Stowarzyszenie Polska Wolna od GMO

Association GMO-Free Poland

ul. Jagiellońska 21, 44-100 Gliwice, Poland

Formal Request for Clarification and Action Regarding Procedural and Substantive Deficiencies in the Legislative Process of COM(2023)0411 on NGTs

To:
European Commission
DG SANTE / Secretariat-General
Rue Breydel 4 / Breydelstraat 4
1040 Brussels, Belgium

From:
Association GMO-Free Poland
represented by: Paweł Połanecki and Jacek Nowak (Power of attorney attached)

Contact Email: biuro@polskawolnaodgmo.org

Address: ul. Jagiellońska 21
44-100 Gliwice, Poland

Gliwice, Date: 05 August 2025

PART I : Introduction

Having regard to the fundamental principles underpinning the legal order of the European Union — in particular the principles of the rule of law, transparency of the legislative process, subsidiarity, proportionality, and the guaranteed participation of citizens and civil society in shaping public policy,

—Having regard to the provisions of the Treaty on European Union, the Treaty on the Functioning of the European Union, and the Charter of Fundamental Rights of the European Union,

And having regard to the case law of the Court of Justice of the European Union, in particular the judgment in Case C-528/16 [2],

the Association GMO-Free Poland expresses its profound concern regarding the conduct of the legislative procedure concerning the European Commission's legislative proposal — COM(2023)0411 — on the use of New Genomic Techniques (NGTs) [7].

Acting in the interest of a broad cross-section of Union citizens — including farmers, scientists, consumers, and civil society organisations —the Association hereby submits a formal request for clarification to the European Commission regarding the legal and substantive concerns outlined below, which — in our view — compromise the principles of legality, democratic legitimacy, and scientific integrity that are the very foundation of the Union's law-making process.

The following sections set out our claims, each supported by relevant legal provisions, jurisprudence, and scientific evidence.

1. Deviation from the European Parliament position of 24 April 2024

The subsequent Council compromise texts of 7 January 2025 and 7 March 2025 under 2023/0226(COD), prepared under the Polish Presidency (Council Document ST-5076-2025-INIT) [9] executed the Commission's agenda by overturning key safeguards enshrined in the Parliament's opinion [8]

Specifically, these texts:

- **Removed the explicit ban on patenting NGT plants and traits**, reintroducing the possibility of patent protection and corporate monopoly over seeds;

- Narrowed the scope of Category 2 regulatory requirements, weakening environmental risk assessments and public health safeguards;

- **Weakened labelling and traceability provisions** for Category 1 NGT plants, undermining consumer choice and the rights of organic and GMO-free producers.

This sequence of amendments violates the positions adopted by the European Parliament on 24 April 2024 [8] and demonstrates deliberate legislative capture by corporate interests at the expense of farmer rights, biosafety, and the precautionary principle [1] [10]

2. Scientific Opinion of EFSA Contains Critical Errors and Omissions

The EFSA opinions underpinning the draft regulation (2020, 2022a, 2022b) [3] [4] [5] are based on a flawed assumption that NGT products "do not pose additional risks"

compared to conventional breeding. EFSA failed to apply the precautionary principle and risk assessment methodology consistent with Directive 2001/18/EC [1]

This central assumption is scientifically and legally flawed and reflects a pattern of minimization and selective reasoning.

Specifically:

- EFSA's opinions **ignore the inherent complexity and unpredictability of outcomes produced by genome editing tools such as CRISPR/Cas9**. Unlike conventional breeding, these techniques can cause off-target mutations, genomic rearrangements, and unintended pleiotropic effects that remain undetected by superficial analysis [3] [4]

- EFSA **explicitly limits its risk assessment** to molecular characterisation criteria (e.g. presence of exogenous DNA, insertion type, allele history) [5] excluding cumulative effects, epigenetic changes, off-target events, and systemic unintended consequences – despite extensive literature pointing to such risks as real, significant, and difficult to anticipate. These factors are crucial in long-term environmental and health impact assessments required under EU law [1]

- EFSA **fails to engage with or reference a broad body of peer-reviewed, independent scientific studies** documenting unintended effects and systemic risks, as well as the open letter from over 100 independent European scientists urging full regulatory scrutiny of NGTs [6].

By omitting this evidence, EFSA's opinion becomes biased toward deregulation, misrepresenting the actual state of scientific knowledge.

Furthermore, EFSA's opinion explicitly states:

"On a case-by-case basis, a lesser amount of data might be needed for the risk assessment of cisgenic or intragenic plants obtained through NGTs." (EFSA 2022a, Abstract)

This formulation distorts the meaning of the "case-by-case" principle, which, according to Directive 2001/18/EC and the ECJ judgment in Case C-528/16, requires that each GMO be assessed under specific and differentiated environmental and use conditions — including soil type, humidity, temperature, atmospheric pressure, wind exposure, geographic elevation, and the model of agricultural production.

Contrary to this intention, EFSA uses the concept of "case-by-case" as a pretext for reducing the amount of data required, rather than expanding the scope of testing in relation to release conditions. This represents a blatant violation of the precautionary principle and the logic of EU environmental law.

Instead of applying the precautionary principle — fundamental to EU environmental and health law — EFSA inverts the burden of responsibility by presuming safety

and shifting the burden of proof away from applicants and regulators onto civil society and the future victims of unintended consequences. This shift violates established EU legal doctrine and undermines public trust in the scientific foundations of the regulatory process [1] [2].
This concern is supported by the public statement of over 100 internationally recognized scientists who, in their November 2023 open letter, expressed serious concerns regarding the lack of scientific rigor, the premature safety assumptions, and the deregulatory nature of the Commission's NGT proposal [6].

Such an approach has broader implications:

- It facilitates the legal fiction that genome-edited organisms can be equated with conventionally bred ones, opening the door to their blanket exclusion from GMO regulation, notification, labelling, and traceability systems [7] [8]

- It aligns structurally with the Commission's proposal COM(2023)0411 [7] which intentionally omits meaningful impact assessments for NGTs in agriculture, including on farmers' rights, biodiversity, and coexistence strategies [10]

- It reveals that EFSA's opinions were effectively commissioned to legitimise and support the predetermined provisions of COM(2023)0411 [7] [9] rather than to provide an independent scientific assessment.

- It contributes to regulatory capture, wherein the interests of large biotechnology corporations dominate scientific and policy assessments through selective evidence usage and lack of independent review [10]

Given these omissions and methodological failures, EFSA's scientific opinions cannot serve as a credible or lawful foundation for the sweeping regulatory changes proposed by the European Commission. An independent, publicly accountable re-assessment must be conducted before any legislative act is finalized.

In the next sections, we present a structured legal and scientific analysis of the Commission's proposal, highlighting the most serious flaws in its rationale, semantic framing, patent implications, and legislative procedure – all of which fundamentally undermine the legitimacy and safety of the proposed Regulation.

