THE DEVELOPMENT OF GMO REGULATORY FRAMEWORK IN THE EUROPEAN UNION: ENVIRONMENTAL LAW PRINCIPLES AND BIOETHICAL CHALLENGES

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Abstract

This study investigates the evolution of the European Union's regulatory framework for genetically modified organisms (GMOs), with a focus on the integration of environmental law principles. It highlights the influence of soft law mechanisms in shaping legislative processes and examines contemporary regulatory challenges posed by new genomic techniques (NGTs). The analysis addresses bioethical considerations and evaluates the impact of recent legislative developments on the enforcement of environmental law principles and the protection of the right to a healthy environment. By synthesizing legal, ethical, and environmental perspectives, this study contributes to understanding the dynamic interplay between technological innovation and regulatory governance in the EU.

Keywords: *biodiversity, genetic modification, gene editing, NGTs, EU law, Fundamental Law, future generation*

1. INTRODUCTION

Genetic technologies enable the precise modification of an organism's genetic material to achieve specific traits, such as herbicide tolerance or drought resistance, which do not occur naturally. Since the 1980s, genetic engineering has been instrumental in the pharmaceutical and fermentation industries. Beyond medical applications, genetically modified organisms (GMOs) have significantly impacted agriculture and food production. The global population's continuous growth has driven the demand for sustainable agricultural innovations to ensure food security.

In the European Union (EU), the regulatory framework for genetic engineering was initially established through two directives in the 1990s. These directives, later amended and supplemented by additional legislation, have governed agricultural activities involving GMOs for nearly three decades, adapting to the field's rapid advancements.

The term "new genomic techniques" (NGTs) refers to advanced genetic modification methods developed over the past two decades, following the EU's initial regulatory framework. A prominent example is CRISPR/Cas9, which allows precise editing of genetic material at the nucleotide level. In 2018, the European Court of Justice ruled that organisms modified using NGTs are subject to the same GMO regulations as those created with earlier genetic engineering techniques, ensuring consistent oversight across all genetic modification processes.

The regulation of genetically modified organisms (GMOs) and new genomic techniques (NGTs) has sparked ongoing professional and scientific debates. Proponents highlight their potential to mitigate climate change impacts and enhance food security for a growing global population. Conversely, critics, adhering to the precautionary principle, argue that existing legislation is inadequate for monitoring these technologies, raising significant challenges in labeling and consumer information.

GMOs, which emerged in the early 1990s, and NGTs, which gained prominence in the 2020s, differ fundamentally despite both involving gene modification. GMOs typically involve inserting foreign DNA into a plant, whereas NGTs, such as those employing CRISPR/Cas9, edit the plant’s native DNA without introducing foreign genetic material. According to the Presidium of the Hungarian Academy of Sciences, NGTs produce outcomes distinct from GMOs, as they mimic directed mutations akin to traditional breeding methods (e.g., irradiation or chemical mutagenesis) but with greater precision.

Successful applications include disease-resistant cereals, male-sterile maize, and herbicide-resistant crops, offering both agronomic and economic benefits, such as viral resistance.

However, an opposing scientific perspective, represented by groups like the European Network of Scientists for Social and Environmental Responsibility (ENSSER), contends that NGTs warrant regulatory scrutiny comparable to GMOs. Their 2017 statement emphasized that NGTs pose similar risks, including unintended genetic changes, rendering their products incompatible with organic farming. Critics argue that shifting from the precautionary principle to a "proof of harm" approach undermines safety, as proponents may evade demonstrating the absence of risks.

The precautionary principle remains central to regulating this rapidly evolving field, given uncertainties about long-term impacts—a common challenge in scientific discourse. Legal frameworks for GMOs and NGTs in agriculture are driven by multiple factors, including potential health risks, which remain only partially understood, and economic benefits, particularly for seed companies. European Union law mandates that Member States and the Commission ensure regular, independent research into the risks of GMO release and market placement, with adequate funding and access to materials while respecting intellectual property rights.

Debates persist due to conflicting stakeholder interests. Breeders emphasize increased yields, reduced environmental impacts (e.g., lower chemical use and greenhouse gas emissions), and adaptation to climate change through innovations like drought-tolerant varieties. Conversely, conservationists and organic farmers highlight ecosystem risks, such as gene flow ("genetic environmental pollution"), unintended genetic alterations, and increased chemical use due to resistant varieties. Additionally, breeders argue that restrictive regulations hinder global market competitiveness, while critics view slow legislative progress as a safeguard.

This study shifts focus to the legal regulatory aspects of GMO and NGT use in agricultural field applications, analyzing new legislative challenges and the evolving role of the precautionary principle.

2. MATERIALS AND METHODS

2.1. Materials

This study investigates the regulatory frameworks of Hungarian and European Union (EU) environmental legislation, with a specific focus on the application of the precautionary principle. The analysis evaluates both existing regulations and emerging trends in regulatory development from the perspective of this principle.

The research begins by elucidating the conceptual and practical dimensions of the precautionary principle within environmental law, providing a foundation for its application. Subsequently, it examines Hungarian legislation, with particular emphasis on the jurisprudence of the Hungarian Constitutional Court, to highlight the domestic implementation of the principle.

The study then shifts to the EU legal framework, analyzing the current regulatory landscape and identifying recent shifts in policy direction. The final section critically evaluates the alignment of these regulatory trends with the precautionary principle, offering insights into their adequacy and potential areas for refinement. The methodology integrates descriptive, analytical, and comparative approaches, drawing on legal texts, case law, and policy documents to provide a comprehensive assessment of the subject matter.

2.2. Methods

The study examines the application of the precautionary principle within the regulatory domain. In the relatively brief history of environmental law, amidst the development and implementation of legal frameworks in a rapidly evolving field, the enforcement of the precautionary principle is regarded as a primary consideration among environmental law principles. Generally, in areas characterized by complex mechanisms impacting both environmental conditions and human health, the precautionary

principle should be applied. The research employs a descriptive, expository, and analytical methodology.

