Paweł WOJCIECHOWSKI*

Regulation of genetically modified organisms, food and feed in the EU with particular reference to Poland – protection of consumers and the environment or merely a response to public expectations?**

Abstract

This article aims to establish the rationale for its introduction within the European Union and subsequent changes to the legal regulation of its release into the environment, genetically modified organisms (GMOs), and the placement of genetically modified food and feed on the market. Following the presentation of the original regulation, public reactions to GMOs and the resulting changes in the European Union and national regulations are discussed based on cases before the European Court of Justice. The analysis leads to the conclusion that in the case of GMOs and genetically modified food and feed, the legislature has acted mainly based on public expectations, while neglecting a full scientific assessment of the solutions adopted to protect consumers and the environment.

Keywords: genetically modified organisms (GMOs), genetically modified (GM) food and feed, ban on the cultivation of GMOs; GM food labelling, consumer expectations, Polish regulations of GMOs

1. Introduction

The release of genetically modified organisms (GMOs) into the environment and the placing on the market of genetically modified (GM) food and feed has generated controversy and debate for years at the international, European Union (EU), and national levels.[1]

Attention has been drawn to the risks associated with the release of GMOs into the environment and the GM food and feed marketplace, primarily for the environment and biodiversity, but also for human health and the sustainable development of rural areas and communities.[2] In addition, the risk of monopolizing the seed supply by multinational corporations, which are also producers of agricultural chemicals, has been recognized. Conversely, the significant advantages of biotechnology are pointed out, which can increase the efficiency of agricultural production while reducing the number of chemicals used and, in the long term, reduce world hunger, which is becoming an

Pawel Wojciechowski: Regulation of genetically modified organisms, food and feed in the EU with particular reference to Poland – protection of consumers and the environment or merely a response to public expectations? *Journal of Agricultural and Environmental Law* ISSN 1788-6171, 2023 Vol. XVIII No. 35 pp. 161-177, https://doi.org/10.21029/JAEL.2023.35.161

* dr hab., prof. at Warsaw University, Food Law Section, Chair of Agricultural and Food Law, Faculty of Law and Administration, University of Warsaw.

** *This study has been written as part of the Ministry of Justice programme aiming to raise the standard of law education.*

[1] On the public discussion and controversy related to GMOs, see Rotkiewicz 2017.

[2] For the Hungarian viewpoint, see Páczay 2017, 101–116.

https://doi.org/10.21029/JAEL.2023.35.161

increasingly important issue due to ongoing climatic, economic, and demographic changes, resulting in reduced access to agricultural land and increased demand for food. Characteristically, despite the lack of scientific evidence of a real risk from GM products to the environment, health, and life, GM food is viewed negatively by most of the European public.[3]

Concurrently, it should be emphasized that the cornerstone of EU food law, Regulation (EC) No 178/2002,[4] assumes that to achieve the general objective of a high level of protection of human health and life, food law should be based on risk analysis, which is a process consisting of three interconnected components risk assessment, risk management, and risk communication.[5] Furthermore, risk assessment should be based on available scientific evidence and undertaken in an independent, objective, and transparent manner.[6] Moreover, the implementation of environmental objectives should be based on a scientific risk assessment.

This study aimed to establish a rationale for introducing and making subsequent changes to the legal regulation of the environmental release of GM plants and the marketing of food and feed. Assuming that the regulation of GMOs is intended to reduce the risks associated with the genetic modification of plants, it was assumed as an initial hypothesis that EU regulations of genetically modified agricultural products and national regulations, initially based on the precautionary principle, over the years have become a reflection of public expectations rather than the result of science-based risk analysis.

Achieving the stated objective requires presenting background information on genetically modified plants, food, and feed; the development of genetic engineering in this field; and the origins and evolution of EU law. An essential aspect of this research is the analysis of The Court of Justice of the European Union (CJEU) case law, which makes it possible to present national regulations determined by social expectations. Special attention is given to Polish regulations, as Polish agricultural land transactions have a significant impact on judicial practice.[7]

2. Origins of GMOs and basic concepts

Creating new crop varieties or animal breeds has accompanied the development of civilization for centuries. The plants used in crops are the result of the classical method of varietal selection based on intraspecific variation, where the human role is to create conditions conducive to variation and select appropriate forms.[8]

A breakthrough came with the discovery that the material carrier of genetic information in every living cell is DNA and the deciphering of the code by which this information is recorded in DNA, which made it possible to develop methods for

[3] Małyska & Twardowski 2011, 96.
[4] Regulation (EC) No 178/2002 of the European Parliament and of the Council of January 28, 2002 establishing the general principles and requirements of food law, establishing the European Food Safety Authority, and procedures in matters of food safety (OJ L 31, 1.2.2002, p. 1–24).
[5] See Article 3(10) and Article 6(1) of Regulation (EC) No 178/2002.
[6] See Article 6(2) of Regulation (EC) No 178/2002.
[7] See more: Zombory 2021, 174–190; Kubaj 2020, 118–132; Blayer 2022, 7–27.
[8] Wrześniwska-Wal 2008, 16.

manipulating DNA fragments containing specific hereditary information, that is, genes, so that it became possible to transfer DNA fragments from one organism to another, that is, transgenesis (e.g., from bacteria or plants to animals).[9] It has become possible to create new organisms (primarily new varieties of plants but also animals) in which the genetic material is altered in a way that does not occur naturally through cross-breeding or natural recombination, but through genetic engineering. The new organisms such as bacteria, plants, and animals that result from such 'manipulation' are called genetically modified organisms (GMOs) or transgenic organisms.[10]