On this basis, we hereby submit this formal Request to the European Commission – a reasoned appeal to suspend the ongoing legislative procedure and to uphold the democratic and legal standards upon which the Union has been founded.

PART II. Misleading and Unscientific Use of "Precise" and "Targeted" Mutagenesis Terminology

In the final phase of the legislative procedure for COM(2023)0411, the Commission and co-legislators introduced substantial changes that fundamentally altered the scope and effect of the regulation — without reopening consultations or conducting appropriate impact assessments. These late-stage modifications raise serious concerns regarding transparency, respect for legislative procedure, and the democratic legitimacy of the legislative process [1]. They may constitute a violation of Article 296 TFEU and infringe upon the principle of good administration enshrined in Article 41 of the Charter of Fundamental Rights of the EU [2].

Put differently, the substitution of the term *"precise"* (i.e. *precise mutagenesis*) with *"targeted mutagenesis"* (i.e. mutagenesis that is merely *aimed* or *intended*) at the final stage of the legislative process is not only scientifically unfounded, but also legally deceptive. The term *"targeted"* is semantically broader, less specific, and more prone to interpretative ambiguity, allowing GMO operators to define the scope of "targeting" according to their own criteria. In contrast, *"precise"* at least imposed a theoretical requirement to assess the actual accuracy and predictability of genetic modifications. The adoption of this weaker term thus constitutes a legislative manoeuvre aimed at circumventing the requirements of risk assessment as established in Article 27(2) of Regulation (EC) No 178/2002 and Article 191 of the TFEU.

One of the most troubling aspects of these changes is the editorial and semantic reinforcement of the narrative of "precision" and "targeting" applied to genome editing techniques. The draft regulation employs ambiguous and misleading scientific terminology, conflating the concepts of "precision" and "targeting" despite their distinct scientific and regulatory implications [3].

Under molecular biology and biotechnology definitions, "precision" refers to nucleotide-level edits, ensuring exact sequence modifications within a targeted locus, often at nanometre-scale resolution, as verified by molecular assays such as next-generation sequencing or CRISPR-Cas off-target profiling [4]. In contrast, "targeted" merely denotes

an intended locus, gene, or even cell population selected for manipulation, without guaranteeing molecular-level accuracy or the absence of unintended genomic alterations [5].

By replacing “precise” with “targeted,” the Council Presidency ordered to shift terminology from objective molecular precision to a subjective, intention-based operational definition [6]. This rhetorical manoeuvre masks the reality: NGT techniques do not achieve the molecular precision implied by “precise.” Instead, “targeted” creates an illusion of safety and control while these interventions remain mutation-induced artificial genetic modifications with inherent risks [7]. Even highly targeted interventions may result in unpredictable outcomes, including on-target but unintended effects, off-target mutations, genomic rearrangements, insertion–deletion events, epigenetic disruptions, and pleiotropic consequences that cannot be reliably anticipated or controlled with current methodologies [8].

Both terms are presented in the proposed regulation as inherently safe and equivalent to conventional breeding, which grossly misrepresents the current state of scientific knowledge [9]. This categorization serves a clear regulatory function: to exempt mutation-induced artificial genetic modifications generated by NGTs from standard GMO oversight, despite the absence of scientific consensus or robust evidence justifying such exemptions under Directive 2001/18/EC [10].

Such framing distorts the scientific reality of genome editing technologies. Even highly targeted interventions do not guarantee molecular precision, as sequence-specific nucleases can induce off-target cleavage, microhomology-mediated end joining, or large genomic deletions beyond the edited site . By promoting the illusion of precision through ambiguous terminology, the regulation dismantles essential precautionary safeguards, thereby undermining the protection of environmental and human health .

Moreover, the regulation introduces arbitrary thresholds (e.g. permitting up to 20 genetic modifications or traits used for up to 15 years in conventional breeding) as criteria for exclusion from GMO legislation. These thresholds lack any scientific or legal basis and undermine legal certainty. They directly conflict with the ruling of the Court of Justice of the European Union in case C-528/16, which held that organisms obtained

through mutagenesis are genetically modified organisms and are, in principle, subject to the obligations of Directive 2001/18/EC.

Finally, the term “targeted” appears to shift regulatory responsibility from objective molecular criteria to subjective declarations made by the operator (i.e. the biotech company) . In effect, it is the company itself that determines what constitutes a “target,” thereby escaping independent control and redefining risk solely on the basis of intention rather than outcome, while ignoring the rigorous molecular precision regime described above.

This seemingly minor terminological change from “precise” to “targeted” constitutes a deliberate legal manipulation by the Commission, effectively dismantling objective safety standards, undermining the precautionary principle enshrined in EU law, and transferring regulatory responsibility from public authorities to private operators — exposing society to risks defined, monitored, and adjusted solely in favour of private corporate interests [1][2][7]. Therefore, in light of the above, we must firmly reject this substitution.

This terminological and regulatory failure is wholly unacceptable from the perspective of any objective, and scientifically grounded risk assessment framework **for risk assessment and public health protection,** and therefore must be excluded from the final NGT regulation.

PART III – Unlawful Redefinition of GMO Contrary to Directive 2001/18/EC and ECJ Ruling C-528/16

It is necessary to stress that under EU and general legal theory, definitions are not mere semantic tools; they are normative foundations that determine the scope of rights and obligations [1]. A definition is a constitutive element of legal norms – it delineates what is regulated and what is not, who is subject to a rule, and what the legal consequences are. **Changing a legal definition without formal legislative amendment or due process amounts to changing the law itself, bypassing democratic safeguards and undermining the rule of law [1].**

Namely the proposed regulation introduces a new legal category of *New Genomic Techniques (NGTs)* that departs significantly from the definition of genetically modified organisms (GMOs) enshrined in **Directive 2001/18/EC** [1]. This redefinition lacks a valid scientific or legal justification and was adopted without public consultation or meaningful stakeholder engagement [6][7].

This is not a technical adjustment. It is a profound legal change implemented through a definitional sleight of hand, without a formal amendment of primary law, public scrutiny, or democratic debate. Such practice exemplifies regulatory capture and democratic deficit within EU structures, raising serious questions about the legitimacy of the Commission's law-making processes .

One of the most serious legal concerns arising from the Commission's proposal is its direct contradiction with the binding 2018 ruling of the Court of Justice of the European Union (CJEU). In its landmark judgment in **Case C-528/16**[8], the Court unambiguously stated:

"Organisms obtained through mutagenesis techniques such as CRISPR-Cas9 are genetically modified organisms (GMOs) and must be subject to the full regulatory framework of Directive 2001/18/EC[1]."