3. THE PRECAUTIONARY PRINCIPLE

The precautionary principle is rooted in international environmental law, along with many other related principles. The principles of environmental protection are of paramount importance because environmental legislation is in a state of constant transformation, and environmental aspects that require some kind of regulation are appearing one after another (Bándi, 2005, p. 453). On the other hand, "legislation is not able to provide a sufficient, secure basis for the application of the law, precisely because of the diversity of life situations. Thus, the application of the law can only meet the challenge generated by changing circumstances if it applies and interprets the principles more intensively. This applies in particular to adversarial proceedings, but the application of administrative law cannot escape this general tendency either" (Bándi, 2005, p. 453).

The precautionary principle in international environmental law was formulated in the preamble to the Convention on Biological Diversity at the United Nations Conference on Environment and Development in Rio de Janeiro (1992) as follows: ″noting also that where there is a threat of significant loss or loss of biodiversity, the lack of full scientific certainty cannot be used as an argument for the threat of such a threat to the Rio de Janeiro. measures to avoid or mitigate the use of the Labour Market' (Cartagena Protocol on Biosafety, 2000).

The concluding sentence of the preamble notes with regard to the material scope of the Convention that 'Technology includes biotechnology' (On 28 January 2000, at the Conference of the Parties to the Convention on Biological Diversity, the Protocol on Biosafety for the Safe Transport, Handling and Use of Living Modified Organisms from Modern Biotechnology confirmed the key function of the precautionary principle).

One of the best examples of defining the principles of environmental policy in a broader sense has been provided by the European Community. (Bándi 2005. p. 454.)The principle of prevention was one of the eleven objectives and principles listed in the EEC's first Environment Action Programme in 1973 (Council of the European Communities, 1973) and has since been applied in all specific areas of environmental policy.

The precautionary principle is now one of the main pillars of the European Union's environmental policy. Article 191(2) of the Treaty on the Functioning of the European Union (TFEU) states that 'Union policy on the environment shall aim at a high level of protection, while taking into account the diversity of situations in the various regions of the Union. This policy is based on the precautionary and preventive principles, the principle that environmental damage should be rectified primarily at source, and the polluter pays principle.'

As a result, institutions and Member States are obliged to apply this principle in their actions in the environment.

The boundary between prevention and precaution can be defined as prevention addressing tangible risks, while precaution deals with scientific uncertainty. Risks for which there is a causal link between the event and the injury are supported by irrefutable scientific evidence fall within the scope of the principle of prevention. Such risks can be classified as certain, since a causal relationship between the initial event and its adverse effects can be established and the likelihood of their occurrence can be calculated.

The case law of the Court of Justice of the European Union has had a major impact on the further development of the precautionary principle in EU law, with landmark cases such as Sandoz (Sandoz BV, 1983), Pfizer (Pfizer Animal Health SA v Council, 2002) and the BSE crisis (National Farmers' Union and Others, 1998). In the Pfizer case, the Court outlined the reasons behind it: '146. The precautionary principle should therefore only be applied in situations where there is a risk, namely to human health, which, although not based on mere hypotheses that have not been scientifically confirmed, has not yet been fully demonstrated.' The BSE case in United Kingdom v Commission

clarified the implications: '99. Where there is uncertainty as to the existence or extent of risks to human health, the institutions may take protective measures without having to wait until the reality and seriousness of those risks become fully apparent.' Since then, it has been applied in relation to actions taken by both the EU institutions and the Member States, derogating from the rules on free movement (Bándi, 2005, p. 453).

The Hungarian Constitutional Court (hereinafter: CC) has already interpreted the principle of prevention constitutionally in its first decision, which presented a detailed analysis of the right to a healthy environment. The Court has held that among the means of protecting the right to a healthy environment, the application of legal measures based on the principle of prevention takes precedence (Hungarian Constitutional Court, 1994). In constitutional practice, after the entry into force of the Fundamental Law (2012), the precautionary principle, prevention and planning appeared as a whole system of long-term thinking. A good example of this is a 2017 resolution, which stresses that failure to protect nature and the environment can trigger irreversible processes, so the precautionary and preventive principles must be taken into account when developing legislation to protect the environment (Hungarian Constitutional Court, 2017). In the following, we will examine how the precautionary principle relates to the conservation of biodiversity and the use of genetic modification.

Biodiversity is the natural capital of our Earth. Genetic modification activities pose a threat to the preservation of the planet's biodiversity due to the significant use of chemicals and the spread of monocultures. In addition, newer, legally regulated technologies have (Sowa et al., 2021) appeared on the market, (Dederer and Hamburger, 2019) and due to their economic usefulness, rapid spread can be expected.

Biodiversity means the diversity of the living world, encompassing the totality of species of living beings. Biodiversity can also be understood as genetic diversity within species, but the concept can also mean the species richness of certain areas, plays a significant role in maintaining ecological balance, and is also an important indicator of it.

The artificial modification of the genetic material of living organisms, the technical intervention in the natural order and system of inheritance, made it possible to produce and thus economically exploit living beings that never existed in nature. However, this possibility also entails risks that are difficult to calculate, as natural habitats and organisms, as well as the human body, interact directly or indirectly with species and varieties with characteristics not experienced in evolution, or products made from them.

As a result, the application of gene and biotechnological methods may raise problems primarily in the field of agriculture and the food industry. First-generation genetically modified crops created by incorporating genes from alien species offered crop technology advantages, but in return they pose nutritional health risks and potentially threaten biodiversity (Hilbeck et al., 2015).

The interpretation of the precautionary principle may also show differences in the field of biotechnology. The report (2017) on the importance of cooperation between each country, its regulatory authorities and its funding bodies and professional associations, published by the Scientific Advisory Board of the European Academies (EASAC), formulated the message in connection with the latest genetic modification method, genome editing (European Academies' Science Advisory Council, 2017) that when creating legal requirements, it is not the specific technology that should be taken as a basis, but its expected applications and results (the product). The regulation of applications should be based on concrete evidence, taking into account both the potential benefits and the risk factors, and proportionate to these and being flexible enough to adapt to future technological developments.