In the 1980s, genetically modified (transgenic) plants were obtained (in Belgium, tomatoes and tobacco contained the Bt gene responsible for synthesizing the insect-repellent Bt protein; in the USA, soybean, maize, cotton, and canola were resistant to harmful insects and certain herbicides; and the *FlavrSavr* tomato retained skin hardness for longer, which was the first transgenic crop to be commercially introduced in the USA in 1994).[11] In 2018, the acreage of transgenic crops grown worldwide reached 191.7 million hectares across 26 countries (transgenic soybeans account for 78% of all crops, maize 30% of all crops, cotton 76% of all crops, canola 29% of all crops).[12]

3. Public reaction to GMOs

Ongoing research into genetic modification in the USA and, in particular, the announcement of the first GM crops on the market, was met with an intense reaction from a group of anti-biotechnology activists who pointed out the enormous risks associated with transgenesis and undertook court battles to ban the cultivation of GM crops, which was unsuccessful.[13] Anti-GMO movements are particularly fertile in Europe. For many years, the opinions of social groups in Poland and other EU countries have been unequivocally unfavorable for biotechnology in agriculture and GMOs.[14]

It is worth noting that while Americans favor GMOs in principle, Europeans are skeptical. This difference is primarily due to the different roles of agriculture and the countryside, tasks of government institutions, and certification systems.[15] In this public attitude, the reasons for adopting a specific regulation of GMOs at the EU level are apparent. Concurrently, however, placing GMOs under special regulation has the feedback effect of reinforcing public fears about GMOs.

[9] Wrześniwska-Wal 2008, 17.
[10] Szalata, Słomski & Twardowski 2020, 15–22.
[11] Ibid. 14–18.
[12] Ibid. 38.
[13] The vital role of Jeremy Rifkin and the think tank he created, the 'Foundation on Economic' Trends (FET), should be pointed out here. See Rotkiewicz 2017, 69. See also an interview with J. Rifki.
[14] Twardowski 2007, 50; Małyska & Twardowski 2011, 96; Szalata, Słomski & Twardowski 2020, 82; Dzwonkowski 2015, 21; Stępień M 2017, 165; Micińska-Bojarek 2013, 264. See also data from the GMO survey conducted by IPSOS on behalf of the Greens EP Group in February and March 2021.
[15] Twardowski 2007, 50.

4. EU regulation on GMOs and GM food and feed

The first European Economic Community regulations on GMOs were issued in the early 1990s. Council Directive 90/220/EEC of 23April 1990 on the deliberate release into the environmentof genetically modified organisms[16] which was subsequently repealed by the Directive 2001/18/EC of the European Parliament and of the Council of 12March 2001on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC (Directive 2001/18/EC)[17] and Council Directive of 23April 1990 on the contained use of genetically modified micro-organisms (90/219/EEC),[18] which was subsequently repealed by Directive 2009/41/EC of the European Parliament and of the Council of 6May 6, 2009.[19]

The preamble to Directive 90/220/EEC explains that community action concerning the environment should be based on the principles of preventive action. In contrast, living organisms released into the environment in large or small quantities for experimental purposes or as commercial products may multiply in the environment and cross national borders. The effects of this release on the environment may be irreversible. The protection of human health and the environment requires that due attention be paid to controlling the risks arising from the deliberate release of GMOs into the environment. Environmental risk analyses should always be performed before GMOs are released into the environment. The rule of thumb is that the scale of release increases incrementally (step-by-step) only when an assessment of the previous measures to protect human health and the environment indicates that the next step can be taken. The same principles were also indicated in the preamble to Directive 2001/18/EC, which is still in force, and its issuance was justified by the need to clarify the provisions previously in force and the need for order in connection with earlier amendments to Directive 90/220/EEC.

The explanations of these community normative acts indicate that EU institutions recognized the potential risks of GMO cultivation to the environment and human health. Although no scientific studies have confirmed this, its fundamental importance is attributed to the precautionary principle, which applies in the absence of scientific certainty regarding specific risks. The solution adopted contrasts with that adopted in US law, where action is only taken when there is indisputable scientific evidence of a threat (the science-based approach).[20] However, given the uncertainty regarding the risks to GMOs at the time and the need to protect the environment, the approach taken by the EU was fully justified.

[16] OJ L 117, 8.5.1990, 15–27.
[17] OJ L 106, 17.4.2001, 1–39.
[18] OJ L 117, 8.5.1990, 1–14.
[19] OJ L 125, 21.5.2009, 75–97.
[20] Korzycka & Wojciechowski 2017, 77, 93.

Specific regulations for GM food and feed have been adopted independent of GMO regulations. It is important to emphasize that GM food and feed are not the same as GMOs; while GMOs are organisms with the ability to reproduce (replicate), food and feed may contain GMOs, but may also contain substances that are no longer GMOs but are produced from GMOs (e.g., flour from GM maize). Since 1997, the issue of the placing on the market of GM foods has been covered by Regulation (EC) No 258/97 concerning novel foods and novel food ingredients, which, concerning GM foods, has been replaced since April 18, 2004, by two regulations: Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003, on genetically modified food and feed (Regulation (EC) No 1829/2003), and 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 modified organisms and amending Directive 2001/18/EC.

Regulation (EC) No 1829/2003 on genetically modified food and feed focuses on protecting consumer health. As explained in the Preamble, to protect human and animal health, food and feed containing or produced from genetically modified organisms must undergo a safety assessment through an EU procedure before being placed in the market.[21] Concurrently, it was considered necessary that the authorization procedures for genetically modified food and feed should also include the principles introduced by Directive 2001/18/EC. Consequently, genetically modified food and feed should be authorized to be placed in the EU market after a scientific assessment fulfilling the highest possible requirements regarding any risk that it may pose to human and animal health and, where appropriate, to the environment.[22]

The EU regulation on genetically modified foods was prompted not only by the need to protect the environment and the health of consumers, but also by the desire to provide consumers with complete and reliable information about GMOs and the products, food, and feed made from them to enable consumers to make informed choices around food.

