market is Regulation (EC) No 1334/2008 on flavourings refers to these categories when specifying conditions for the use of flavourings in food. Selected food categories according to the official numeration are presented in Table I.

**Table I.** List of food categories. Based on [5]

<b>Category number</b>	<b>Food category</b>
0.	All food categories
01.	Dairy products and their analogues

02.	Fats and oils, fat and oil emulsions
04.	Fruit and vegetables
06.	Cereals and cereal products
08.	Meat
09.	Fish and fishery products
10.	Eggs and egg products
11.	Sugars, syrups, honey and table-top sweeteners
12.	Salts, spices, soups, sauces, salads and protein products
13.	Foods for special nutritional uses within the meaning of Directive 2009/39/EC
14.	Beverages
17.	Food supplements

Once a foodstuff has been classified into one of the above categories, it serves as a reference point for the manufacturer's further obligations regarding the use of additives, processes, labelling and product safety assessment. Next, a list of additives that can be used in specific products is assigned to a given food category. This list includes the type of additives and the amount that can be used [4,5]. The food categorisation system is also a reference point for labelling rules in accordance with Regulation 1169/2011. Once the category has been determined, it is determined whether the product is subject to the obligation to provide specific information such as: allergens, percentage content of ingredients, nutritional values and whether it may be subject to specific regulations, e.g. alcoholic beverages, baby food, dietary supplements [6]. In accordance with Regulation 1169/2011, each food product must contain information on:

- the name of the food,
- a list of ingredients, except for foods consisting of only one ingredient where the name of the food is the same as the name of that ingredient or clearly identifies its nature,
- allergens,
- net quantity,
- the date of minimum durability or use-by date,
- storage conditions,

- and nutritional value.

In addition to these general requirements, certain categories of food products are subject to a mandatory notification procedure before being placed on the market. In Poland, food business operators must notify the Chief Sanitary Inspectorate (GIS) of dietary supplements, fortified foods, infant formula and foods for special medical purposes. The notification dossier includes product composition, labeling and intended use, and GIS may raise objections if safety concerns arise. These procedures ensure that products in sensitive categories undergo prior control before reaching consumers [6].

Once all applicable food law requirements, including those related to food type and labelling, are fulfilled, the food business operator is required to notify the competent authority and ensure registration or, where applicable, approval of the establishment in accordance with EU food hygiene regulations. Depending on the type of activity, general food must be reported to the State Sanitary Inspection (PIS, pol. Państwowa Inspekcja Sanitarna), and products of animal origin such as meat, milk, fish and eggs to the Veterinary Inspection (IW, pol. Inspekcja Weterynaryjna), and then approved [2,7]. However, before the product leaves the establishment, the operator must have an implemented and documented HACCP system, good hygiene practices (GHP) and good manufacturing practices (GMP), a complete register of suppliers and recipients (for traceability) and documentation of batches and technological processes.

### **Food safety, control system and criminal liability of the producer or food business operator**

Food safety in the European Union is mainly based on the ‘hygiene package’. The key acts are:

- Regulation (EC) No 178/2002 laying down general principles of food law, food safety, producer responsibility, the RASFF system,
- Regulation (EC) No 852/2004 on the hygiene of foodstuffs – obligations of all food businesses,
- Regulation (EC) No 853/2004 laying down additional hygiene rules for food of animal origin,
- Regulation (EC) No 854/2004 (replaced by 2017/625) - official controls on products of animal origin,
- Regulation (EU) 2017/625 - integrated system of official controls throughout the food chain.

Regulation 178/2002 establishes rules designed to ensure food safety [2]. The principle of producer responsibility (Article 17) forms the basis of EU food law. According to this principle, ‘Food business operators shall be responsible for the safety of the food they produce, process or distribute’. This means that every producer, importer, processor and distributor is fully responsible for ensuring that food is safe and compliant with regulations, while state authorities monitor but do not assume responsibility [2]. The precautionary principle (Article 7) stipulates that if there is a risk