Most importantly, it contradicts the authoritative interpretation of EU law delivered by the European Court of Justice , thereby violating the principles of legal certainty and the primacy of EU case law. According to that ruling, all organisms obtained through mutagenesis techniques developed after **12 March 2001** — the date of adoption of

Directive 2001/18/EC — fall within the scope of GMO legislation. The Court stated unequivocally that such organisms are not exempt from the requirements of the Directive unless the techniques used were "**conventionally used in a number of applications and have a long safety record**" [1] [2]. This condition is clearly not fulfilled by modern genome editing tools such as CRISPR-Cas9, TALENs, or ODM [3] [4] [5], which have only existed for a few years and lack any established record of safe use.

Nevertheless, the Commission — in **COM(2023)0411** [7] and subsequent amendments — introduces arbitrary and scientifically unsubstantiated criteria to classify certain NGT products as equivalent to conventional breeding. These include:

- A numerical threshold of "**no more than 20 genetic modifications**" [9],
- A requirement that the resulting trait has been used in agriculture "**for at least 15 years**" [10],
- And the notion that organisms are "**comparable**" to conventional ones based on undefined outcomes, rather than the technique used [7].

None of these thresholds exist in current EU law [1], nor are they grounded in any scientific consensus or internationally recognized biosafety standard [3]. On the contrary, they represent biotech corporations' regulatory inventions (sic!) — fund to carve out a new legal space outside the existing GMO framework, in direct defiance of the ECJ ruling, which is legally binding and must be respected by all EU institutions under Article 267 TFEU [2].

Such "legal engineering" constitutes a serious breach of public confidence and a striking departure from the legal certainty guaranteed by the Treaties.

This manoeuvre amounts to the unlawful circumvention of primary EU legislation via secondary law. It effectively rewrites the scope of Directive 2001/18/EC without undergoing a formal legislative amendment procedure. This undermines both the principle of legality and the hierarchy of EU law, and discredits the Court of Justice as the final interpreter of the Treaties and secondary legislation [1][2].

Furthermore, by portraying NGT plants as "non-GMOs" or assigning them to the newly invented "Category 1," the regulation strips Member States of their right to apply

precautionary bans or national coexistence measures under Articles 23 and 26a of the Directive [1]. It also eliminates labelling and traceability requirements [7], thereby depriving farmers, consumers, and environmental authorities of their right to information and the freedom to choose.

In one of its scientific opinions, EFSA states the following:

"*Depending on the case (case-by-case), a lesser amount of data might be required for the risk assessment of cisgenic or intragenic plants obtained through NGTs." (EFSA 2022a, abstract)*

- This formulation distorts the meaning of the "case-by-case" principle, which — according to Directive 2001/18/EC and the judgment of the Court of Justice of the European Union in Case C-528/16 — requires that each GMO be assessed under specific and differentiated environmental and use conditions, such as: soil type, humidity, temperature, atmospheric pressure, wind exposure, altitude, and the model of agricultural production.
- Contrary to this intent, EFSA uses the concept of "case-by-case" as a pretext to reduce the amount of data required, rather than — as intended by the Directive — to expand the scope of testing based on release conditions. This constitutes a flagrant breach of the precautionary principle and of the internal logic of EU environmental law.

Instead of applying the precautionary principle — fundamental to EU environmental and health protection law — EFSA reverses the burden of responsibility by presuming safety and shifting the burden of proof away from applicants and regulators onto civil society and the potential future victims of unintended consequences. This inversion contradicts established EU legal doctrine and undermines public trust in the scientific foundations of the regulatory process [1][2].

These concerns are reinforced by the public statement of more than 100 internationally recognised scientists who, in an open letter published in November 2023, expressed serious concerns regarding the lack of scientific rigour, the premature assumption of safety, and the deregulatory nature of the Commission's NGT proposal [6].

Such an approach has broader implications:

- It perpetuates the legal fiction that genome-edited organisms can be equated with conventionally bred ones, thus opening the door to their full exclusion from GMO regulation, notification, labelling, and traceability requirements [7] [8];
- It structurally supports the Commission's proposal COM(2023)0411 [7], which deliberately omits meaningful impact assessments for NGTs in agriculture — including effects on farmers' rights, biodiversity, and coexistence strategies [10];
- It reveals that EFSA's opinions were effectively commissioned to legitimise and support the pre-established provisions of COM(2023)0411 [7] [9], rather than to provide an independent scientific assessment;
- It contributes to regulatory capture, wherein the interests of large biotechnology corporations dominate scientific and policy assessments through selective evidence use and lack of independent peer review [10].

Given these shortcomings and methodological flaws, EFSA's scientific opinions cannot serve as a credible or lawful foundation for the sweeping regulatory changes proposed by the European Commission. An independent, publicly accountable reassessment must be conducted before any legislative act is finalised.

In the following sections, we present a structured legal and scientific analysis of Commission's proposal, highlighting the most serious flaws in its rationale, semantic framing, patent implications, and legislative procedure — all of which fundamentally undermine the legitimacy and safety of the proposed Regulation.

On this basis, we hereby submit this formal Request to the European Commission — a reasoned appeal to suspend the ongoing legislative procedure and to restore the democratic and legal standards upon which the European Union has been founded.

These actions not only violate the legal foundations of the European Union, but also pave the way for an even more serious legislative abuse — the quiet redefinition of the GMO concept, carried out beyond public scrutiny and outside the formal legislative process. This issue is examined in detail in the following section.

PART III/A Redefinition – quiet reshape of the scope of Regulation

At this point, we must introduce our most serious objection concerning the manner in which the redefinition of GMOs has been incorporated into the legislative procedure for the contested Regulation.

The redefinition was operationalised primarily through the ad hoc insertion of Annex I and Annex III into the Council's final negotiating mandate of 7 March 2025 (Council Document ST-6426-2025-INIT) [10], after the public consultation phase had closed, and entirely outside the scope of the original legislative proposal COM(2023)0411 [7].

These annexes were not part of the Commission's initial Impact Assessment, nor were they presented during the interinstitutional consultations with national parliaments, stakeholders, or civil society.

They were introduced at a late stage in response to mounting legal and scientific criticism — including explicit references to the ECJ ruling in case C-528/16 [2] — confirming that NGT organisms fall fully within the legal definition of GMOs as provided by Directive 2001/18/EC [1], confirming that NGT organisms fall fully within the legal definition of GMOs as provided by Directive 2001/18/EC [1], and must therefore comply fully with all its legal requirements.

Rather than address these substantive concerns transparently and in accordance with EU legal principles, the Council Presidency opted to reshape the scope of the Regulation through technical annexes (Annexes I, II and III) that quietly circumvent primary legislation. The contents of Annexes I and III, presented below, illustrate the scale and intent of this manoeuvre. Annex II will be examined separately in the following section.

- Annex I introduces complex and novel equivalence criteria — such as permitting up to 20 defined genetic modifications — that are entirely absent from the Directive and are clearly intended to circumvent it by reclassifying certain GMOs as "non-GMOs" through regulatory sleight of hand. This transforms the definition of GMO not through legislative amendment, but through annexed technical thresholds that were never consulted on publicly.