The guiding principle for both GM organisms and GM food and feed in EU legislation is that the possibility of placing such products on the market (or releasing them into the environment, in the case of seeds) is subject to prior authorization after assessing individual potential adverse effects on the environment and human health.[23] The authorization procedure for placing GM foods in the market provided in Regulation (EC) No. 1829/2003 is complex and multi-stage. Only after the European Food Safety Authority (EFSA) has given its opinion, the Member States and the public[24] have had the opportunity to comment, and the Standing Committee on the Food Chain and Animal Health has given its favorable opinion does the European Commission issue a decision, which is published in the Official Journal of the EU. The issued authorization is valid throughout the European Union for ten years. It is renewed based on an application addressed to the Commission by the authorization holder at least one year before the

[21] See Point 3 of Regulation (EC) No 1829/2003.
[22] See Point 9 of Regulation (EC) No 1829/2003.
[23] See Article 4(3) of Directive 2001/18/EC and Point 9 of Regulation (EC) No 1829/2003.
[24] See Articles 5–6 of Regulation (EC) No 1829/2003.

expiration date. Directive 2001/18/EC regulates the procedure for assessing the environmental risks of primary importance. Where an application for authorization to place a product on the market submitted under Regulation (EC) No 1829/2003 concerns food containing or consisting of GMOs, authorization under Directive 2001/18/EC is generally required, in addition to this authorization. However, the EU legislator Regulation (EC) No 1829/2003 introduced a solution allowing for only one procedure, according to the principle of 'one key for one door.' The applicants were free to choose. In marketing authorization proceedings under Regulation (EC) No. 1829/2003, applicants may submit a copy of the marketing authorization decision obtained under Directive 2001/18/EC. However, the applicant may also apply for an environmental risk assessment and a safety assessment carried out as part of a procedure under Regulation (EC) No. 1829/2003 on the same basis as provided for in Directive 2001/18/EC, thus avoiding the need for two procedures.[25]

Based on Regulation (EC) No 1829/2003, the Commission has issued dozens of decisions authorizing food products containing, consisting of, or produced from GMOs. In one case (MON 810 maize), authorization extends not only to the placing on the market of GM food and feed, but also to the cultivation of GMOs[26] (most of the Commission's decisions concern GM maize and soya, and in addition, GM rapeseed, sugar beet, and cotton are included in the register).[27]

However, the European public demanded the possibility of making an informed choice regarding GM food; therefore, the labelling requirements for GM food and feed were regulated.[28] Labelling is regulated by regulation (EC) No. 1829/2003, which defines the labelling requirements for products containing GMOs. Therefore, notwithstanding the need to obtain authorization from the European Commission for the release of a GM organism into the environment or placing GM food and feed on the market, any food or feed containing, consisting of, or produced with 0.9% or more of GMOs must be labelled with the applicable information.[29]

In the EU, one of the strictest regulations on GMOs and GM food has been adopted from the outset. Furthermore, Directive 2001/18/EC and Regulation (EC) No 1829/2003 provide instruments allowing Member States to temporarily restrict or prohibit the use or sale of an EU-approved GMO as or in a product within their territory,

[25] Korzycka & Wojciechowski 2017, 472.

[26] By comparison, it is worth noting that the number of permits and notifications for environmental releases in the USA is enormous. Starting in 1985, when four permits and notifications were granted, the annual number of permits increased, reaching more than 1,100 on 2002. In the following years, it is around 800 permits and notifications per year. See Genetically Engineered Crops in the United States, ERR-162 Economic Research Service/USDA, p. 3.

[27] The Community register of genetically modified food and feed can be found at https://webgate.ec.europa.eu/dyna/gm_register/index_en.cfm. The majority of entries in the register were made at the request of one of only a few entities: Monsanto, BASF, Bayer, Syngenta, Pioneer.

[28] Wrześniewska-Wal 2018, 10.

[29]Appropriate to the case: 'genetically modified', produced from 'genetically modified (name of ingredient)' or with reference to an ingredient in the ingredient list: 'contains genetically modified (name of organism)', 'contains (name of ingredient) produced from genetically modified (name of organism).'

subject to specific circumstances (i.e., Member States obtain additional information affecting the assessment of risks to the environment or human or animal health).

Notwithstanding the Commission's approval under Directive 2001/18/EC or Regulation (EC) No 1829/2003, genetically modified varieties must also comply with the requirements of EU law on the marketing of seeds and plant propagating material, among other things, in Directives 2002/53/EC[30] and 2002/55/EC,[31] which also contain provisions allowing Member States to prohibit, under certain well-defined conditions, the use of a variety in all or part of their territory, or to lay down appropriate conditions for the cultivation of that variety. The possibility of imposing these restrictions was made conditional, among other things, on the demonstration that the variety poses a risk to human health or the environment (Article 16 2002/53/EC).

The solutions adopted are justified by the need to protect the environment from the effects of the uncontrolled release of GMOs and to protect consumer health.

5. CJEU case law on GMOs

Despite adopting stringent regulations at the EU level, practice has shown that these regulations have not been sufficiently rigorous to meet public expectations in some Member States.

Due to concerns about the cultivation of GMOs and related public expectations, some Member States have decided to adopt national regulations aimed at a complete ban on the cultivation of GM plants. To restrict or prohibit the cultivation of GMOs, these countries have chosen not to implement or only partially implement Community legislation or have applied the safeguard clauses and emergency measures provided for in Directive 2001/18/EC and Regulation (EC) No 1829/2003, citing the post-authorization receipt of new or additional information affecting the environmental risk assessment or as a result of a reassessment of the information previously held. Other Member States used the notification procedure of Articles 114 (5) and (6) of the Treaty on the Functioning of the European Union (TFEU), which requires the submission of new scientific evidence concerning environment protection or the working environment.

The introduction of national regulations triggered reactions from the European Commission, which issued a letter of formal notice under Article 226 of the EC to such Member States and subsequently brought action before the CJEU.

