Stowarzyszenie Polska Wolna od GMO

Association GMO-Free Poland

ul. Jagiellońska 21, 44-100 Gliwice, Poland

To:

European Ombudsman
Ms. Teresa Anjinho
1 avenue du Président Robert Schuman
CS 30403
F-67001 Strasbourg Cedex
France

From:
Stowarzyszenie Polska Wolna od GMO
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, Warsaw, 18 September 2025

Complaint

Concerning Breaches of Good Administration Principles and Citizens' Rights of the European Union in the Legislative Process Relating to the *Proposal for a Regulation of the European Parliament and of the Council on plants obtained by certain new genomic techniques and their food and feed, and amending Regulation (EU) 2017/625* (Doc. No. 2023/0226(COD) (https://data.consilium.europa.eu/doc/document/ST-5076-2025-INIT/en/pdf), (European Commission (2023). *Proposal for a Regulation on Plants Obtained by New Genomic Techniques,* Brussels. Interinstitutional File: 2023/0226(COD0) with further amendments/changes), hereinafter referred to as NGT Regulation, **accompanied by a Strong and Formal Demand to Immediately Suspend All Further Legislative Proceedings Unless and Until the Allegations Raised Are Fully and Transparently Remedied.**

Part I

1.1 Subject of the Complaint

This Complaint concerns irregularities in the conduct of European Union institutions — in particular the European Commission and the Council of the European Union — in connection with the legislative process leading to the adoption of the NGT Regulation.

The Complaint specifically addresses allegations of:

1. breaches of the principles of transparency and due diligence in the legislative process,
2. infringement of citizens' rights to participate in the legislative procedure,
3. manipulation of the legislative timetable to limit debate and accelerate the adoption of controversial measures without sufficient public scrutiny.

This Complaint is based on the analysis and contents of the following official documents of the European Union institutions:

Appendix No. 1
Regulation on new genomic techniques (NGT) – Revised Presidency text
• Council document No. 5076/25 of 7 January 2025
• Link: https://data.consilium.eropa.eu/doc/document/ST-5076-2025-INIT/en/pdf

Appendix No. 2
Steering note on the revised Presidency text on the Regulation on new genomic techniques (NGT)
• Council document No. 5093/25 of 7 January 2025
• Link: https://data.consilium.europa.eu/doc/document/ST-5093-2025-INIT/en/pdf

Appendix No. 3
Mandate for negotiations with the European Parliament – Proposal for a Regulation on plants obtained by certain new genomic techniques and their food and feed products, and amending Regulation (EU) 2017/625
• Council document No. 6426/25 of 7 March 2025
• Link: https://data.consilium.europa.eu/doc/document/ST-6426-2025-INIT/en/pdf

The current approach, as reflected in the official statements of the Polish Presidency, constitutes a serious violation of the fundamental principles of the rule of law, transparency, and citizens' participation rights guaranteed under EU law. It also represents a concealment of substantive legislative changes following the closure of the formal consultation phase.

Furthermore, the necessity of submitting this Complaint is reinforced by the public stance expressed by the Polish Minister of Agriculture, who, in an official communication dated 7 April 2025 (mentioned above and attached as a whole document in Appendix No. 4), openly praised the fact that the Polish Presidency of the Council of the European Union had "accelerated" the legislative process concerning the NGT Regulation.

We attach herewith: the proofs of our utmost but unsuccessful efforts to obtain proper consideration from the Polish authorities and European Commission regarding our protest against the deregulation of NGT, namely:

Appendix No. 4
Summary announcement/reply on the NGT issue issued by the Ministry of Agriculture dated 7 April 2025 to the letters and appeals concerning works on the NGT Regulation.

Appendix No. 5
Examples of earlier interventions undertaken in Poland, the Member State basis (art. 2 of the Statute of the European Ombudsman, art. 228 TFEU and art. 41–42 of the Charter of Fundamental Rights of the European Union), including:

5.1. Letter to the Minister of Agriculture and Rural Development (dated 28.07.2023) and evasive/de facto negative answer (date 17.08.2023)

5.2. Letter to the Minister of Climate and Environment (dated 27.01.2024) and negative answer (date 6.02.2024)

5.3. Letter to the Minister of Agriculture and Rural Development (date 15.05.2024) and negative answer (date 31.05.2024)

5.4. Letter to the Minister of Climate and Environment (date 16.12.2024) and negative answer (date 23.01.2025)

5.5. Letter to the President of the Republic of Poland (date 16.12.2024) and evasive answer (date 21.02.2025) *(de facto refusal to deal with the matter raised in the petition)*