- Annex III creates a framework of selective incentives based on arbitrary "sustainability traits", many of which serve corporate breeding interests. The inclusion of only one exclusionary trait (herbicide tolerance) underscores the lack of objective biosafety standards and reinforces the impression that Annex III was constructed to facilitate expedited approvals of specific NGT products, rather than to ensure health or environmental protection.

The legal and political implications of these annexes are deeply negative and far-reaching. They must be fully acknowledged, as these are not merely innocuous technical supplements. They are substantive legal instruments that redefine the scope of what is — and is not — considered a GMO. Their post hoc insertion constitutes a violation of the principles of democratic lawmaking, transparency, and procedural fairness. More seriously, these annexes reflect a deliberate attempt to circumvent the binding effect of EU primary law and the jurisprudence of the Court of Justice, by means of a regulatory shortcut — in breach of the principle of institutional balance and Article 10(3) TEU, which enshrines participatory democracy.

We therefore submit that Annexes I and III are procedurally invalid and incompatible with EU substantive law, and that any legal effects derived from them must be annulled or suspended pending a full review of their compliance with Directive 2001/18/EC and the ECJ judgment in case C-528/16.

PART III/B – Undermining of EU Safety Standards in the NGT Regulation

One of the most alarming elements of the proposed regulation is found in Annex II, which was introduced without any scientific rationale or procedural mandate, and which effectively eliminates the obligation to carry out a full environmental and health risk assessment for a broad class of NGT products.

Annex II sets out a narrow list of criteria that, if met, would exempt these products from the standard risk evaluation required under Directive 2001/18/EC [1]. This constitutes a

radical departure from well-established EU norms based on the precautionary principle and the obligation of case-by-case safety assessment.

Despite its brevity, Annex II has far-reaching consequences. It states that an NGT organism does not require full risk assessment if the resulting trait is deemed "comparable" to conventional organisms — a term left undefined and scientifically ambiguous. Even more concerning, the Annex proposes that if a developer can show that a trait has existed in nature or conventional breeding for at least 15 years, the product is exempted from any testing, monitoring, or scientific scrutiny. Such assumptions are not supported by any recognised body of scientific literature, and they ignore well-documented risks of off-target effects and ecological disruption [3] [4].

Although presented as a measure for technical simplification and administrative relief, the real effect of Annex II is to create a de facto fast track for commercial release of NGT plants by removing the burden of scientific oversight and rendering biosafety agencies legally powerless.

This is not a simplification of procedures — it is the dismantling of the scientific gatekeeping system that protects public health, biodersity, anivd farmers' rights.

By shielding an entire class of organisms from evaluation based on vague, manipulable, and non-verifiable criteria, the Commission opens the door to a form of disguised deregulation that lacks any democratic legitimacy.

The fact that Annex II was introduced outside the public consultation and interinstitutional dialogue only reinforces the suspicion that it constitutes a backdoor mechanism — deliberately designed to circumvent legal constraints and suppress public awareness.

It is necessary to note that among all traits considered in Annex II, only one — "herbicide tolerance" (HT) — has been explicitly excluded from eligibility under Category 1 NGT plants. This exclusion was unavoidable. HT crops have been the target of broad societal protest due to their association with the application of glyphosate — a broad-spectrum systemic herbicide, lethal to virtually all green plants (monocots, dicots, algae) through inhibition of the EPSPS enzyme in the shikimate pathway — and thus remain subject to the full regulatory regime of Directive 2001/18/EC.

In addition, while the term “tolerance” is routinely used in EFSA and Commission documents, it serves as a euphemism introduced by the biotechnology industry to soften public perception. In reality, it refers to plants genetically engineered to survive herbicide application — which kills surrounding weeds — by carrying a transgene encoding glyphosate oxidoreductase. This enzyme is produced in each and every cell of the HT plant. This protein has never been authorised for human consumption — yet it is indirectly ingested on an industrial scale, embedded in millions of tonnes of HT soy and maize circulating in EU food and feed chains.

The exclusion of this single trait from Annex II is not an act of precaution, but a calculated attempt to avoid political embarrassment in light of the officially acknowledged risks associated with glyphosate and the growing public resistance to Roundup Ready-type GM crops.

Did the Commission — together with its corporate sponsors — truly think that this manipulation of the law would pass unnoticed by the legal and scientific community, or by the European public?

We therefore denounce Annex II as a paradigmatic case of unlawful regulatory manipulation. It represents:

- a breach of the procedural and scientific standards of the European Union,
- a violation of the precautionary principle embedded in EU primary law,
- and a dangerous precedent for removing scientific evidence from the core of risk governance.

It must be rejected in its entirety — not amended, not clarified — but revoked as a matter of legal integrity and public safety.

Part III/C When Definitions Become Weapons: Historical Parallels and Democratic Risk in Action

From the perspective of legal history, it is clear that arbitrary redefinitions of core legal terms have often served as systemic tools for avoiding legal or moral accountability — especially by governments seeking to bypass constitutional safeguards.

For instance, in the 19th century, Prussian legal doctrine attempted to narrow the definition of “assembly” (Versammlung) in order to circumvent constitutional protections for political gatherings. This led to widespread public outrage and accusations of deliberate constitutional evasion (see footnote 1 at the end of this Part).

In more recent times, redefining the term "torture" — by excluding certain coercive techniques such as "enhanced interrogation" — enabled state actors to carry out grave human rights violations while maintaining a façade of legal compliance (see footnote 2 at the end of this Part).

These examples illustrate that altering legal definitions is never a neutral act — it is a deliberate form of legal manipulation that undermines fundamental rights and democratic legitimacy.

The above historical patterns confirm that redefining legal concepts is not a technical or procedural adjustment, but a political choice with far-reaching consequences for civic rights and the integrity of democratic systems.

The examples cited are neither remote nor abstract. They clearly illustrate the systemic risks that arise when legal definitions are reshaped to serve ad hoc or narrowly defined political or economic interests. Such practices may erode the integrity of democratic governance and the protection of fundamental rights — guarantees that depend on a stable legislative process, as defined in the EU Treaties, and on a legal order grounded in rigidly pre-established and democratically determined legal norms.

Summaries and sources for the historical examples mentioned above are provided in the footnote at the end of PART III.

PART III/D. NO EXCUSE FOR ANOTHER DEFINITION

In light of the above, we repeat — as already stated:

In COM(2023)0411 [2], the Commission:

- Introduces arbitrary thresholds (e.g. “up to 20 genetic changes” or “a trait used for 15 years”), which have no basis in Directive 2001/18/EC nor in any recognised scientific standard;
- Defines “targeted mutagenesis” in a way that shifts the focus from objective, precise molecular criteria to subjective declarations made by operators, thereby undermining risk assessment and legal enforceability;
- Equates NGT organisms with conventionally bred ones, despite clear legal precedent (C-528/16), which affirms that all organisms obtained through mutagenesis techniques developed after 2001 fall under the GMO framework — unless it has been proven that they have a long-term safety record in conventional use.