In connection with this, it should be noted that the above-mentioned method was not first proposed in connection with genome editing, but we have already encountered it in relation to GMOs. According to the EASAC report, there is evidence that the EU's previous decisions on GM products have adversely affected scientists, farmers and politicians in developing countries (Hajnócz, 2018, p. 95.).

At this point, they obviously refer to competitive considerations.

The position of the Hungarian Academy of Sciences also highlights this situational duality, which, in addition to a cautious attitude towards research associated with scientific uncertainty, may mean a competitive disadvantage.

The position paper of the Presidium of the Hungarian Academy of Sciences (MTA) (2017) is based on the position of EASAC, and even argues for its full acceptance. "It is in our national interest that domestic life science research based on genome editing methods should be able to join international processes and help biotechnological developments as an innovative factor. The new technologies, primarily their most efficient, versatile and cheapest version, the so-called CRISPR/Cas9 method, are already used in basic research by a number of Hungarian university, academic and industrial laboratories. It is important that new knowledge is also included in education" (Presidium of the Hungarian Academy of Sciences, 2017).

In its statement, the Hungarian Academy of Sciences distinguishes between genome editing as precision breeding and the creation of genetically modified organisms. It emphasizes the possibilities of the most common CRISPR/Cas9 technology, the advantages of the new method, and identifies a "more livable world" as its application goal. He also touches on the possible relationship between genome editing and the Fundamental Law, according to which he says: "Scientific considerations support the fact that genome editing – following the recommendation of EASAC – should not be considered as a GMO by the Hungarian legislation, so the utilization of such organisms would not be in conflict with the Fundamental Law" Presidium of the Hungarian Academy of Sciences, 2017).

Another group of representatives of the scientific world – including András Székács or Béla Darvas – have a different attitude towards genome editing.

The scientific position of the European Network of Scientists for Environmental and Social Responsibility (ENSSER), an independent professional organization of scientific experts, is similar (Gelinsky and Hilbeck, 2018).

The position of the Deputy Commissioner for the Protection of the Interests of Future Generations in Relation to the Use of Genetically Modified Organisms and Gene Editing also drew attention to the importance of regulation in accordance with the precautionary principle (Commissioner for Fundamental Rights of Hungary, n.d.).

Following the precautionary principle is undisputed in the professional scientific discourse around gene editing. Differences arise from the degree of caution involved in the actual enforcement of the precautionary principle: does it make a difference that human intervention results in the creation of an organism that would never evolve in nature? On the other hand, when legislation is being drafted, the precautionary principle must apply to the technique or the product resulting from it.

Thirdly, with regard to liability, the emphasis of the supporting positions shifts from this precautionary approach to the principle of proving damage.

4. PRECAUTIONARY PRINCIPLE IN THE HUNGARIAN GMO REGULATORY FRAMEWORK

The recognition of the interests of future generations began in international law, at the UN World Conferences in Stockholm and Rio de Janeiro. The obligation of the present generation, arising from the principle of intergenerational equity, to preserve choices for future generations, (Bándi, 2020) is correlated with the free right of future generations to decide (Weiss, 1989).

The Hungarian Constitutional Court ruled in its decision No. 28/1994. (V.20.) AB: "In contrast to all this, the right to environmental protection is primarily an independent and self-contained institutional protection, i.e. a specific fundamental right of which the objective, institutional protection side is predominant and determining. The right to the environment raises the guarantees of the fulfilment of the state's environmental protection obligations to the level of fundamental rights, including the conditions for the restriction of the protection of the environment achieved. Due to the peculiarities of this right,

all the tasks that the state performs elsewhere with the protection of subjective rights must be performed here by providing legal and organizational guarantees." (Hungarian Constitutional Court, 1994).

According to Article P) of the Fundamental Law, natural resources, in particular – among others – biodiversity, constitute the common heritage of the nation, the protection, maintenance and preservation of which for future generations is the duty of the state and everyone.

The fundamental rights aspect of the careful and sustainable use of the physical conditions affecting future generations appears in Article XX of the Fundamental Law, paragraph (1) of which states that everyone has the right to physical and mental health, and Hungary promotes the enforcement of this right – among other things – through agriculture free of genetically modified organisms (...) and by ensuring the protection of the environment. Pursuant to Article XXI (1) of the Fundamental Law, Hungary recognises and enforces the right of everyone to a healthy environment (Hungarian Constitutional Court, 2017, [27]).

As the Constitutional Court stated, the Fundamental Law not only preserved the level of protection of the constitutional fundamental right to a healthy environment, but also contains significantly more extensive provisions in this area than the Constitution (Hungarian Constitutional Court, 2017, [27]).

"In the course of examining the obligation to protect institutions, the Constitutional Court determined who exactly is subject to this obligation under the Fundamental Law and what its content is." (Hungarian Constitutional Court, 2017, [29]).

"(...) the intention of the Constitutionalist can be derived directly from Article P) of the Fundamental Law that human life and its living conditions, in particular arable land and the related biodiversity, must be protected in such a way that it ensures the life chances of future generations and does not impair it in any way as a consequence of the generally accepted principle of the prohibition of retreat" (Hungarian Constitutional Court, 2018, [14]).

The concept of agriculture free from the use of genetic modification was formulated in Hungary even before the adoption of the Fundamental Law, initially in a five-party consensus.