In addition, in connection with disputes pending before national courts, the participants of which were often multinational corporations producing genetically modified plant varieties (e.g., Monsanto, BASF, Bayer, Syngenta) and, conversely, social organizations fighting against GMOs (e.g. Greenpeace), national courts have repeatedly made preliminary questions concerning doubts about the direction of interpretation of EU legislation regulating GMOs and GM food and feed.

[30] Council Directive 2002/53/EC of June 13, 2002 on the common catalogue of varieties of agricultural plant species.
[31] Council Directive 2002/55/EC of June 13, 2002 on the marketing of vegetable seed.

France has taken steps to ban GMO cultivation, but this issue has been highly controversial since the beginning of community regulation. References can be made, among others, to Case C-6/99[32] or Case C-296/01,[33] in which the Commission alleged that France had not correctly and fully transposed Directive 90/220/EEC. The explanation provided by France shows that the reason for this was public concern regarding GMOs.[34] Similarly, in Case C-419/03,[35] the Commission alleged, and the CJEU held, that France had incorrectly and incompletely implemented Council Directive 2001/18/EC. Judgment C-419/03 has not been implemented in France. Therefore, in the subsequent case C-121/07,[36] the European Commission requested the CJEU to declare that, by failing to take the measures required to implement the judgment in Case C-419/03, the French Republic had failed to fulfil its obligations under Article 228(1) EC. Explaining the reasons for not enforcing the judgment in Case C-419/03, France explicitly pointed to the fact that GMOs and, in particular, their deliberate release into the environment, have become a significant subject of debate and conflict, sometimes violent, in France, as evidenced by the numerous actions taken to destroy crops in the field.[37]

The importance of regulating GMO cultivation in public perception is also illustrated by another French case (C-552/07[38]), which concerned the clarification of the accuracy with which information on GMO cultivation should be provided, taking into account public order considerations.[39] The issue of the public disclosure of the exact location of a GMO release also surfaced in the Netherlands, as evidenced by a preliminary ruling request from a Dutch court that was subsequently withdrawn (Case C-359/08). Another French case (C-58/10 to C-68/10[40]) concerned the legality of two national interim measures that successively suspended the sale and use of GMO MON 810 maize seeds in France and banned the cultivation of seed varieties derived from this maize line.

GMOs have also been an important issue in the public discourse in Italy, as evidenced by national regulations adopted to ban the cultivation of GMOs. For example, in Case C-236/01[41] Monsanto Agricoltura Italia, the national court asked the CJEU to interpret the legislation providing for precautionary measures to be taken by a Member

[32] Judgment of March 21, 2001, Case C-6/99, Greenpeace, ECLI:EU:C:2000:148.
[33] Judgment of November 20, 2003, Case C-296/01, Commission of the European Communities v. French Republic; ECLI:EU:C:2003:626.
[34] See judgment of November 20, 2003 in Case C-296/01, Points 73, 140.
[35] Judgment of July 15, 2004, Case C-419/03, Commission of the European Communities v. French Republic, ECLI:EU:C:2004:467
[36] Judgment of December 9, 2008, Case C-121/07, Commission of the European Communities v. French Republic, ECLI:EU:C:2008:695.
[37] See judgment of December 9, 2008 in Case C-121/07, Points 6 and 72.
[38] Judgment of February 17, 2009, Case C-552/07, Commune de Sausheim v. Pierre Azelvandre ECLI:EU:C:2009:96.
[39] See judgment of February 17, 2009 in Case C-552/07, Points 49–50.
[40] Judgment of September 8, 2011 in Cases C-58/10 to C-68/10 Monsanto SAS and Others v. Ministre de l'Agriculture et de la Pêche, ECLI:EU:C:2011:553.
[41] Judgment of September 9, 2003, C-236/01 Monsanto Agricoltura Italia SpA and Others v. Presidenza del Consiglio dei Ministri and Others, ECLI:EU:C:2003:431.

State because the national legislation invoking health protection temporarily suspended the trade and use of two varieties of genetically modified maize in Italian territories.[42]

In another Italian case (C-36/11[43]), the question of a preliminary ruling concerned the interpretation of the provisions of Directive 2001/18/EC, governing measures to prevent the unintended presence of GMOs, which was linked to the actions of Italian authorities in delaying the adoption of legislation allowing the coexistence of conventional, organic, and genetically modified crops. A question from an Italian court on one aspect of this issue was submitted in 2021 (Case C-24/21). The issue of precautionary measures was also addressed in Case C-111/16,[44] in which the CJEU interpreted Article 34 of Regulation (EC) No. 1829/2003, which allowed Member States to take emergency measures.

Issues concerning Poland also provide evidence of the importance of GMOs in public perception. In proceedings against Poland (Case C-165/08[45]), the Commission alleged that, by prohibiting the free circulation of genetically modified seed varieties and the inclusion of genetically modified varieties in the national register of varieties,[46] Poland breached Directive 2001/18/EC and Directive 2002/53. In response to the Commission's objections, the Republic of Poland referred to concerns about risks to public health and the environment, explicitly pointing to the strong opposition of a large part of public opinion in Poland to GMOs and the need to respect ethical principles under Point 9 of Directive 2001/18/EC, claiming that it would be unethical to introduce provisions into the Polish legal order with which the majority of Polish society does not agree.[47] The Republic of Poland also invoked the Christian conception of life, which opposes the fact that living organisms created by God are subject to manipulation and transformed into materials that are the subject of industrial property rights, and the Christian and humanist conception of progress and development, which prescribes respect for the plan of creation and the search for harmony between man and nature. Finally, Christian and humanist principles of social order, such as the reduction of living organisms to the status of products with purely commercial purposes, may particularly undermine the foundations of the functioning of society.[48] In another proceeding against

[42] It concerned Zea mays L. line Bt-11 maize – approved by the Commission by Decision 98/292/EC of April 22, 1998 – and Zea mays L. line MON 810 maize – approved by the Commission by Decision 98/294/EC of April 22, 1998.