This is not a technical adjustment. It is a fundamental change to substantive law, introduced through a definitional sleight of hand — without a formal amendment to primary law, without public scrutiny, and without democratic debate. Such conduct exemplifies regulatory capture and a democratic deficit within EU structures, raising serious concerns about the legitimacy of the Commission’s legislative actions.

This is not merely a regulatory overreach — it is a violation of core principles of Union law. By redefining GMOs through non-legislative annexes — without amending Directive 2001/18/EC or initiating a proper legislative procedure — the Commission has acted ultra vires, exceeding the powers conferred upon it, in breach of the principle of conferral (Article 5 TEU) and the principle of institutional balance.

Furthermore, the lack of transparency and public deliberation violates Article 10(3) TEU, which guarantees participatory democracy, and Article 296 TFEU, which requires that legislative acts be duly reasoned.

We therefore reiterate: the use of definitional manipulation to reshape substantive law without due legislative process undermines legal certainty, public trust, and the democratic foundations of EU governance.

Accordingly, any regulation adopted on such a basis must be considered legally invalid and politically illegitimate..

Footnotes: Instrumental Redefinition of Legal Concepts – Two Cases

1. The Case of "Assembly" in 19th Century Prussia

The Prussian state's attempt to restrict the constitutionally protected right of assembly after the 1848 revolutions illustrates a classic example of **instrumental legal redefinition**. Rather than formally abrogating constitutional guarantees, Prussian authorities pursued a subtler strategy: **narrowing the scope** of protected rights through statutory redefinition of key legal concepts.

Most notably, the term *Versammlung* ("assembly") was progressively confined to mean *political gatherings*, excluding social, religious, or cultural meetings from constitutional safeguards. This allowed for the imposition of notification requirements, prior authorizations, and, eventually, blanket prohibitions on oppositional assemblies. Scholars have widely recognized these measures as a **form of constitutional evasion**, wherein the **spirit of the constitution was undermined by the letter of ordinary legislation**.

Such redefinition enabled the state to present itself as formally compliant with constitutional liberalism while **preserving administrative control** over public space and dissent. Courts often upheld these restrictions by invoking historical narratives or contextual interpretations — an approach critically examined in La Vopa's account of adjudication strategy.

Sources:

1.1 Anthony J. La Vopa, 'Constitutions, Courts, and History: Historical Narratives in Constitutional Adjudication' (1994) 12 *Law and History Review* 1, 15–22.

1.2 James J. Sheehan, *German Liberalism in the Nineteenth Century* (University of Chicago Press 1978) ch 5.

1.3 Stefan-Ludwig Hoffmann, *Politics of Sociability: Freemasonry and German Civil Society 1840–1918* (University of Michigan Press 2007) 112–119.

1.4 Constitution of Prussia (1850) art 27; discussed in Michael Stolleis (ed), *Constitutional Documents of Germany and the United States*, Max Planck Encyclopedia of Comparative Constitutional Law.

2. Redefining Torture: Legal Manipulation in Post-9/11 U.S. Policy

Following the terrorist attacks of September 11, 2001, the U.S. government undertook a strategic redefinition of torture to enable the use of coercive interrogation techniques that had previously been

prohibited under both domestic law and international treaties. This semantic shift was not merely rhetorical—it had profound legal and ethical consequences.

The term *"enhanced interrogation techniques"* was introduced to describe methods such as waterboarding, prolonged stress positions, and sleep deprivation. These practices had long been recognized as torture under the UN Convention Against Torture and 18 U.S.C. §§ 2340–2340A, yet were reclassified through legal memoranda issued by the Office of Legal Counsel (OLC)—most notably the Bybee Memo of August 2002.

This redefinition served a dual purpose: it shielded officials from criminal liability and created a legal framework for the CIA's global detention program. The Senate Intelligence Committee's 2014 report later confirmed that these techniques were not only ineffective but also misrepresented to policymakers and the public, undermining democratic oversight.

Legal scholars such as Philippe Sands and Henry Shue have argued that this manipulation of legal definitions constitutes a betrayal of constitutional values and a departure from rule-of-law principles. Shue, in particular, warns against the seductive logic of "ticking bomb" hypotheticals, which abstract away the systemic consequences of institutionalizing torture.

Sources:

2.1 US Department of Justice, Office of Legal Counsel, 'Memorandum for Alberto R Gonzales, Counsel to the President, Re: Standards of Conduct for Interrogation under 18 USC §§ 2340–2340A' (1 August 2002) (Bybee Memo).

2.2 Karen J Greenberg and Joshua L Dratel (eds), *The Torture Papers: The Road to Abu Ghraib* (Cambridge University Press 2005).

2.3 Philippe Sands, *Torture Team: Rumsfeld's Memo and the Betrayal of American Values* (Palgrave Macmillan 2008).

2.4 Senate Select Committee on Intelligence, *Committee Study of the Central Intelligence Agency's Detention and Interrogation Program* (SSCI Report, 2014).

2.5 Henry Shue, 'Torture in Dreamland: Disposing of the Ticking Bomb' (2006) 37 *Case Western Reserve Journal of International Law* 231.

PART IV – Hidden Patent Trap: Undemocratic Late-Stage Legalisation of Seed Ownership and IP Control

Finally, and with a sense of profound disbelief, we feel compelled to highlight and formally request the removal of what appears to be the most far-reaching and indefensible element of the proposed NGT regulation – namely, the legalization and integration of patent-based control over NGT seeds and traits.

That such a provision could be inserted without consultation, at the very final stage of the legislative process, is a legislative manoeuvre so procedurally and ethically questionable that we struggle to believe it occurred within the legal framework of the European Union [5] [7].

Since the earliest applications of GMOs in agriculture in the 1990s, civil society across both the United States and Europe has consistently rejected the notion that seeds, traits, or food crops should be owned through intellectual property monopolies. Large-scale public protests, farmer mobilisations, legal challenges, and the emergence of seed sovereignty movements have all testified to widespread resistance against corporate capture of agricultural genetics.

Despite these well-documented facts, the European Commission appears to assume that, having reclassified NGT plants as “non-GMOs” in the proposed Regulation, such provisions would pass unnoticed by public opinion — in Poland and other Member States alike.

This regulatory sleight of hand would enable biotechnology corporations to gain sweeping legal control over Europe’s food and farming systems under the guise of mere technical legislative alignment.

Such a plan must not be allowed to succeed.

Should it be implemented, one must expect broad civic resistance, including the recourse to legally grounded forms of civil disobedience — as a legitimate response in a democratic state governed by the rule of law, where citizens retain the sovereign right to oppose legislation that violates constitutional principles and fundamental rights.

The intellectual property and patent-related implications of the proposed Regulation have been systematically downplayed or omitted.

1. No impact assessment was conducted regarding farmers' and breeders' freedom to operate [4];
2. The regulation opens the door to extensive corporate control via patent thickets [6];
3. No consultation took place on the consequences of deregulating patentable NGT seeds [4].