Hungary's strategic position, which with the entry into force of the Fundamental Law was placed at the top of the legal hierarchy with Article XX (2). However, GMO-free agriculture and access to healthy food do not provide for a subjective right to food safety. The Hungarian Constitutional Court pointed out that the provisions of the National Confession and Article P) referred to "(...) It expects legislation to take into account not only the individual and collective needs of the present generation, but also to ensure the living conditions of future generations, and to act in accordance with the principles of precaution and prevention, and to act in accordance with the principles of precaution and prevention, based on the current state of science, when considering the expected effects of certain decisions." (Hungarian Constitutional Court, 2018, [20]). "(...) Therefore, as a consequence of the precautionary principle, if a regulation or measure may affect the state of the environment, the legislator must prove that the regulation does not constitute a step backwards and thus does not cause irreversible damage in certain cases, or does not create the theoretical possibility of such damage. (…) It is the constitutional obligation of the legislator to take into account the risks that are considered by science to be highly probable or certain to occur with due weight when making a decision. The principle of prevention, on the other hand, means the obligation to act at the source of potential pollution, but before it occurs: to ensure that processes that may harm the environment do not occur (Hungarian Constitutional Court, 2018, [20]). "(...) The restriction under Article I(3) of the Fundamental Law is consistently enforced by the Constitutional Court in relation to the principle of the prohibition of retreat, with the proviso that, in accordance with the precautionary principle, the actual deterioration of the state of the environment is not necessary in order to violate the prohibition of retreat, but the risk of deterioration already justifies the violation of the prohibition of retreat." (Hungarian Constitutional Court, 2015, [65] [110])

The Constitutional Court also ruled that "(...) The prohibition of *non-derogation*, as an additional obligation of the state with regard to environmental regulation, must apply to the substantive and procedural rules of the environment, as well as to the organisational regulation of the institutional system

{3223/2017. (IX.25.) AB decision, Justification [27]-[28]}" (Hungarian Constitutional Court, 2017, [28]).

Within the scope of the constitutional protection of the interests of future generations, the Constitutional Court pointed out that "Article *P(* 1) confers on future generations a hypothetical legacy. The wording 'common heritage of the nation' in Article P) can be considered as a concretisation of the 'common cause of humanity' within the meaning of the Convention on Biological Diversity, as well as the concept of 'heritage of European peoples' in the Birds Directive and 'natural heritage' in the Habitats Directive. According to this, Hungarian citizens and the Hungarian state undertake that the institutional system of the state will ensure the protection of the values set out in Article P) (1) in a non-exhaustive manner for future generations. All this can be seen as a concrete commitment compared to the 'common cause of humanity' in international law" (Hungarian Constitutional Court, 2017, [31]).

According to the Hungarian position published during the European Union's regulatory processes of NGTs, “we support research, as it can contribute to development and the competitiveness of our country. At the same time, while environmental and health risks can be eliminated with the appropriate safety measures in the case of closed-system uses, i.e. laboratory research and drug development, cultivation, which in fact means the deliberate release of the plant into the environment, can carry environmental and health risks that must be examined before such a product is placed on the market.” (Hungary, Government of, 2024).

5. THE INTERNATIONAL AND EUROPEAN REGULATORY FRAMEWORK FOR GMO REGULATION

The key elements of relevant international law, European Union (EU) legislation, and domestic regulations are summarized below. The precautionary principle underpins EU environmental legislation, as reflected in the preambles of most EU legal instruments in this domain. The most important document of relevant international law is the Convention on Biological Diversity (Council of the European Communities, 1993). Between 1995 and 2000, the acceding countries and organizations developed a detailed set of rules, which was adopted on 29 January 2000 under the name of the Cartagena Protocol (hereinafter referred to as the Protocol) (Secretariat of the Convention on Biological Diversity, 2000).

On 16 October 2010, the 160 States Parties to the Protocol unanimously adopted the so-called Nagoya-Kuala Lumpur Additional Protocol on Liability and Remedy. In December 2022, the UN renewed its Convention on Biological Diversity. The Kunming-Montreal Global Biodiversity Framework (GBF) (Secretariat of the Convention on Biological Diversity, 2022) was adopted at the fifteenth meeting of the Conference of the Parties (COP 15) after four years of consultation and negotiations.

This historic Framework, which supports the achievement of the Sustainable Development Goals and builds on the Convention's previous strategic plans, sets out an ambitious path to achieving the global vision of a world living in harmony with nature by 2050. Its implementation is also supported by the six overarching decisions adopted at COP15, which includes the GBF Monitoring Framework, which is an improved mechanism for planning, monitoring, reporting and reviewing implementation, the financial resources needed for implementation, the strategic framework for capacity building and technical and scientific cooperation, as well as the Agreement on Digital Sequence Information on Genetic Resources.

Decision 93/626/EEC provides for the approval of the United Nations Convention on Biological Diversity by the European Community (Council of the European Communities, 1993).

The decision reinforces the commitment of EU countries to its implementation. Both the Cartagena Protocol to the Convention on Biological Diversity on Biosafety and the Nagoya Protocol to the Convention on Biological Diversity on Access to and Benefit from Genetic Resources and the Fair and Equitable Sharing of Benefits from Their Utilization, are part of EU legislation.

The European legal system for the agricultural application of genetic modification in the open field has been developed along the precautionary principle. Given the close link between the right to health and the protection of the environment, the TFEU declares that EU environmental policy contributes to the

protection of human health at international level (Article 191) and that the objectives of environmental policy (Articles 191-193) give the EU the power to take action. (Constitutional Court of Hungary, 2022, [59])

In 2011, the EU adopted its Biodiversity Strategy to 2020. The European Parliament endorsed its Biodiversity Strategy for 2030 in June 2021 and made further proposals to strengthen it.

As part of the European Green Deal, the European Commission presented its Farm to Fork Strategy in May 2020.

According to the current European Union legislation, only food or feed that has previously been approved by an official licensing procedure may be placed on the market or cultivated in the European Union. At present, the authorisation of the marketing of commercial products, such as products containing genetically modified organisms (GMOs), is outside the competence of the Member States. However, the Member States can decide on the release of GMOs for experimental purposes and, since the amendment of Directive 2001/18/EC in 2015 (European Parliament and Council of the European Union, 2015) they can also restrict the cultivation of GMOs authorized in the EU. According to this, if a GMO is authorized for food or feed use in the EU, it can be placed on the market throughout the EU due to the free movement of goods. For food and feed, food and feed produced from or containing GMOs are subject to mandatory labelling under EU legislation.