to health but no conclusive scientific evidence, the authorities may temporarily restrict the placing of the product on the market, and the producer is obliged to withdraw or suspend sales until safety is confirmed [2]. The principle of traceability (Article 18) stipulates that every entity must know the source and recipient of its products [2]. The principle of transparency and information (Article 10) – if food poses a risk, the authorities and the business operator are obliged to immediately inform consumers, cooperate with the control authorities, and withdraw or destroy the dangerous batches [2]. In practice, the obligation to withdraw or recall food products does not result solely from the general principles set out in Regulation 178/2002, but is closely linked to compliance with detailed safety requirements established in sector-specific EU legislation. These provisions define measurable microbiological standards, contaminant limits and other technical criteria that determine whether a product may be considered safe. When laboratory analysis or official controls reveal that such thresholds have been exceeded, the food business operator is required to take immediate corrective action, including withdrawal or recall. Therefore, product withdrawal is not only a legal obligation based on abstract safety principles, but also a consequence of objective, science-based benchmarks forming part of the EU food safety system. The food control and supervision system is carried out by official controls in accordance with Regulation 2017/625, which regulates the rules for official controls throughout the food chain: from production to retail. Official controls are non-selective and unannounced, include inspections, audits, sampling and laboratory tests, and may be carried out by various institutions. In Poland, official food control is performed by inspection authorities operating within the State Sanitary Inspection, the Veterinary Inspection (IW) and the Agricultural and Food Quality Inspection system (IJHARS, pol. Główny Inspektorat Jakości Handlowej Artykułów Rolno-Spożywczych), coordinated at the central level by the Chief Sanitary Inspector (GIS, pol. Główny Inspektorat Sanitarny) [8]. Each institution has strictly defined tasks shown in Table II.

**Table II.** Main Authorities Responsible for Food Safety Control in Poland

GIS	deals with general food hygiene and safety, additives, labelling and supplements,
IW	checks and supervises products of animal origin, slaughter, milk, eggs and meat,
IJHARS	examines the commercial quality of food products,
Trade Inspection (IH, pol. Inspekcja Handlowa)	deals with the control of labelling, advertising and compliance with declarations, its role in food safety is currently limited compared to other authorities,

National Revenue Administration (KAS, pol. Krajowa Administracja Skarbowa)	supporting authority in border or fiscal controls
Plant health, seeds, plant protection products (PIORiN, pol. Państwowej Inspekcji Ochrony Roślin i Nasiennictwa)	is responsible for the safety of plants, seeds and plant protection products

They all cooperate within the RASFF system, which is a European rapid alert system for dangerous food and feed [2]. It enables immediate exchange of information between EU countries, withdrawal of products from the market, and blocking of imports from abroad. In Poland, the RASFF coordinator is GIS.

#### *Administrative liability*

Administrative liability is non-financial or financial in nature, but does not lead to entry in the criminal register. It is applied in the event of organisational, formal or technical violations that do not pose a direct threat to human life or health [2,7]. The most common violations include conducting food production or trading activities without the required notification or approval of the establishment by the PIS or IW, inadequate hygiene and sanitary conditions in the establishment, lack of an HACCP system or its incorrect functioning, incorrect product labelling, including the provision of misleading information, failure to comply with the obligation to withdraw a dangerous product from the market. Administrative sanctions may include orders and prohibitions – e.g. an order to suspend production, a prohibition on placing a product on the market, an order to withdraw a batch from the market, financial penalties imposed by a sanitary or veterinary inspector, ranging from 1,000 - 500,000 PLN, depending on the nature and scale of the violation, withdrawal of the establishment's approval or entry in the register when the entrepreneur persistently violates the regulations or threatens public health, entry in the registers or publication of the decision – in cases of gross violations. The authorities competent to impose administrative penalties are primarily the PIS, IW, IJHARS and, in some cases, the GIS [2,7].