These omissions violate the principle of informed public participation and contradict the European Parliament's own reports on IP and food sovereignty [7]. The entire patent-related framework (Title IVa) was absent from the original Commission proposal COM(2023)0411 [5] and was not subject to public consultation, scientific scrutiny, or impact assessment [4].

According to Council Document ST-5076-2025-INIT [5], prepared by the Polish Presidency on 19 January 2025, the revised draft of the Regulation introduced, **for the first time**, a structured legal framework on patenting (Title IVa). These provisions were put forward as part of a Presidency-led initiative aimed at securing a political compromise ahead of trilogue negotiations [5] [7].

Internal Council documents further reveal that this entire section was inserted under **explicit political instruction** addressed to the **politically compliant Polish Presidency** [5] [7]. This approach strongly suggests the existence of **coordinated efforts to bypass public oversight** and to fast-track provisions enabling **corporate intellectual property control over NGT organisms** [4].

This course of action constitutes a **direct violation of the principles of transparency and inclusive consultation**, as such substantial additions were made without prior publication, stakeholder scrutiny, or targeted consultation [4] [5]. The document was circulated under **LIMITE classification**, restricting public access and thereby **circumventing standard participatory safeguards** [5] [7].

Moreover, **all available evidence suggests that the Polish Presidency explicitly steered Member States to adopt this version of the draft** during the Working Party meeting on 20 January 2025 [5][7] — a clear indication of **coordinated political pressure aimed at legitimising provisions that had never been subject to open democratic debate**.

Furthermore, the **enforcement of patent law mechanisms and the establishment of intellectual property control over NGT seeds** pose **serious risks to the rights of farmers and breeders — should these provisions and NGT seeds enter into force despite our protest** [6].

These rules would **expose small-scale farmers to legal claims for alleged patent infringement**, **undermine food sovereignty** by transferring control over seeds from local communities to multinational corporations, and **limit consumer choice** by consolidating corporate power over seed supply chains and food production [6] [9].

Importantly, the constitutional and agricultural laws of Poland – as well as similar frameworks in other Member States – protect farmers' ownership rights to land, crops, and harvests. The introduction of patent-dependent NGT seeds threatens these rights directly by creating legal liability for unintentional contamination, such as transgene flow onto neighbouring fields, which can result in financial losses, forced destruction of crops, and infringement proceedings against farmers who have not chosen to use NGT seeds but are nonetheless exposed to their legal risks.

This manoeuvre – the last-minute insertion of Title IVa on patentability during the final phase of trilogue preparations, under the auspices of a *politically compliant Polish Presidency* – is not only legally and procedurally flawed. It represents an act of deliberate institutional overreach and legislative arrogance.

What constitutes an especially serious violation is the fact that the insertion of Title IVa stands in direct and open contradiction and completely disregards – both in spirit and in letter - the formal position of the European Parliament adopted at first reading on 24 April 2024 [4], which in which the Parliament precisely and expressis verbis *called for a complete ban on patenting NGT plants, plant material, traits, and associated genetic information,* It explicitly:

- *Demanded the addition of a new Article 4a to the Regulation excluding such material from patentability,*
- *Proposed comprehensive amendments to Directive 98/44/EC to close existing legal loopholes exploited by patent applicants,*
- *Limited the legal effect of already granted or pending patents on plant genetic material derived from NGT plants,*
- *Affirmed that intellectual property protection for NGT organisms should be limited to the CPVR system, preserving the breeder's exemption,*
- *Requested the Commission to assess and propose further legal reforms to prevent the monopolisation of plant genetics and to protect innovation and seed diversity, especially for small-scale breeders and farmers.*

In clear terms, the Parliament declared that " *Patents on these products must be banned"[4, Amendment 167]*

In legislative requirements , the Parliament introduced Article 4a of the draft Regulation:

"NGT plants, plant material, parts thereof, genetic information and the process features they contain shall not be patentable." [4, Amendment 33]

The Commission's decision to override this democratic mandate by covertly reinserting patent provisions through Title IVa not only bypasses public scrutiny and institutional checks, but also undermines the co-legislator's authority and violates the principle of sincere cooperation enshrined in Article 13(2) TEU.

This is a fundamental breach of EU law and legislative legitimacy.

We therefore reiterate our formal request that Title IVa be removed in its entirety from the proposed Regulation.

If this request is not addressed with due seriousness and transparency, we reserve the right to submit a formal complaint to the European Ombudsman.

More broadly, we reiterate our opposition to the entire draft Regulation, which we consider to be legally, scientifically, and ethically flawed in its substance, procedure, and purpose.

The unlawful insertion of Title IVa merely exemplifies a corrosive pattern of democratic erosion, marked by procedural arbitrariness, disregard for public consultation, and the systematic favouring of corporate interests over the rights of farmers, consumers, and Member States.

If this pattern is not incidental — and the record suggests it is not — then it must be recognised as a deeply troubling structural failure of the legislative process, which risks seriously undermining public trust in the Union's institutions.

We therefore not only request the removal of Title IVa, but also call upon the Commission to suspend the legislative procedure altogether and to initiate a new process grounded in Directive 2001/18/EC — one that complies with the fundamental principles of EU law, institutional accountability, and the precautionary principle.

Before we pass to the final summary in Part V, we wish to reaffirm our legitimacy and competence to submit this complaint. As an association that has operated continuously since 2001 (and whose founders were active in GMO-related public advocacy even earlier), we have for over 25 years focused exclusively on defending the public interest in matters related to genetically modified organisms, including consistent legal and civic opposition to the patenting of living organisms and seeds. This long-standing commitment confirms not only the relevance but also the necessity of our intervention in the present case.

We wish to draw particular attention to the profound ethical and societal dimension of the issues raised by the proposed Regulation — especially with regard to patent claims over genetic information embedded in seeds and crops. In this context, we emphasise the specific cultural and historical conditions of Polish agriculture — a perspective which, it appears, has been entirely overlooked by the drafters and promoters of the Regulation.

Unlike most of their Western European counterparts, Polish farmers had to fight to preserve land rights under a totalitarian regime.

Poland was the only country in the Soviet-dominated Eastern Bloc where farmers succeeded in preserving private ownership of land. This legacy has left a lasting mark on Poland's legal culture and rural consciousness, where private ownership of land and seeds is not merely an economic asset, but a symbol of freedom, dignity, and resistance.

Therefore, in light of the above axiological context (arguably foreign to many EU officials), and the still-living historical experience of Polish agriculture, we wish to underline that violations of property rights in this sector are especially unacceptable in the Polish context.

This historical legacy has created a deep cultural and legal attachment among Polish farmers to the inviolability of property rights over land, crops, and harvests. Any attempt to undermine these rights through patent-based regulation will be met with resolute civic, legal, and political opposition.

We do not only consider the insertion of Title IVa to be a flagrant violation of EU law and the common good — we also warn that its implementation may trigger a lasting crisis of public trust in the institutions of the Union, and mobilise citizens to undertake determined defensive action.