It is also a precautionary approach that Directive 2001/18/EC has made not only the labelling of GMOs mandatory, but also public consultation with society. The European Commission is obliged to consult the relevant scientific committees on any matter affecting human health or the environment. In addition, registers should be established to record information on genetic modifications and the location of GMOs.

While this directive allows EU countries to restrict or prohibit the release of GMOs that pose a risk to human health or the environment, Directive 2015/412 (European Parliament and Council of the European Union, 2015) amended it by allowing EU countries to prohibit or restrict GMOs that have already been authorized or are in the process of being authorized at EU level on broader grounds. The amending directive also sets out the deadlines and responsibilities governing decisions to adjust the geographical scope of consent, including the right to opt-out on the basis of new, objective circumstances. The previous precautionary regulation gave even more room for caution with the 2015 amendment.

The introduction of this regulation was also an important milestone because by that time, many European regions had already declared themselves GMO-free (Alps-Adriatic GMO-Free Zone Initiative https://www.gmo-free-regions.org/). As GMO production can be allowed in the European Union according to the directives in force, it has been raised whether GMO-free areas have lawfully excluded themselves from the territorial scope of the current regulation. An EU Member State had the opportunity to do so within the framework of the safeguard clause procedure prior to the legislation.

The European Commission, the European Food Safety Authority (EFSA), and EU Member States participate in the decision-making process for authorizing products containing genetically modified organisms (GMOs). Prior to a decision, a comprehensive environmental and health risk assessment of the product is conducted. The European Commission proposes authorization based on EFSA's scientific opinion, which is then subject to a vote by the Member States.

Since 3 April 2017, EU Member States cultivating genetically modified organisms (GMOs) have implemented appropriate measures in their border regions to prevent potential cross-border contamination of neighboring countries that prohibit GMO cultivation, unless such measures are deemed unnecessary due to specific geographical conditions.

New genomic techniques (NGTs), such as gene editing, may differ fundamentally from traditional genetic modification methods. In NGTs, foreign genes are temporarily introduced into the genome during the modification process, resulting in precise, targeted changes to the organism's gene pool without permanent integration of foreign DNA. As noted in the introduction, unlike transgenesis, which involves the insertion of foreign DNA, mutagenesis encompasses techniques that alter an organism's genome without incorporating exogenous genetic material. These mutagenesis techniques have

facilitated the development of seed varieties resistant to specific selective herbicides. The emergence of NGTs has sparked intense debates regarding their legal regulation, particularly whether they should be subject to the stringent licensing, control, labeling, and monitoring requirements applied to genetically modified organisms (GMOs) under existing EU legislation.

In 2018, the Court of Justice of the European Union (CJEU) delivered a landmark judgment (Court of Justice of the European Union, 2018) ruling that organisms obtained through mutagenesis are considered genetically modified organisms (GMOs) and, in principle, are subject to the obligations of Directive 2001/18/EC (the GMO Directive). However, the Court clarified that organisms produced by mutagenesis techniques conventionally used in numerous applications with a long-established safety record are exempt from these obligations.

According to the Court's interpretation, 'the release into the environment or the placing on the market of organisms produced using such a mutagenesis technique/method may, in certain cases, have adverse effects on human health and the environment, possibly irreversible and affect several Member States, even if these characteristics are not related to the way in which the mutagenic material modifies the genetic material of the organism concerned'.

Member States may, while respecting EU law, impose obligations under the Directive or other national measures on such organisms. The CJEU emphasized that the release into the environment or the placing on the market of organisms produced by modern mutagenesis techniques, such as new genomic techniques (NGTs), may, in certain cases, pose risks to human health and the environment. These risks, which could be irreversible and affect multiple Member States, are not necessarily linked to the method by which the mutagenic technique modifies the organism’s genetic material. This ruling has significantly shaped scientific and regulatory discussions on gene editing, particularly regarding the classification and oversight of NGTs.

6. EUROPEAN COMMISSION REGULATORY PROPOSAL FOR THE USE OF NGTS

The EU is preparing to ease the surveillance of genetically modified organisms, focusing in particular on plants and products produced using certain new genomic techniques. The aim is to promote new genomic techniques as innovative technologies and use them as a tool to transform agriculture towards sustainability (Winter, 2024). On July 5, 2023, the European Commission presented a bill to regulate "new genomic techniques" (NGT) (European Commission, 2023). NGT allows the genetic material of plants to be modified without necessarily having to introduce a gene from another species, as is the case with first-generation GMOs. According to it, NGTs are "innovative tools that can help increase the sustainability and resilience of our food system and support the goals of the European Green Deal and the Farm to Fork Strategy. They allow for the precise and efficient development of improved crop varieties that can be resistant to climate and pests, require less fertilizers and pesticides, or provide higher yields."

In its proposal, the Commission distinguishes between two categories of NGT. According to this, there are varieties that can be considered "equivalent to conventional plants" – genetic mutations introduced into them can occur in nature without human intervention. The Commission proposes more lenient regulations in this regard, stating that there is no reason to consider these varieties GMOs and can be deregulated. By contrast, plants obtained from crosses of 'non-crossing' species remain in principle subject to GMO legislation. The draft emphasizes that the use of NGTs in organic farming will be banned in all cases. In a sense, this regulatory proposal represents a step backwards compared to the previous European Union regulation, which fully respected the precautionary principle. Supporters of the activities are keen to refer to the fact that in addition to freer regulation, this serves the goals of the European Green Deal.