#### *Criminal liability*

Criminal liability applies to acts that may endanger human life or health, mislead consumers or deliberately violate food law. In accordance with the Food and Nutrition Safety Act and the Criminal Code [2,7,9]. Criminal liability shall be incurred by anyone who: places foodstuffs on the market that are harmful to human health or life, fails to withdraw foodstuffs from the market that are known to be dangerous, falsifies foodstuffs (e.g. changes their composition, removes expiry dates, substitutes raw materials), provides false information on the label that may mislead the consumer, produces food without the required sanitary or veterinary approval, hinders or prevents

control by official authorities [9]. The penalties provided for by law include a fine, restriction of liberty, imprisonment for up to 3 years, and in cases of endangering life or health – up to 5 years (Article 165 §1 of the Criminal Code), and a ban on conducting business activities in the field of food production and trade [9]. According to Article 103 of the Food and Nutrition Safety Act [7]: ‘Anyone who places on the market a foodstuff that is harmful to human health or life shall be subject to imprisonment for a term of between 3 months and 5 years.’ Article 104 of the same Act states that: “Anyone who fails to comply with a decision of an official food control authority or obstructs its enforcement shall be subject to a fine, restriction of liberty or imprisonment for up to one year”. Regardless of administrative and criminal sanctions, an entrepreneur may also be held civilly liable to consumers for damage caused by a dangerous product. Pursuant to Articles 449-449 of the Civil Code [10], a manufacturer is liable for damage to persons or property if the product placed on the market was dangerous. The consumer may claim compensation, reimbursement of medical expenses, compensation for pain and suffering, and compensation for property damage (e.g. damage to equipment caused by a defective food product).

### **RASFF – the situation in Poland and worldwide**

The Rapid Alert System for Food and Feed (RASFF) is used to exchange information between official control authorities in Europe. The system contains information on food, feed and food contact materials that are potentially dangerous to human health, animal health or the environment, and follow-up actions taken as a result of the identification of such products [11]. Commission Implementing Regulation (EU) 2019/1715 lays down rules for the operation of the IMSOC information management system, which integrates and coordinates the exchange of data in the context of official controls on food, feed, animal and plant health. This Regulation was adopted to improve and harmonise communication between EU Member States and EU institutions in the field of food safety and public health. Chapter 3, Section 1, Articles 12-28 contain all the most important information concerning the above-mentioned RASFF system. The members of the RASFF network are RASFF contact points representing: the European Commission, the European Food Safety Authority (EFSA), EU Member States and EFTA Member States. There are three types of notifications:

- alert notifications – notifications about serious risks requiring rapid action in member country,
- informative alerts – inform about direct or indirect risks related to food that do not require rapid action by other countries belonging to the network,
- border rejection – notification of the rejection of a batch or consignment of food, feed, or food contact materials at the border due to identified risk,
- news – provides information on risks related to food that comes from an informal source [12].

Such notifications are received from one of the official control authorities, i.e.: the State Sanitary Inspection (PIS), the Veterinary Inspection (IW), the State Plant Health and Seed Inspection Service (PIORiN, pol. Państwowa Inspekcja Ochrony Roślin i Nasiennictwa), the Agricultural and Food Quality Inspection (IJHARS) [13]. Current information on the risk is available on the RASFF Window website. Information is available on: the type of product, identified risks, analytical test results (if available), country of origin of the products, countries to which the product was delivered, country reporting the notification, basis for reporting the notification, actions taken and distribution status reported by RASFF network members to the RASFF contact point of the European Commission [14]. The detailed procedures for the functioning of the RASFF system have been laid down by the European Commission in a document entitled ‘Standard Operating Procedures for the Rapid Alert System for Food and Feed and the Assistance and Administrative Cooperation Network’, which is regularly updated [15].