[43] Judgment of September 6, 2012, C-36/11, Pioneer Hi Bred Italia Srl v. Ministero delle Politiche agricole alimentari e forestali, ECLI:EU:C:2012:534.

[44] Judgment of September 13, 2017, C-111/16, Criminal proceedings against Giorgi Fidenat and others, ECLI:EU:C:2017:676.

[45] Judgment of July 16, 2009, Case C-165/08 Commission of the European Communities v. Republic of Poland, ECLI:EU:C:2009:473.

[46] According to Article 5(4) and Article 57(3) of the Act of June 26, 2003 on Seed Production (Journal of Laws No 137, item 1299) in force until December 27, 2012, genetically modified varieties could not be entered in the national register, and seed material of genetically modified varieties could not be authorised for marketing in the territory of the Republic of Poland.

[47] See judgment of July 16, 2009, Case C- 165/08, Points 17 and 19.

[48] See judgment of July 16, 2009, Case C- 165/08, Point 31.

Poland (Case C-313/11[49]), when replying to the Commission, the Republic of Poland highlighted the framework position adopted by the Polish Council of Ministers as part of the ongoing political and social debate in Poland around genetically modified feed, in which this body spoke out against placing this feed on the market.[50]

6. Changing the EU approach

Ongoing cases and the resulting practice of many Member States directed at *"defending the public against GMOs"* view the GMO issue as an opportunity for national governments to demonstrate to their electorate their willingness to defend the public, and especially consumers, against a group of large multinational corporations with interest in the marketing of GM seed, food, and feed. However, regardless of the cases before the CJEU, the issue of GMOs surfaced in the actions of EU legislators under pressure from Member States.

In March 2009, the Council rejected Commission proposals asking Austria and Hungary to reject their national safeguard measures because, according to the European Food Safety Authority (EFSA), they lacked the scientific justification required under EU legislation. As a result, a group of 13 Member States[51] called on the commission to prepare proposals, giving Member States the freedom to decide on the cultivation of GMOs.[52]

As a result of negotiations between the Commission and the Member States, the Commission prepared a draft amendment to Directive 2001/18/EC, proposing a compromise solution in the form of an opt-out clause.[53] On March 11, 2015, Directive 2015/412 amended Directive 2001/18/EC regarding the possibility for Member States to restrict or prohibit the cultivation of genetically modified organisms (GMOs) in their territory.[54] As explained in the preamble, experience has shown that the cultivation of GMOs is an issue that is dealt with in more detail at the Member State level, which requires more flexibility than EU regulations, as it has precise national, regional, and local dimensions because of its links with land use, local agricultural structures, and the protection or maintenance of habitats, ecosystems, and landscapes.[55] It was noted that, in the past, some countries had used safeguard clauses and emergency measures under Article 23 of Directive 2001/18/EC and Article 34 of Regulation (EC) No 1829/2003 to restrict or prohibit the cultivation of GMOs or have used the notification procedure under Article 114(5) and (6) TFEU, which requires new scientific evidence for the protection of the environment or the working environment. It was also noted that the decision-making process has proven particularly difficult regarding GMO cultivation

[49] Judgment of November 18, 2013. Case C-313/11 European Commission v. Republic of Poland, ECLI:EU:C:2013:481.
[50] See judgment of November 18, 2013 in case C-313/11, Point 15.
[51] Austria, Belgium, Ireland, Greece, Cyprus, Latvia, Lithuania, Hungary, Luxembourg Malta, the Netherlands, Poland, and Slovenia.
[52] Individual discussions took place at Council meetings on March 2, March 23, and June 25, 2009.
[53] Wrześniewska-Wal (2018b), 105.
[54] Journal of Laws 68, 13.03.2015.
[55] See Point 6 of the preamble to Directive 2015/412.

owing to national concerns about the safety of GMOs for health or the environment.[56] In this context, Member States have been given more freedom to decide whether to cultivate GMOs in their territories.

First, during the authorization procedure for a given GMO, any Member State may demand an adjustment of the geographical scope to exclude all or part of its territory from cultivation (Article 26b of Directive 2001/13/EC). The demand is made available to the applicant for approval (notifier), who may either adjust their application to the state's demand or confirm the geographical scope of their initial notification; in the absence of confirmation of the original notification, the request for adjustment of the geographical scope is granted. If the application is granted, the cultivation of a particular GMO will not be allowed in the territory of the concerned country.

Second, if no demand was made, or if the applicant (notifier) has confirmed the geographical scope of its initial application (notification), the concerned Member State, after informing the Commission, may adopt measures restricting the cultivation or prohibiting the cultivation, in all or part of its territory, of a particular GMO or groups of GMOs defined by the type or trait of cultivation already authorized, provided that these measures conform with Union law, are reasoned, proportionate, and non-discriminatory. Furthermore, the measure must have compelling grounds, such as those related to: (a) environmental policy objectives; (b) town and country planning; (c) land use; (d) socio-economic impacts; (e) avoiding the presence of GMOs in other products; (f) agricultural policy objectives; (g) public policy (whereby this basis must only be used in conjunction with another). While the scope of these grounds is broad, experience from proceedings before the CJEU has shown that those with an interest in the approval of a particular GMO can defend their interests actively. Therefore, the introduction of a ban based on one such ground requires robust justification by the concerned Member State.