The interpretation of the new European Union legislative framework may open a new chapter in the European regulation of genetic modification activities following the Commission's proposal (European Commission, 2023), as NGTs describe a number of techniques that alter the genetic material of an organism, but they did not yet exist in 2001, when the EU legislation on genetically modified organisms

(GMOs) was adopted. Thus, under the current legislation, NGT crops are subject to the same rules as GMOs, but due to the different risk profile of NGT crops, the proposal creates two separate pathways for NGT crops to be placed on the market.

The regulatory framework outlined in the European Commission's proposal for new genomic techniques (NGTs) can be summarized as follows. NGTs that occur naturally or can be achieved through conventional breeding will undergo a verification procedure based on criteria specified in the proposal. NGTs meeting these criteria will be classified as equivalent to conventional crops and thus exempted from the requirements of existing genetically modified organism (GMO) legislation. Consequently, these crops will not require a risk assessment and may be labeled identically to conventional crops. However, this interpretation of the material scope appears to conflict with the legal interpretation provided by the Court of Justice of the European Union in its 2018 ruling.

All other NGTs will remain subject to the provisions of current GMO legislation, requiring a mandatory risk assessment and market authorization procedure. These crops will also be subject to adapted detection methods and tailored monitoring requirements. The proposal applies exclusively to plants produced through targeted mutagenesis and CIS genesis, as well as their derived food and feed products. Plants obtained through NGTs involving the introduction of genetic material from non-crossable species (transgenesis) are excluded from this proposal and remain subject to existing GMO legislation.

To develop the legislative proposal, the European Commission consulted EU-level scientific advisory bodies. The European Food Safety Authority (EFSA) conducted comprehensive safety assessments and issued several scientific opinions on NGTs. The Commission further incorporated evidence and opinions from a broad range of stakeholders and experts during the preparation of the impact assessment. Additionally, the Commission's Joint Research Centre (JRC) analyzed recent scientific advancements in NGTs to assess their development, focusing on plant species, traits, and stages of research and development. The JRC also conducted case studies to evaluate the impacts of specific NGT-derived plants. (EFSA Panel on Genetically Modified Organisms, 2020).

The Commission also took into account evidence and opinions from a wide range of stakeholders and experts in the preparation of the impact assessment.

Under the Commission's proposal, NGT products subject to the authorization procedure will continue to comply with the traceability and labeling requirements of the current GMO framework. However, the proposal's approach to exempting certain NGT plants—those occurring naturally or achievable through conventional breeding—may undermine the precautionary principle, potentially reducing the level of protection currently afforded.

To enhance transparency and ensure freedom of choice for farmers, all NGT crops will be registered in a public database. Additionally, seeds and other plant reproductive materials derived from NGTs will be labeled, and information on these materials will be included in the common plant variety catalogues, enabling farmers to make informed decisions about their use. Monitoring is another key component of the proposal, with the first monitoring report to be published no earlier than three years after the verification or authorization of the first NGT product. A legislative evaluation is mandated to occur no sooner than two years thereafter.

7. PRECAUTIONARY PRINCIPLE IN THE COMMISSION'S PROPOSED TEXT AS AMENDED BY THE EUROPEAN PARLIAMENT

7.1. Application of Precautionary Principle

The new regulation on the governance of NGTs is being prepared within the framework of the European Union's ordinary legislative procedure (co-decision procedure), which begins with the submission of a proposal by the European Commission, followed by separate reviews, possible amendments, and final joint adoption by the European Parliament and the European Council (the body representing the governments of the member states).

To enforce the principle of social participation, the proposal was put out for public consultation between July 7 and November 5, 2023, with the results summarized by the European Commission. Feedback was mixed: supporters highlighted the benefits of innovation and sustainability, while opponents criticized the disregard for the precautionary principle and the lack of labeling.

The European Parliament's vote at first reading was in favour (European Parliament, 2024) but it amended some points of the Commission's text proposal presented above (European Parliament, *Amendments,* 2024).

Of these, the main amendments related to the enforcement of the precautionary principle are presented, according to the extent to which they contributed to the more prudent regulatory requirement. Amendments have been made to three major regulatory areas: patents, the framework of national competences, and monitoring and labelling.

A new feature of the text following the EP amendment is the concept of "One Health": "'One Health Approach' means an integrated, unifying approach that aims to sustainably balance and optimise the health of people, animals, plants and ecosystems and recognises that the health of humans, domestic and wild animals, plants, and the wider environment including ecosystems are closely interlinked and inter-dependent" (European Parliament, *Amendments, 28 Proposal for a regulation Article 3 – paragraph 1 – point 15 a,* 2024).

which is an integrated, unifying approach that aims to achieve and optimize a sustainable balance between the health of humans, animals, plants and ecosystems, and recognizes that the health of humans, domestic and wild animals, plants and the wider environment (including ecosystems) are closely interlinked and interdependent.

A precautionary amendment to Article 30(2), which previously referred only to ethical compliance, has been replaced by a substantially expanded list: "The report shall also identify and address any issues regarding biodiversity and environmental, human and animal health, changes to agronomic practices as well as socio-economic and ethical issues that may have arisen with the application of this Regulation."

Reference to the precautionary principle (not necessarily its enforcement) has been included in the text at several points (e.g. in recital (43)) (European Parliament, *Amendments, 22 Proposal for a regulation Recital 43,* 2024).

The ethical requirements were supplemented by the following by the parliament regarding the application of the precautionary principle. The report shall also identify and address any issues regarding biodiversity and environmental, human and animal health, changes to agronomic practices as well as socio-economic and ethical issues that may have arisen with the application of this Regulation (European Parliament, *Amendments, 64 Proposal for a regulation Article 30 – paragraph 2,* 2024).

In the text of the Commission's proposal, recital 10 was emphasized as full consideration of the precautionary principle.("*With full regard to the precautionary principle,* the legal framework for NGT plants should share the objectives of the Union GMO legislation to ensure a high level of protection of human and animal health and of the environment and the good functioning of the internal market for the concerned plants and products, while addressing the specificity of NGT plants.")