Responsibility for the consequences of such a decision will lie not only with the EU institutions that imposed it, but also with those Member State governments that actively or silently supported it.

PART V – Final Statement and Demand to the European Commission

If one were to seek a metaphor from the history of human imagination to describe the farreaching consequences of the proposed regulation, one might recall the ancient myth of Pandora's box. The regulation opens a vessel from which not just regulatory chaos but systemic and irreversible risks may spill across Europe and beyond. Its annexes – inserted late, shaped by vested interests, and shielded from scrutiny – resemble venomous serpents concealed within a legal text, silently ready to erode the foundations of agricultural diversity, rural cultural heritage, and human health.

This is not a rhetorical exaggeration. It is a sober warning grounded in legal, scientific, and historical evidence presented throughout this complaint. The European Commission must not disregard the structural dangers inherent in this legislative act. Such an approach cannot be accepted in a democratic legal system — it contradicts foundational principles of accountability, transparency, and the rule of law. These dangers must

be acknowledged and addressed in full. Moreover, the European Commission bears political responsibility before the societies of the European Union, which have been misled, bypassed, and deprived of a genuine democratic voice in the shaping of this legislation. Proceeding in such a manner – through obfuscation, manipulation of definitions, and circumvention of consultation – undermines the public's trust in the institutions of the Union and raises the spectre of a deep legitimacy crisis.

We therefore respectfully request the European Commission to:

1. Clarify the legal and scientific basis of the EFSA opinion and the legislative proposal [3][4];
2. Justify the omission of targeted consultations regarding patents and IPR [5][6];
3. Explain the compatibility of COM(2023)0411[7] with the ECJ ruling in case C-528/16 [2] [1][3];
4. Indicate whether the Commission intends to revise the proposal accordingly;

    4.1 Suspend the current legislative procedure and restart it as a directive, not a regulation [1][4], in order to ensure respect for the principles of subsidiarity and proportionality. A directive would allow Member States to adapt the implementation of new genomic techniques to their national legal systems, environmental policies, and socio-economic contexts, whereas a regulation imposes uniform and immediate application with no room for democratic or regional adaptation – a particularly harmful approach in the case of deeply contested technologies such as NGTs.

5. Suspend the current legislative procedure and restart it as a "directive", not a "regulation" [1][4], in order to ensure respect for the principles of subsidiarity and proportionality.

A Directive, by its very nature, allows Member States to retain national discretion in the implementation of EU law. It provides the flexibility to adapt legal obligations to each country's unique environmental, agricultural, and socio-economic conditions.

By contrast, a Regulation constitutes a binding legislative act with direct and immediate effect in all Member States, bypassing national parliaments, public consultations, and

regional adaptation processes. It imposes top-down, uniform application — a legislative mechanism more appropriate for market harmonisation than for deeply contested areas such asbiotechnology, food production, and environmental governance.

In this context, choosing a Regulation over a Directive is not a neutral procedural decision — it is a deliberate attempt to suppress democratic oversight, eliminate subsidiarity, and impose a centralised, one-size-fits-all biotechnology policy across the EU, against the clearly expressed will of many Member States and civil society groups.

Monopolisation of genetic resources by a handful of biotechnology corporations is a matter of grave public concern, yet this dimension was excluded from the impact assessment and public debate [5] [6].
Given the fundamental importance of agricultural biodiversity, food sovereignty, and the protection of farmers' rights, only a Directive can provide the necessary safeguards, flexibility, and legitimacy for any future legislation on NGT organisms.

As demonstrated above, the monopolisation of genetic resources by a handful of biotechnology corporations is a matter of grave and long-standing public concern. Yet this critical dimension — central to farmers' rights, food sovereignty, and biodiversity — was entirely excluded from the impact assessment and public debate [5] [6].

These late-stage modifications result in flagrant violations of primary EU law. Specifically, they give rise to the following breaches:– Article 296 TFEU: failure to state the reasons and legal basis for the inserted provisions;

– Article 10 TEU: violation of the principle of democratic accountability and participatory law-making;

– Article 41 of the Charter of Fundamental Rights: infringement of the right to good administration, including the right to be heard and the obligation to give reasons.

Each of these violations is explained in detail below:

a) A violation of Article 296 TFEU, which provides: *"Legal acts shall state the reasons on which they are based and shall refer to any proposals, initiatives, recommendations, requests or opinions required by the Treaties"*

The Commission failed to provide a clear and reasoned justification for the insertion of key legal provisions — including Title IVa on patenting — at the final stage of the legislative process, without prior explanation, stakeholder consultation, or any legal mandate.

Even more seriously, the Commission offered no legal rationale whatsoever for the redefinition of core legal terms, such as "GMO" or "mutagenesis," despite the fact that these concepts are already defined in primary law and case law, notably in Directive 2001/18/EC[1] and the ECJ ruling in case C-528/16[2] [1] [3].

This failure to explain or justify the circumvention of existing legal definitions constitutes a deliberate evasion of legislative responsibility and a breach of the duty to state reasons, as required under Article 296 TFEU.

b) A violation of Article 41(1) of the Charter of Fundamental Rights of the European Union, which guarantees:

"Every person has the right to have his or her affairs handled impartially, fairly within a reasonable time by the institutions and bodies of the Union."

The Commission and Council acted in breach of this principle by inserting material legal changes after the consultation phase had closed, thereby depriving stakeholders of the right to be heard and to participate in fair, balanced, and transparent decision-making processes. This constitutes a procedural violation of the right to good administration, as defined in Article 41(1) of the Charter.

We therefore demand that the European Commission:

• Suspend immediately the ongoing legislative procedure for COM(2023)0411[7];

• Withdraw the proposed redefinitions, exemptions, and patent-facilitating provisions [5][6];

• Restart the legislative process from the beginning, in full compliance with the Treaties, by initiating a Directive procedure instead of Regulation, thus ensuring respect for the principle of subsidiarity, Member States' rights to adapt GMO/NGT legislation to their national contexts, and the fundamental requirement of democratic participation and public consultation [1] [4].

In conclusion, all the flaws, omissions, and deliberate ambiguities identified throughout this request converge in one overarching manipulation: the seemingly minor terminological change from "precise" to "targeted," the faux NGT definition, and the late patent provisions favouring corporate interests [3] [5] [6]. Together, these constitute a deliberate legal manoeuvre by the Commission, effectively dismantling objective safety standards, undermining the precautionary principle enshrined in EU law, and abdicating regulatory responsibility by public authorities, thereby leaving society exposed to risks that are defined, monitored, and adjusted solely in favour of private corporate interests [6].

It is deeply concerning that neither the Parliament's advisors nor the Council's legal services have identified or challenged these substitutions, despite their profound implications for public health, environmental safety, and the integrity of EU law.