Third, a transitional measure is provided in connection with the enactment of Directive 2015/412. A Member State may have requested an adaptation of the geographical scope of a given notification submitted or authorization granted under Directive 2001/18/EC or Regulation (EC) No 1829/2003 before April 2, 2015 (Article 26c of Directive 2001/18/EC). As many as 19 Member States made this request[57] for the only plant authorized for cultivation in the EU, MON 810 maize. All applications received by the Commission covered the entire territory of the member states concerned, except for Belgium, which transmitted an application covering only the territory of Wallonia, and the United Kingdom, which transmitted an application covering only the territory of Northern Ireland, Scotland, and Wales. Germany's proposal does not include cultivation for research. The Commission submitted all the requests of the concerned Member States to Monsanto, which did not object and thus did not confirm the geographical scope of the authorization for the cultivation of MON 810 maize. On March 3, 2016, the Commission issued Decision 2016/321 adjusting the geographical scope of the authorisation of GM maize *(Zea mays* L.) MON 810, according to which the cultivation of GM maize *(Zea mays* L.) MON 810 is prohibited in the territories of Latvia;

[56] See Point 7 of the preamble to Directive 2015/412.

[57] Applications were received from: Latvia; Greece; France; Croatia; Austria; Hungary; the Netherlands, Belgium; Poland; Lithuania, the United Kingdom; Bulgaria, Germany and Cyprus; Denmark, Italy; Luxembourg, Malta and Slovenia.

Greece; France; Croatia; Austria; Hungary; the Netherlands, Belgium; Poland; Lithuania, the United Kingdom; Bulgaria, Germany and Cyprus; Denmark, Italy; Luxembourg, Malta and Slovenia.

In addition, as of April 3, 2017, Member States where GMOs are cultivated are obliged to take appropriate measures in the border areas of their territories to prevent possible transboundary contamination in neighboring Member States, where the cultivation of the GMO in question is prohibited unless such measures are unnecessary due to specific geographical conditions (Article 26a of Directive 2001/18/EC).

Therefore, the action taken owing to public pressure by many Member States has led to a significant change in the EU regulation of GMO cultivation. Instead of a stringent regulation, which was uniform throughout the EU, a solution was adopted whereby each country could, for the most part, decide on its own whether GMO cultivation was allowed in its territory.

7. GM food labelling and regulation of GM feed in Poland

A country's ban on the cultivation of GMOs is not the same as its ban on the marketing of GM food and feed (including GMOs). Meanwhile, in public discourse, the issue of using GMOs as food and feed has been raised independent of GMO cultivation.

For both GM food and GM feed, a compromise has been found at the EU level to the effect that, as a general rule, there is an obligation to indicate on the label of GM products that the food or feed contains or consists of GMOs in its composition or is produced from or contains ingredients produced from GMOs.[58] This obligation does not apply to food or feed containing material that contains, consists of, or is produced from GMOs in a proportion no higher than 0.9%, provided that its presence is adventitious or technically unavoidable.[59] As explained in the preamble to Regulation (EC) No. 1829/2003, the introduction of a requirement for compulsory GMO labelling meets the expectations of a large majority of consumers, as expressed in numerous consumer surveys, enables them to make informed choices, excludes the potential for consumers to be misled about production or manufacturing methods, and enhances the fairness of transactions.[60] It should be emphasized that the labelling obligation applies to GM foods. In contrast, food produced using (with the help of) GMOs (e.g., products of animal origin, such as meat, eggs, and milk, derived from animals fed genetically modified feed) is not considered GM food per EU regulations. Therefore, these products are not subject to the specific regulations applicable to GM foods.[61] This means that there is no obligation to inform consumers that the food comes from animals fed GM feed.

However, responding to consumer demand, many traders have also started to use the voluntary label 'GMO-free', including foods of animal origin. The lack of legislation on this issue at the EU level has been exploited by the many EU Member States, which,

[58] See Articles 13 and 25 of Regulation (EC) No 1829/2003.
[59] See Articles 12 and 24 of Regulation (EC) No 1829/2003.
[60] See Points 17, 20 and 21 of the preamble to Regulation (EC) No 1829/2003.
[61] See Point 16 of Regulation (EC) No 1829/2003.

responding to public expectations, have introduced various national regulations relating to the use of the 'GMO-free' label.[62]

In addition, the Polish legislature enacted a law on June 13, 2019, on the labelling of products produced without the use of genetically modified organisms as free of these organisms,[63] which entered into force on January 1, 2020. According to this regulation, in the case of food of plant origin, it is permissible to use the label 'GMO-free' if the content of genetic modification in this GMO is no more than 0.1% and the presence of GMOs in this food is accidental or technically unavoidable. However, in the case of products of animal origin and food consisting of more than one ingredient which includes a product of animal origin, the indication 'produced without the use of GMOs' may be used if the food was obtained from animals on which no genetically modified feed was used during the withdrawal period preceding its acquisition and the plant ingredients of the food meet the requirement for the use of the indication 'without GMOs.'

In the explanatory memorandum to the draft of this law,[64] it is explicitly indicated that the development of provisions allowing for the labelling of products produced without the use of genetically modified organisms results from requests made by social organizations, consumer organizations, and some producers. Public opinion polls were quoted, showing that 65% of Poles favored a ban on GMO cultivation and that 56.8% of Poles would choose a product derived from animals fed with non-GMO feed. It has also been pointed out that due to continuing uncertainty and concerns about the long-term impact of genetic modifications on human health, public discussions on GMOs continue to arise. In addition to appealing to public expectations, the bill's explanatory memorandum also notes that the introduction of GMO-free labelling regulations should contribute to increasing the domestic production of plant proteins for feed purposes. During the presentation of this bill, there was a discussion on several GMO issues (ultimately, as many as 421 MPs voted in favor and only three against).[65]

Therefore, explanations in the memorandum of the law show that it was primarily the public's expectations of GMOs that underpinned the introduction of this regulation. Simultaneously, it intended to support domestic feed producers, including small Polish farmers (an influential group of voters).