Recital 13 of the Commission's proposal has also been supplemented with a precautionary clause: NGT plants shall be assessed with the highest level of control for the impact of such plants on nature and the environment. ("(13a) NGT plants with the potential to persist, reproduce or spread in the environment, within or beyond fields, should be evaluated with the highest level of scrutiny in respect of such plants' impact on nature and the environment.")

According to the precautionary supplement to paragraph 29 of the preamble, in view of the precautionary principle, an environmental impact monitoring plan should always be required when consent is first granted. The requirement for monitoring may be waived when the consent is renewed only if it has been demonstrated that the category 2 NGT plant does not pose a risk requiring monitoring, such as indirect, delayed or unforeseeable effects on human health or the environment.

To strengthen the precautionary approach, the European Parliament included the following additional new points in the text: „NGT plants with the potential to persist, reproduce or spread in the environment, within or beyond fields, should be evaluated with the highest level of scrutiny in respect of such plants' impact on nature and the environment" (European Parliament, *Amendments, 8 Proposal for a regulation Recital 13 a (new)* 2024).

And later with the following text: "In order to effectively select new varieties that help the agricultural sector increase food security, as well as sustainability, adaptation and resilience in relation to the consequences of climate change, it is necessary to consider the specificity of polyploid plants, which are plants that contain more than two genomes. For such plants, the maximum number of genetic modifications allowed for inclusion in category 1 NGT should be proportionate to the number of genomes they contain" (European Parliament, *Amendments, 12 Proposal for a regulation Recital 18 a (new)* 2024).

Further strengthening the precautionary approach, the parliament made a further addition: "In view of the precautionary principle, a monitoring plan for environmental effects should always be required when consent is first given. It should only be possible to waive the requirement for monitoring upon the renewal of consent, provided that it has been demonstrated that the category 2 NGT plant does not pose risks that need monitoring, such as indirect, delayed or unforeseen effects on human health or on the environment" (European Parliament, *Amendments, 17 Proposal for a regulation Recital 29* 2024).

8.2. Breeder's Exemption

The new provision inserted by Parliament concerned the breeder exemption: "[t]he European Parliament has called for the Union and its Member States not to grant patents on biological material and to safeguard the freedom to operate and the breeders' exemption for varieties. It should be ensured that breeders have full access to the genetic material of NGT plants, which by definition are not transgenic plants. Access to genetic materials can best be secured when the right of patent holders is exhausted in the hand of the breeder (breeder's exemption)" (European Parliament, *Amendments, 23 Proposal for a regulation Recital 45 a (new)* 2024).

8.3. The Framework of National Competences

The following parliamentary addition reflects a precautionary approach. The other key issue is the extent of the competence of the Member States. According to the new paragraph (47a), "[t]he European Green Deal, the 'Farm to Fork', and the EU Biodiversity Strategies put organic farming at the core of a transition to sustainable food systems, with a target to expand European agricultural land under organic production to 25 % by 2030. This is a clear recognition of the environmental benefits of organic farming, for less dependency on inputs for farmers, and a resilient food supply and food sovereignty. This Regulation must not adversely undermine the pathway to a transition of European food systems to organic farming to 25 % by 2030." (European Parliament, *Amendments, 241 Proposal for a regulation Recital 47 a (new)* 2024).

8.4. Monitoring and Labeling

The third key issue is the monitoring and labelling rules. The text as amended by the European Parliament contains the following guarantee supplement with regard to traceability and labelling. "Decisions declaring the category 1 NGT plant status should assign an identification number to the NGT plant concerned in order to ensure transparency and traceability of such plants when they are listed in the database. The information listed should include information on the technique or techniques used to obtain the trait or traits." (European Parliament, *Amendments, 14 Proposal for a regulation Recital 21* 2024).

A new point has been added that "[t]raceability requirements for food and feed produced from NGTs should be established to facilitate the accurate labelling of such products, in accordance with the requirements of Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed, so as to ensure that accurate information is available to operators and consumers to enable them to exercise their freedom of choice in an effective manner, as well as to enable control and verification of labelling claims. Requirements for food and feed

produced from NGTs should be similar in order to avoid discontinuity of information in cases of change in end use.' (European Parliament, *Amendments, 243 Proposal for a regulation Recital 47 b (new)* 2024).

"Decisions declaring the category 1 NGT plant status should assign an identification number to the NGT plant concerned in order to ensure transparency and traceability of such plants when they are listed in the database. The information listed should include information on the technique or techniques used to obtain the trait or traits." (European Parliament, *Amendments, 14 Proposal for a regulation Recital 21,* 2024).

The EP amendment introduced strict monitoring and labelling requirements for labelling, similarly to the previous European Union GMO regulatory frameworks.

Appropriate document-based traceability for NGTs shall be provided by the transmission and holding of information that products contain or consist of NGT plants and product, and the unique codes for those NGTs, at each stage of their placing on the market (European Parliament, *Amendments, 265 Proposal for a regulation Article 10 – paragraph 1 a (new)* 2024).

According to this, products containing or consisting of Category 1 NGT plants, plant reproductive material, including propagating material for breeding and scientific purposes, must be labelled with the words 'New gene management techniques'. In the case of plant propagating material, this is followed by the identification number of the NGT plant(s) representing the source of the material. Adequate document-based traceability shall be ensured for NGTs by transmitting and storing at all stages of the marketing process information on whether products contain or are produced from NGT plants and products, as well as the unique codes of those NGTs. (European Parliament, *Amendments, 264 Proposal for a regulation Article 10 – paragraph 1,* 2024).

The codification of the European Union is in progress, but at the same time, a picture emerges that represents the possibilities of releasing new gene editing technologies into the free environment, and the application of the precautionary principle in EU law so far seems to be disrupted by the two categories established by the two categories – NGT1 and NGT2 – despite the legal interpretation of the 2018 decision of the court interpreting the law.