5.6. Letter to the Prime Minister (date 16.12.2024) from the International Coalition to Protect the Polish Countryside (ICPPC) and the Association GMO-Free Poland
and an almost identical letter to the Prime Minister (date 27.12.2024) from the Polish Association for the Protection of the Environment and Human Rights (PSOŚ) and evasive/de facto negative answers (date 2.01.2025) – transmission of the petition to the Ministry of Agriculture

5.7. Letter to the Minister of Health (date 16.12.2024) from the International Coalition to Protect the Polish Countryside (ICPPC) and the Association GMO-Free Poland to the Minister of Health and the same Letter to the Minister of Health (date 27.12.2024) from the Polish Association for the Protection of the Environment and Human Rights (PSOŚ) and negative answer (date 3.01.2025) – transmission of a petition to the Ministry of Agriculture…

5.8. Request for a MEETING WITH THE MINISTER OF AGRICULTURE: Objection to the deregulation of NGT regulations (date 16 December 2024) and no response from the Minister of Agriculture

Appendix No. 6
Request to European Commission (date: 05.08.2025) entitled: Formal Request for Clarification and Action Regarding Procedural and Substantive Deficiencies in the Legislative Process of COM(2023)0411 on NGTs.
No answer as of the date of this Complaint.

In the light of the above, we firmly confirm that we fulfill all the formal and legal conditions for submitting this Complaint, as required under Article 2 of the Statute of the European Ombudsman, supported by Article 228 TFEU and the Charter of Fundamental Rights of the European Union (Articles 41 and 42).

This acknowledgment, combined with a deliberate disregard for citizens' concerns and scientific warnings, demonstrates the scale and effectiveness of persistent corporate pressure on EU decision-makers, allowing them to override democratic standards and public interest safeguards.

For this reason, and in view of the urgent need for legal scrutiny, this Complaint is not only justified but necessary and inevitable.

1.2 Preamble of the Complaint

Having regard to:

- The European Commission's persistent push for the rapid adoption of the NGT Regulation, despite significant scientific, legal, and societal concerns.
- The fact that the Polish Presidency is under pressure to accelerate negotiations, in contrast to the previous Hungarian Presidency's more cautious and deliberate approach. (*Working Party on Genetic Resources and Innovation in Agriculture – Meeting of 20 January 2025 – Steering note on the revised Presidency text on the Regulation on new genomic techniques*).
- The European Commission's violation of fundamental EU legal principles, including:

• The precautionary principle, which requires a thorough risk assessment before market authorization of biotechnological innovations (TFEU, Article 191).
• The principle of environmental protection, which mandates safeguarding biodiversity from irreversible genetic contamination.
• The principle of consumer rights, which guarantees transparency and the right to informed choice regarding food production (Regulation (EC) No. 1830/2003).
• The lack of democratic consultation.

• The failure to ensure biosafety measures that would prevent uncontrolled contamination of traditional and organic agriculture, undermining Europe's agroecological resilience (JOINT STATEMENT…, 2025).
• The precedents from the COVID-19 crisis, demonstrating the risks of uncontrolled biotechnological applications, underscoring the need for strict governmental oversight and containment of GMOs used for medical purposes (Polykretis et al, 2023).

Whereas:

- The Association GMO-Free Poland represents the voice of European citizens who oppose the unregulated release of NTGs into the environment.

Notwithstanding that:

1. This position does not preclude the controlled use of GMOs for medical and scientific purposes, provided they remain understrict isolation in supervised laboratories, unlike past cases where lax oversight led to global consequences.

The Association upholds the interests of public health, environmental safety, and sustainable agriculture, calling for full compliance with EU legal frameworks and comprehensive risk assessment procedures.

The Association GMO-Free Poland therefore presents its strong and vital position as follows:

1.3 Abstract of the Complaint

The Polish Association GMO-Free Poland presents a critical legal and scientific analysis of the European Parliament and Council's draft regulation on plants obtained through new genomic techniques (NGTs) and their derived products, including food and feed. This regulation, formulated under significant influence from the biotechnology industry, introduces regulatory changes that threaten public health, environmental safety, and the legal sovereignty of EU Member States (Bohle et al, 2024).