An even more far-reaching solution aimed not only at restricting the use of GMOs in food and feed but also to ban the use of GMOs in feed altogether was provided in the Feed Law passed in 2006.[66] According to this law, it is prohibited to produce, market, or use genetically modified feed in animal nutrition and organisms intended for feed usage.[67]

[62] See European Commission, Directorate General for Health and Consumers, Evaluation of the EU legislative framework in the field of GM food and feed, Final Report submitted by Food Chain Evaluation Consortium (FCEC), July 12, 2010, 130.
[63] i.e., Journal of Laws 2021.763.
[64] Act of June 13, 2019 on labelling products produced without using genetically modified organisms as free of such organisms (i.e., OJ 2021.763).
[65] See the Stenographic report of the 82nd meeting of the Sejm of the Eighth Tenure of the Republic of Poland of June 12, 2019, 43–54.
[66] Act of July 22, 2006 Feed Law (i.e., Journal of Laws 2021.278).
[67] See Article 15(1) Point 4.

However, it should be emphasized that the provision introducing the ban has not yet entered into force. The ban came into force two years after the feed law came into force. However, the moratorium on the ban was postponed several times, from 2008 to 2012,[68] 2017[69] to 2019,[70] 2021,[71] and 2023.[72]

The justifications for successive amendments postponing the entry into force of the ban have invariably pointed out for years that, in Poland, as in the case of many other EU Member States, the issue of the production, marketing, and use of genetically modified feed in animal nutrition raises many controversies, which are reflected in social discussions, polemics, and political debates. Simultaneously, studies conducted in Poland found no negative impacts of feeding GM feed on the quality and safety of animal products, human and animal health, or the environment. It is also stressed that there is no possibility of substituting GM soya for animal feed in Poland, because the world's leading soya producers and exporters have switched almost entirely to growing GM soya.

It is characteristic that, despite the awareness of those in power that the ban on the marketing of GM feed is in breach of Regulation (EC) No 1829/2003,[73] no parliamentary majority in Poland (from 2008 onwards) has decided to repeal the Commission's questioned Article 15(1) Point 4 of the Feed Law, choosing only to postpone the entry into force date of this provision several times. Moreover, with successive amendments amounting to nothing more than a change in the date of entry into force, heated discussions were held during deliberations regarding GMOs.[74]

[68] See the Act of June 26, 2008 amending the Feed Law.
[69] See the Act of July 13, 2012 amending the Feed Law.
[70] See the Act of November 4, 2016 amending the Feed Law.
[71] See the Act of November 22, 2018 amending the Feed Law.
[72] See the Act of November 19, 2020 amending the Feed Law.
[73] This is evidenced, for example, by the words of the Member presenting the bill to amend the Feed Act, who, in presenting the arguments in favor of the bill (print no. 457), explicitly pointed out that *"this Article 15(1) Point 4 is indeed incompatible with EU law."* See the stenographic report of the 17th meeting of the Sejm of the Seventh Tenure of the Republic of Poland of June 27, 2012, p. 116.
[74] The stormy nature of these discussions can be evidenced by the fact that, on the occasion of yet another postponement of the entry into force of this provision during the first reading, as many as 30 MPs signed up to speak, and the representatives of the various parties represented in the Sejm, in presenting their position, referred to arguments of various nature, ranging from health issues, through the destruction of Polish agriculture by the importation of GMO feed, to the citation of various reports and opinions. See the stenographic report of the 17th meeting of the Sejm of the Seventh Tenure of the Republic of Poland of June 27, 2012, pp. 115–135. A heated discussion was also held at the following amendment in 2016 when the parliamentary majority submitted a proposal for another postponement of the effective date, which had so far taken a position opposing further postponement of the effective date. During the discussion, among other things, it was alleged that the PiS party used the fight against GMOs during the election campaign as a trump card to win the elections and changed its stance once in power (p. 125). See Stenographic report of the 29th meeting of the Sejm of the Eighth Legislature of November 29, 2016, 122–133.

8. Summary

The use of non-naturally occurring methods of transgenesis (and, in light of CJEU jurisprudence, mutagenesis through genetic engineering), which makes it possible to obtain expected and planned properties of plants (e.g., resistance to certain herbicides or pest repellence), is seen as a natural, scientifically driven development process that makes food production more efficient. However, potential threats to the environment, human health, and farmers' interests are pointed out. Deciding whether GMOs are beneficial or pose a risk is beyond the scope of legal sciences. Concurrently, there is no doubt that the genetic modification of plants and their use in food and feed have been of interest to both EU and national legislators for many years.

While the US and other countries (mainly from the Americas) relied on the principle of 'listening to science' and considered that since there was no scientific evidence to show beyond doubt that GMOs used for food purposes posed a risk, there was no need for specific regulation of GM food, the European Union, based on the precautionary principle, recognized the need for specific regulation of GM plants, food, and feed. Based on the precautionary principle and appealing to public concerns about GMOs, the EU decided to adopt stringent regulations for GM products. Some Member States have introduced additional national restrictions.

The inclusion of GMOs and GM food and feed in the regulations was undoubtedly linked to the cautious stance of European societies towards GMOs. This position was reinforced by the objections raised by various organizations against GMOs, ranging from environmental, health, and economic. It seems that issuing a regulation at the community level based on the risk principle was not insignificant to the public interest on this issue. Indeed, the introduction of specific procedures for releasing GM plants into the environment and placing GM food and feed in the market confirmed the thesis of the increased risk associated with GMOs. Therefore, a feedback loop has occurred, where regulation responding to the public expectation of protecting against possible GMO risks has further heightened the fear of GMOs. In addition, the arrangements adopted in the EU, whereby an entity interested in introducing a GMO product must provide evidence that it does not pose a risk, have led to the fact that only entities with the necessary capacity to afford to fund research have met these requirements. Therefore, in practice, applications for genetically modified products are submitted by several large multinational corporations, an additional argument raised by opponents of GMOs regarding monopolization, and, in principle, the dependence of agriculture on a few entities with rights over GM varieties.