While Directive 2001/18/EC of the European Parliament and of the Council imposed a case-by-case assessment of the application of genetically modified organisms on the application of the precautionary principle in relation to the deliberate release into the environment of genetically modified organisms, the regulations formulated so far for the use of new modification techniques cannot by their nature be enforced in the previous framework.

The changes in regulation go back to the interpretation of the concept of genetically modified organism and, as can be seen, the literature views are also divided. Judging whether a genetically modified organism is GMO is a task for natural science, but the 2018 decision of the Court of Justice of the European Union (CJEU) concluded with the tools of legal interpretation that the applications of gene editing are also gene modification type processes, and therefore fall under the material scope of the precautionary and strict European GMO legislation.

Although the EP's amendments have added additional precautionary provisions to the draft text, "in fact, they undermine the entire business model of GMO-free agriculture" (Winter, 2024, p. 9).

By proposing regulations under the two NGT categories, it would deprive producers, traders and consumers of product information and access to GMO-free products who suspect that NGT1 crops and products pose a risk to human health and the environment.

The precautionary principle enshrined in Article 191(2) TFEU remains contrary in a number of respects (Winter, 2024, p. 10.).

Namely, "compatibility with precautionary measures cannot be established by mere assumption, e.g. when Article 1 of the EP amendment states that the rules created "are in accordance with the precautionary principle."

The codification challenge continues to be the preservation of the competitive position of the natural sciences and research in addition to the formulation of sufficiently precautionary requirements.

8. CLOSING THOUGHTS - CONCLUSIONS

8.1. Summary

The European Union maintains one of the world's strictest regulatory frameworks for genetically modified organisms (GMOs), governed primarily by Directive 2001/18/EC (deliberate release of GMOs), Regulation (EC) No 1829/2003 (GM food and feed), and Regulation (EC) No 1830/2003 (traceability and labeling). These regulations ensure a high level of protection for human, animal, and environmental health while facilitating the EU internal market. Key features include pre-market authorization means that GMOs require rigorous risk assessments by the European Food Safety Authority (EFSA) before market placement. As of 2025, 118 GMOs, primarily transgenic, have been authorized. Traceability and labeling means that products containing more than 0.9% GMOs must be labeled, ensuring consumer choice and environmental monitoring. The third pillar is member state autonomy**:** Directive 2015/412 allows Member States to restrict or prohibit GMO cultivation in their territories, leading to bans in countries like Austria, France, Germany, and Poland (e.g., on MON810 maize). Transparency required by Regulation (EU) 2019/1381 enhances risk assessment transparency, amending earlier regulations to improve public access to data. The only GM crop cultivated in the EU is MON810**,** an insect-resistant maize, grown mainly in Spain. The EU imports significant quantities of GM animal feed (e.g., maize, soybean) from North and South America, reflecting a paradox where cultivation is restricted, but imports are permitted under strict conditions.

The precautionary principle is a cornerstone of EU environmental and health policy, explicitly embedded in GMO legislation to address scientific uncertainty. It allows regulators to take protective measures when there is a potential risk to health or the environment, even without conclusive scientific evidence. In the context of GMOs, the principle is applied as follows: Before any GMO is placed on the market, it undergoes a case-by-case risk assessment by EFSA, evaluating potential adverse effects on human health, animal health, and the environment. These assessments prioritize the precautionary principle, requiring applicants to provide comprehensive data, including long-term studies if risks are identified. According to the member state flexibility Directive 2015/412 enables Member States to ban GMO cultivation based on precautionary grounds, such as potential environmental impacts or socioeconomic concerns, without needing definitive scientific proof of harm. This reflects a "strong" interpretation of the principle, allowing action in the face of uncertainty. Judicial interpretations means that the Court of Justice of the European Union (CJEU) has reinforced the precautionary principle, notably in its 2018 ruling (Case C-528/16), which extended GMO regulations to genome-edited crops produced via targeted mutagenesis (e.g., CRISPR). The CJEU argued that such techniques pose potential risks not fully assessed, justifying their inclusion under Directive 2001/18/EC. However, critics note that the CJEU often applies a "weak" interpretation in specific cases, narrowly interpreting scientific evidence, which can limit Member States' precautionary bans.

8.2. Expectations and Challenges for 2025

The European Commission has proposed revising GMO rules to differentiate NGTs (e.g., gene-edited crops like those using CRISPR) from traditional GMOs. Plants with modifications equivalent to conventional breeding (up to 20 genetic changes) would be exempt from GMO regulations and labeling, while others remain subject to strict rules. This proposal aims to balance innovation with precaution but faces opposition from environmental groups like Greenpeace, who argue it undermines the precautionary principle by reducing risk assessments and monitoring for Category 1 NGTs. There is growing debate over the proportionality of the precautionary principle's application. Critics, including biotech advocates, argue that the EU's strict approach stifles innovation and economic benefits, as seen in the limited cultivation of GMOs compared to imports (e.g., 36 million tonnes of GM soybean annually). Proposals for reform emphasize a risk-based approach, weighing benefits against potential harms rather than assuming high risk.

Public skepticism and political resistance, particularly in countries like Austria and Hungary, reinforce the precautionary approach. However, Poland's 2025 EU Council presidency has pushed for compromise on NGT deregulation, suggesting a potential shift toward lighter regulation if a qualified majority is reached. This could weaken the precautionary principle's dominance if not balanced with robust safety measures.

In 2025, EU GMO legislation remains one of the world's most stringent, driven by the precautionary principle to protect health and the environment amid scientific uncertainty. While the framework ensures rigorous safety assessments and Member State autonomy, proposed reforms for NGTs signal a potential shift toward more flexible regulation to foster innovation. Expectations for the precautionary principle's application include greater proportionality, clearer legal interpretations, and alignment with scientific advancements, though tensions between precaution, innovation, and public perception persist. Ongoing debates and legislative reviews will shape how the EU balances these priorities in the coming years.

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