### *RASFF statistics*

The paper entitled "A 10-year analysis of RASFF notifications for mycotoxins in nuts. Trend in key mycotoxins and impacted countries" by Iyiola O Owolabi, Nitsara Karoonuthaisiri, Christopher T Elliott, and Awanwee Petchkongkaew showed that between 2011 and 2021, a total of 4,752 notifications concerning the presence of mycotoxins in food products such as herbs and spices, fish and fish products, cereal and bakery products, nuts and seeds, fruit and vegetables, poultry meat and poultry meat products. Of all notifications, as many as 63% (3,000 cases) concerned the category ‘Nuts, nut products and seeds’. In this group, the highest number of reports concerned peanuts (52%, or 1,545 reports), pistachios (27%, or 795 reports), hazelnuts (10%, or 311 reports) and almonds (5%, or 149 reports). Other products, such as Brazil nuts (0.7%, or 22 reports), walnuts (0.1%, or 4 reports), pine nuts, cracker nuts and candlenuts (one report each, or 0.03%), were reported much less frequently. Reports concerning seeds accounted for 4.7% of the total number in this category. For further analysis, the authors selected only data on peanuts, pistachios, hazelnuts and almonds, due to their frequent export to the European Union and the large number of reports. In the case of peanuts, most reports concerned peanuts in the shell (52%, or 798 reports), shelled peanuts (30%, or 469 reports), blanched peanuts (10%, or 153 reports) and peanut butter or paste (3%, or 52 reports). For pistachios, most reports concerned pistachios in shell (62%, or 489 reports), shelled pistachios (19%, or 153 reports), roasted pistachios (8%, or 62 reports) and roasted and salted pistachios (7%, or 54 reports). In the case of hazelnuts, the reports mainly concerned shelled nuts (55%, or 172 reports), nuts in shell (18%, or 57 reports), roasted and chopped nuts (7%, or 22 reports) and roasted nuts (5%, or 16 reports). For almonds, most reports concerned almonds in shell (46%, or 69 reports) and shelled almonds (45%, or 67 reports). Peanuts are among the most important oilseeds grown in the world. In the 2018/2019 season, their production amounted to approximately 46.78 million tones. They are particularly susceptible to aflatoxin contamination

because they grow in soil where fungi that produce these toxins are present. Nut and seed products undergo various technological processes – mechanical (such as shelling, crushing, blanching, chopping, grinding) and thermal (such as boiling, roasting, frying at temperatures ranging from 120 to 280°C). Mechanical processes, especially in the case of nuts in shells, may increase the risk of aflatoxin contamination compared to thermal processing [16]. The authors of the publication "Microbial Food Safety Assessment of Organic Food and Feed: Notifications in the EU RASFF during 2020–2022. A Systematic Review" showed that between January 2020 and December 2022, 42 cases involving organic food were reported, of which as many as 88.1% were classified as serious risks. The most frequently detected pathogen was *Salmonella*, present in 69% of reports, including *Salmonella* spp., *S. Typhimurium*, *S. Enteritidis* and other serotypes. The next most frequently reported pathogens were *Listeria monocytogenes* (19%), Shiga toxin-producing *E. coli* strains (7.1%) and *Bacillus cereus* (4.8%). In one case of food poisoning, 31 cases were reported after consumption of organic eggs contaminated with *S. Enteritidis*. The reports came mainly from Germany, Belgium and France, and most often concerned nuts, dietary supplements and meat. In the case of organic feed, 26 reports were identified, most of which did not pose a serious risk. The dominant pathogens were *Salmonella* spp. and *S. enterica*, with 12 different serotypes detected. In one case, the report concerned the presence of antibiotic resistance genes in a feed additive, but no health risk was identified [17]. The authors of the study Savin C et al. entitled "Cross-border outbreak of *Yersinia enterocolitica* bioserotype 2/O:9 infections associated with consumption of French unpasteurised soft goat's milk cheese, 2024" showed that by 3 September 2024, 175 cases of *Yersinia enterocolitica* bioserotype 2/O:9 infections had been confirmed in 12 regions of France, 42% of which were from the Provence-Alpes-Côte d'Azur region. Most samples were from faeces and four from blood. The average age of patients was 48 years, and symptoms mainly included abdominal pain and diarrhoea. The epidemiological investigation determined that consumption of unpasteurised soft goat's milk cheese from southern France may have been the source of the infections. The cheeses were made from milk from eight farms, one of which supplied 65% of the milk to the manufacturer. The pathogen was also detected in environmental samples from this farm. After the contamination was detected, corrective measures were implemented, including suspension of production, cleaning, disinfection and temporary pasteurisation of milk. Production was resumed after negative microbiological results were obtained. After the incident was reported to the RASFF system on 9 July 2024, it was established that the cheese had been distributed to 17 EU countries and 12 non-EU countries. Seven cases of infection were identified in Belgium, Luxembourg and Norway, which also belonged to the same genetic cluster [18].