An analysis of the CJEU's case law on GMOs includes consideration of the number of cases and their spread over time (the first rulings appeared at the end of the 1990s) and the actors involved in the disputes (multinational corporations with interest in the development of GMO crops, e.g. Monsanto, BASF, Bayer, Syngenta, and conversely, farmers' organizations, e.g. the farmers' trade union, and social organizations associated with environmental protection, e.g. Greenpeace). The arguments raised by the Member States (in some judgments, social concerns and the need to take account of them were explicitly referred to) indicate the Member States in which there was a social discussion on GMOs, though there was a public debate on GMOs. It follows from the arguments put forward by the Member States (some

judgments explicitly mention public concerns and the need to take them into account), as well as from those Member States in which there has been a public debate on GMOs, irrespective of the parliamentary majorities currently in power, even in breach of EU law, that they have taken action in response to the 'voice of the people' (i.e., in response to the negative results of public opinion polls and the negative impact of GMOs on the environment). This implies that both the negative view of GMOs held by the public in a given country as a result of opinion polls, consumers' expectations concerning information on GM food, and, finally, the expectations of domestic farmers, who fear the domination of large multinationals. The Polish experience also shows that the issue of 'protection from GMOs' is actively used in political discourse, with those in power (regardless of political party) taking a similar stance on GMO issues (as exemplified by the repeated postponement of the entry into force of the ban on the marketing of GM feed).

The submission of the EU legislator and national legislators to public pressure has led to a situation where, in the European Union (in those countries where no ban has been introduced), only one GM plant variety (MON 810 maize) is authorized for cultivation based on a 1998 authorization that has been renewed several times. Concurrently, in the USA, there has been a massive increase in the production of GM plants over the last few decades (GM soya and cotton account for more than 95% and GM maize for more than 80%). Furthermore, owing to the massive expansion of GM crops, mainly in the USA and South American countries, GM feeds dominate the world market, including the EU, where GM food and feed from third-country crops are allowed. Indeed, the need to ensure the economic stability of food producers of animal origin does not allow individual Member States to ban the marketing of GM feed in their territories. Instead, the protection of the public in this regard is achieved through the labelling of GMO-free food, including food from animals fed GMO-free feed. Only this full scope of GMO labelling regulation is sufficient to protect consumer interests.

This confirms the hypothesis that the negative public perception of GMOs in European society has been reflected in the actions of those in power in many EU countries, including Poland, and that the shape of EU regulation of genetically modified plants and national regulations has become a response to public expectations and fears without considering the scientific knowledge that should form the basis of risk analysis.

Bibliography

1. Blayer P A (2022) The constitutional aspects of regulation limiting agricultural land transactions in Poland, *Journal of Agricultural and Environmental Law* 17(32), pp. 7–27, https://doi.org/10.21029/JAEL.2022.32.7
2. Dzwonkowski W (2015) *Raport o sytuacji na światowym rynku roślin GMO i możliwościach substytucji genetycznie zmodyfikowanej soi krajowymi roślinami białkowymi w aspekcie bilansu paszowego*, Warszawa.
3. Korzycka M & Wojciechowski P (2017) Regulacja prawna żywności genetycznie modyfikowanej w USA i UE w kontekście planowanego Transatlantyckiego Porozumienia Handlowo-Inwestycyjnego (TTIP), *Studia Iuridica Lublinensia* 26(1), pp. 465–488, https://doi.org/10.17951/sil.2017.26.1.465
4. Korzycka M & Wojciechowski P (2017) *System Prawa żywnościowego*, Warszawa
5. Kubaj A (2020) Land frame for succession/transfer of Agricultural property between the generation acquisition of agricultural property by legal persons – in Poland, *Journal of Agricultural and Environmental Law* 15(29), pp. 118–132, https://doi.org/10.21029/JAEL.2020.29.118
6. Małyska A & Twardowski T (2011) Opinia publiczna o biotechnologii w Polsce i innych krajach Unii Europejskiej, *Nauka* 2011/1, pp. 85–98.
7. Micińska-Bojarek M (2013) Bezpieczeństwo żywności a organizmy genetycznie modyfikowane. Instrumenty administracyjno–prawne, *Studia Iuridica Agraria* 2013/11, pp. 263–274.
8. Páczay Gy B (2017) Another political step towards developing our own GM-free feed, *Journal of Agricultural and Environmental Law* 12(22), pp. 101–116.
9. Rotkiewicz M (2017*) W królestwie monszatana, GMO, gluten i szczepionki*, Wołowiec.
10. Stępień M (2017), Analiza regulacji prawnych w zakresie wykorzystania GMO, *Acta Universitatis Wratislaviensis* nr 3759 Przegląd Prawa i Administracji CVIII, Wrocław, pp. 157–168, https://doi.org/10.19195/0137-1134.108.12
11. Szalata M, Słomski R & Twardowski T (2020) *Biotechnologia 2020 o co najczęściej pytamy?*, Poznań.
12. Twardowski T (2007) Opinia publiczna a GMO, *Prace przeglądowe, Biotechnologia* 2007/3, pp. 46–65.
13. Wrześniewska-Wal I (2018a) Bezpieczeństwo upraw GMO i żywności GM na podstawie nowych regulacji prawnych na poziomie międzynarodowym i krajowym, *Żywność. Nauka. Technologia. Jakość* 25(4), pp. 5–17, https://doi.org/10.15193/zntj/2018/117/255
14. Wrześniewska-Wal I (2018b) Regulacje prawne GMO. Aspekty prawne i środowiskowe, *Zeszyty Problemowe Postępów Nauk Rolniczych* 593/2018, pp. 101–112, https://doi.org/10.22630/ZPPNR.2018.593.19
15. Wrześniwska-Wal I (2008) *Żywność genetycznie zmodyfikowana. Aspekty prawne*, Warszawa.
16. Zombory K (2021) The agricultural land trade-theory and practice, *Journal of Agricultural and Environmental Law* 16(30), pp. 174–190, https://doi.org/10.21029/JAEL.2021.30.174