Consequently, we request a detailed explanation from the Commission regarding these specific changes, their legal justification, and their compatibility with the Treaties, Directive 2001/18/EC **[1],** and the general principles of EU law, including the precautionary principle and the duty of loyal cooperation.

Should the Commission fail to act accordingly within 14 days of receipt of this letter, given the urgency and gravity of the matters raised, the fact that the legislative process concerning COM(2023)0411[7] is still ongoing, as well as the concern that legislative steps might be taken without duly addressing the

points raised in this letter, we reserve the right to pursue all available legal and administrative remedies, including submission of a formal complaint to the European Ombudsman pursuant to Article 228 TFEU.

Respectfully, on behalf of Association GMO-Free Poland

Paweł Połanecki

PODPIS ZAUFANY
PAWEŁ
POŁANECKI
07.08.2025 10:04:20 [GMT+2]
Dokument podpisany elektronicznie
podpisem zaufanym

Jacek Nowak

Reference List

[1] Directive 2001/18/EC on the deliberate release into the environment of genetically modified organisms. (March 2001)

[2] C-528/16 Judgment of the Court (Grand Chamber), 25 July 2018 – confirms organisms obtained by mutagenesis are GMOs under Directive 2001/18/EC[1].

[3] EFSA (2020). Applicability of the EFSA Opinion on site-directed nucleases type 3 for the safety assessment of plants developed using site-directed nucleases type 1 and 2 and oligonucleotide-directed mutagenesis. EFSA Journal 18(11):6299. https://doi.org/10.2903/j.efsa.2020.6299

[4] EFSA (2022a). Updated scientific opinion on plants developed through cisgenesis and intragenesis. EFSA Journal 20(10):7621. https://doi.org/10.2903/j.efsa.2022.7621

[5] EFSA (2022b). Statement on criteria for risk assessment of plants produced by targeted mutagenesis, cisgenesis and intragenesis. EFSA Journal 20(10):7618. https://doi.org/10.2903/j.efsa.2022.7618

[6] Open Letter (2023). Serious concerns about the EU Commission proposal on New Genomic Techniques. NewGMO.org, 19 November 2023. https://newgmo.org/2023/11/19/open-letter-serious-concerns-about-the-eu-commission-proposal-on-new-genomic-techniques/

[7] COM(2023)0411 Proposal for a Regulation on plants obtained by certain new genomic techniques and their food and feed products. (5 July 2023)

[8] EP-PE_TC1-COD(2023)0226 European Parliament position adopted at first reading, 24 April 2024.

[9] Council Document ST-5076-2025-INIT (Polish Presidency compromise draft, January–March 2025).

[10] Council Document ST-6426-2025-INIT (Final Presidency text for European Parliament, 6 March 2025).

For the attention of:

Mr Olivér Várhelyi – Commissioner for Health and Animal Welfare

Maroš Šefčovič – Commissioner for Trade and Economic Security; Interinstitutional Relations and Transparency

Ms Sandra GALLINA - Director-General for Health and Food Safety

Ms Claire Bury – Deputy Director-General for Health and Food Safety

DG ENV – Directorate-General for Environment

DG GROW – Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs

DG AGRI – Directorate-General for Agriculture and Rural Development

DG RTD – Directorate-General for Research and Innovation

DG JUST – Directorate-General for Justice and Consumers

DG TRADE – Directorate-General for Trade and Economic Security

Stowarzyszenie Polska Wolna od GMO

Association GMO-Free Poland

ul. Jagiellońska 21, 44-100 Gliwice, Poland

POWER OF ATTORNEY

The Association GMO-Free Poland
with its registered office in Gliwice, 21 Jagiellońska Street, Poland
represented by:
Anna Szmelcer – Chairwoman of the Association
hereby grants exclusive power of attorney, for an indefinite period,
to **Paweł Połanecki**
and
Jacek Nowak
to represent the Association GMO-Free Poland before all European Union bodies and national authorities of the Republic of Poland, as well as before other public and private institutions, in matters related to the protection of public health, food safety, the natural environment and the public interest in the context of regulations concerning genetically modified organisms (GMOs), including organisms obtained by New GenomicTechnics (organisms NGT), and to take all intervention, legal, administrative, legislative and informational measures to carry out the Association's statutory tasks, in particular those aimed at:

1. Restricting or completely eliminating the use of GMOs, including NGT plants and animals, in agriculture, food, and feed in Poland and the European Union,
2. Introducing provisions into the Constitution of the Republic of Poland prohibiting the use of genetically modified organisms of any kind in agriculture and in human and animal nutrition.

The Attorneys are also authorized to appoint substitute attorneys, acting on behalf of and in the interest of the Association GMO-Free Poland, with full authority granted under this power of attorney.

Gliwice, 31 July 2025

Signature:

.....
Anna Szmelcer
Chairwoman of the Association
GMO-Free Poland

Stowarzyszenie Polska Wolna od GMO

Association GMO-Free Poland

ul. Jagiellońska 21, 44-100 Gliwice, Poland

PEŁNOMOCNICTWO

Stowarzyszenie Polska Wolna od GMO
z siedzibą w Gliwicach, ul. Jagiellońska 21,

reprezentowane przez:
Annę Szmelcer – Przewodniczącą Stowarzyszenia,

udziela niniejszym **wyłącznego pełnomocnictwa**, na czas nieokreślony,

Pawłowi Połaneckiemu
oraz
Jackowi Nowakowi

do reprezentowania Stowarzyszenia Polska Wolna od GMO przed wszystkimi organami Unii Europejskiej oraz organami krajowymi Rzeczypospolitej Polskiej, a także przed innymi instytucjami publicznymi i prywatnymi, w sprawach związanych z ochroną zdrowia publicznego, bezpieczeństwa żywności, środowiska naturalnego oraz interesu społecznego w kontekście regulacji dotyczących organizmów genetycznie modyfikowanych (GMO), w tym organizmów wytworzonych z pomocą Nowych Technik Genomowych (organizmów NGT), oraz do podejmowania wszelkich działań interwencyjnych, prawnych, administracyjnych, legislacyjnych i informacyjnych w celu realizacji statutowych zadań Stowarzyszenia, w szczególności mających na celu:

1. ograniczenie lub wyeliminowanie stosowania GMO, w tym organizmów NGT, w Polsce i Unii Europejskiej,
2. wprowadzenie do Konstytucji Rzeczypospolitej Polskiej zapisów o zakazie stosowania organizmów genetycznie modyfikowanych wszelkiego typu w rolnictwie oraz w żywieniu ludzi i zwierząt.

Pełnomocnicy są również uprawnieni do ustanawiania pełnomocników substytucyjnych (substitute attorneys), działających w imieniu i na rzecz Stowarzyszenia Polska Wolna od GMO, w pełnym zakresie niniejszego umocowania.

Gliwice, dnia 31 lipca 2025 r.

Podpis:

.....
Anna Szmelcer
Przewodnicząca Stowarzyszenia
Polska Wolna od GMO