In Poland, however, the analysis of notifications submitted to the RASFF system shows a clear upward trend. In 2016 Poland reported 74 notifications, in 2017 – 87, and in 2018 – 131, including 42 risk notifications. Most of these concerned food contamination with pathogenic microorganisms,

such as Salmonella (45 cases) and Listeria monocytogenes (8 cases), as well as mycotoxins (25 cases) and pesticide residues (10 cases). In 2019 the number of notifications increased to 203, of which 48 were risk notifications, with Salmonella again being the most frequently identified hazard (82 cases). By September 2020, member states had submitted 273 notifications concerning products originating from Poland, including 107 risk notifications. Strikingly, 219 of these cases involved Salmonella, while 15 concerned Listeria monocytogenes. This figure represented the highest number of notifications in the EU at that time, accounting for 13% of all RASFF cases. The majority of Polish notifications related to poultry meat and derived products, but also included fish, eggs, fruits, vegetables, ready-to-eat meals, and food supplements [19]. These figures require cautious interpretation. An increase in the number of withdrawals or RASFF notifications does not necessarily indicate a deterioration in food safety standards. Rather, it may reflect enhanced monitoring systems, improved laboratory detection methods, and greater transparency in reporting. At the same time, the globalization of food supply chains significantly increases the complexity of traceability and risk management, as products and raw materials frequently circulate across multiple jurisdictions. This structural transformation of the food market amplifies both the scale and the speed of potential risk transmission. Therefore, the growing number of notifications should also be viewed as an indicator of the system's responsiveness and institutional capacity to detect and manage hazards effectively.

## **Summary**

Food safety is one of the pillars of the health and economic policy of the European Union and the Republic of Poland. It is a particularly sensitive area, as it directly affects the health and lives of consumers, as well as public confidence in producers and the entire food sector. Therefore, the legal system governing food has been designed in a comprehensive manner, combining elements of prevention, control and sanctions. A key role in this system is played by the administrative and criminal liability of entrepreneurs who place foodstuffs on the market.

Administrative liability primarily serves an organisational and preventive function. It enables supervisory authorities – such as the State Sanitary Inspection, the Veterinary Inspection, or the Agricultural and Food Quality Inspection – to respond immediately to irregularities in the production, storage and distribution of food. As part of this responsibility, it is possible to impose financial penalties, issue administrative decisions suspending production, prohibit the marketing of products and, in extreme cases, withdraw the approval of a facility or the decision to enter it in the food business register. These measures aim to promptly eliminate risks and prevent further impacts on public health, ensuring that the food business operator's activities remain compliant with applicable food law standards.

In cases where violations are particularly serious or where unsafe or counterfeit food is knowingly placed on the market, criminal liability applies. This form of liability is personal and may apply to both the owner of the business and those responsible for the production process, quality control or distribution. The criminal sanctions provided for in the Food and Nutrition Safety Act and the Criminal Code include fines, restrictions on liberty and, in the most serious cases, imprisonment for up to 5 years. This liability serves a repressive and preventive function, designed to deter deliberate violations of the law and build legal awareness among food industry entrepreneurs.

Civil liability also plays an important role in food law. An entrepreneur who has placed a dangerous product on the market is liable for damage caused to consumers. This liability is objective in nature, which means that the manufacturer is liable regardless of fault, provided that it can be proven that the damage resulted from the dangerous properties of the product. This mechanism strengthens consumer protection and provides additional motivation for businesses to maintain the highest standards of quality and safety in production. It should be emphasised that responsibility for food safety is multi-level and complementary.

The introduction of such mechanisms also has educational and systemic significance. It requires businesses not only to comply with the law, but also to build a culture of food safety in their daily business practices. This includes, among other things, implementing and maintaining food safety management systems such as HACCP, keeping records, training employees and cooperating on an ongoing basis with official control authorities.

In addition, at EU and international level, the RASFF plays a key role in the food safety system, providing a platform for the rapid exchange of information between EU Member States, the European Commission, the European Food Safety Authority (EFSA) and national control authorities. Its purpose is to immediately report any cases of food or feed hazards that may pose a risk to human or animal health. In practice, this means that if a dangerous product is found in one Member State, the information is immediately forwarded to all other EU countries. This enables rapid action to be taken, such as withdrawing the product from the market, blocking its import or carrying out checks at the manufacturer's premises. The RASFF system enables effective response to crisis situations and limits the consequences of placing unsafe food products on the market.

### **Conflict of interest**

The authors report there are no competing interests to declare.

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