The analysis identifies three primary concerns:

- **Terminological Manipulation** – The regulation subtly alters key definitions, replacing the term "precise" with "targeted" in descriptions of gene-editing techniques, implying a lower level of accuracy while simultaneously reducing regulatory oversight.
- **Redefinition of GMOs** – By excluding NGT-derived organisms from the regulatory framework established by Directive 2001/18/EC, the European Commission circumvents previous rulings by the European Court of Justice, effectively granting NGTs unrestricted access to EU markets (CJEU, 2022).
- **Late-Stage Patent Provisions** – The most controversial element, strategically introduced at an advanced stage of the legislative process, is the reinforcement of corporate patent control over NGT seeds. This measure, omitted from early consultations to avoid public scrutiny, facilitates the monopolization of seed markets by biotechnology corporations, stripping farmers of traditional seed-saving rights and increasing economic dependence on corporate-controlled agricultural inputs (JOINT STATEMENT, 2025).

These provisions, collectively designed to benefit industry stakeholders, undermine fundamental democratic and legal safeguards within EU policy. This Complaint argues that the draft regulation must be rejected in its current form to prevent irreversible economic and ecological consequences. The Association urges EU institutions to restore regulatory oversight in line with Directive 2001/18/EC and to subject all NGT organisms to comprehensive safety evaluations, maintaining transparency and accountability in the legislative process.

1.4 Introduction to the Complaint

The European Union is currently in the process of amending Regulation (EU) 2017/625 through a new legislative proposal: Document No. 2023/0226(COD), which aims to regulate plants obtained by New Genomic Techniques (NGTs), along with their derived food and feed products. The proposed regulation introduces a novel categorization of genetically modified plants, dividing them into NGT 1 and NGT 2 categories, while simultaneously redefining genetically modified organisms (GMOs) within the European legal framework.
The European Commission has justified this legislative shift by claiming that NGTs provide a "more precise" alternative to conventional genetic modification techniques, allowing for targeted modifications that allegedly mimic changes occurring naturally or through traditional breeding methods (European Commission, 2023). However, this claim is highly contested by independent scientific studies, which indicate that gene-editing technologies (leading NGTs), including CRISPR-Cas9, may cause unintended on-target and off-target mutations and unpredictable genetic expressions, posing potential risks to human health, biodiversity, and environmental safety (Kawall, 2019; Eckerstorfer et al., 2019; ENSSER and CSS, 2021; Chu and Agapito-Tenfen, 2022; Expert Group "New Genomic Techniques"; Geng et al, 2023; Park et al, 2023;).

Despite these uncertainties, the proposed regulation seeks to deregulate NGT 1 plants by exempting them from risk assessment, traceability, and labeling requirements, which are otherwise mandatory for conventional GMOs under Directive 2001/18/EC. This deregulation directly contradicts the precautionary principle, a foundational tenet of EU environmental law, which mandates comprehensive risk assessments for any technological intervention that could lead to irreversible harm (Article 191, Treaty on the Functioning of the European Union)[4].

Furthermore, a critical aspect of this legislative process is the delayed inclusion of patent-related provisions, which were strategically introduced after consultations with Member States had already concluded. This raises serious concerns regarding the transparency and democratic legitimacy of the European Commission's legislative approach. The last-minute addition of intellectual property provisions appears to favor biotechnology corporations by granting them extensive control over patented seed varieties, further restricting farmers' rights to save, exchange, and reuse seeds (JOINT STATEMENT, 2025). The economic and social implications of this shift are profound, as they threaten agricultural sovereignty and could increase dependency on corporate-controlled seed markets.

In this Complaint, we conduct a critical legal and scientific analysis of the proposed regulation, focusing on the following three key concerns:

- The manipulative redefinition of key terms, replacing "precise" with "targeted" to create a misleading perception of control and predictability in gene-editing techniques.
- The deliberate revision of the GMO definition, allowing gene-edited organisms to bypass existing regulatory safeguards.
- The covert insertion of patent-related provisions, which strengthens corporate monopolies over plant genetic resources while diminishing the rights of independent farmers.

These three legislative manipulations, introduced under the pretext of regulatory modernization, collectively represent a systematic effort to dismantle the existing GMO regulatory framework and replace it with a model that disproportionately benefits biotechnology corporations at the expense of public interest, biodiversity, and European agricultural sovereignty.

References to Part I

European Commission (2023). *Proposal for a Regulation on Plants Obtained by New Genomic Techniques*, Brussels.

JOINT STATEMENT ON THE DEREGULATION OF NEW GMOS by over 200 Organisations entitled "Protect the business of small and medium size breeders, farmers, and the organic and non GMO sectors in the EU", published 11 February 2025 https://corporateeurope.org/sites/default/files/2025-02/FINAL%20-%20Joint%20statement%20-%20New%20GMOs%20-%2010.02.pdf

Polykretis P, Donzelli A, Lindsay JC, Wiseman D, Kyriakopoulos AM, Mörz M, Bellavite P, Fukushima M, Seneff S, McCullough PA. Autoimmune inflammatory reactions triggered by the COVID-19 genetic vaccines in terminally differentiated tissues. *Autoimmunity*. 2023 Dec; 56(1): 2259123. doi:10.1080/08916934.2023.2259123. PMID: 37710966. (https://pubmed.ncbi.nlm.nih.gov/37710966/)

Bohle, Finja et al* (2024), Where does the EU-path on new genomic techniques lead us? *Front. Genome Ed.*, 14 March 2024, Sec. Genome Editing in Plants, Volume 6 - 2024 | https://doi.org/10.3389/fgeed.2024.1377117, https://www.frontiersin.org/journals/genome-editing/articles/10.3389/fgeed.2024.1377117/full
*Federal Agency for Nature Conservation, Division of Synthetic Biology Assessment, Enforcement of Genetic Engineering Act, Bonn, Germany

Eckerstorfer, M., et al. (2019). An EU Perspective on Biosafety Considerations for Plants Developed by Genome Editing and Other New Genetic Modification Techniques (nGMs).

Frontiers in Bioengineering and Biotechnology 7 (2019). https://www.frontiersin.org/articles/10.3389/fbioe.2019.00031/full

Kawall, K. (2021). The Generic Risks and the Potential of SDN-1 Applications in Crop Plants, *Plants* **2021**, *10*(11), 2259; https://doi.org/10.3390/plants10112259 , https://www.mdpi.com/2223-7747/10/11/2259E

ENSSER and CSS (European Network of Scientists for Social and Environmental Responsibility and Critical Scientists Switzerland) (2021), *Scientific Critique of Leopoldina and Easac Statements on Genome Edited Plants in The EU*, The GREEHS/EFA in the European Parliament, Brussels April 2021 (https://ensser.org/wp-content/uploads/2021/04/Greens-EFA-GMO-Study-1.pdf).

Chu, P.; Agapito-Tenfen, S.Z. (2022), Unintended Genomic Outcomes in Current and Next Generation GM,Techniques: A Systematic Review. *Plants* **2022**, 11, 2997. https://doi.org/10.3390/plants11212997 .

Expert Group "New Genomic Techniques", Ecological Society of Germany, Austria and Switzerland (GFÖ) (), *New genomic techniques from an ecological and environmental perspective: science-based contributions to the proposed regulations by the EU Commission*,

Geng, Keyi et al (2023), Intrinsic deletion at 10q23.31, including the PTEN gene locus, is aggravated upon CRISPR-Cas9–mediated genome engineering in HAP1 cells mimicking cancer profiles, *Life Science Alliance* 20 November, 2023, vol 7 | no 2, https://doi.org/10.26508/lsa.202302128; https://www.life-science-alliance.org/content/lsa/7/2/e202302128.full.pdf ; Summary for non geneticists on https://scitechdaily.com/crisprs-unintended-cuts-alarming-findings-in-cancer-gene-therapy

Park, S. H., Cao, M., and Bao, G. (2023). Detection and quantification of unintended large on-target gene modifications due to CRISPR/Cas9 editing. *Current Opinion in Biomedical Engineering*, 100478. https://www.sciencedirect.com/science/article/abs/pii/S246845112300034X

Directive 2001/18/EC on the Deliberate Release of Genetically Modified Organisms into the Environment.

Treaty on the Functioning of the European Union (TFEU), Article 191.

Part II

Chronological Background and Legal Context

2.1 Chronology of Key Events and Documents

The following timeline reconstructs the legislative process initiated by the European Commission concerning the proposed Regulation on plants obtained through certain new genomic techniques (NGTs). It outlines the sequence of official actions and publications, based on institutional records of the Commission, the European Parliament, the Council, and the European Food Safety Authority (EFSA).

- **05 July 2023** – Legislative proposal published by the European Commission
  COM(2023) 411 final
- **19 October 2023** – Referral to the ENVI Committee (1st reading) and to associated committees
  OEIL procedure file
- **24 January 2024** – Vote in ENVI Committee – 1st reading
  Corporate Europe Observatory report

- **29 January 2024** – Committee report tabled for plenary session
  European Parliament A9-0014/2024
- **06 February 2024** – Debate in European Parliament plenary
  InfoGM report
- **07 February 2024** – Parliament decision – 1st reading
  European Parliament T9-0067/2024
- **22 February 2024** – European Parliament refers scientific concerns to EFSA
  InfoGM note
- **18 March 2024** – EFSA accepts the mandate from Parliament
  EFSA Journal 2024;18(3):8894
- **24 April 2024** – Parliament approves updated proposal – 1st reading
  OEIL procedure file
- **19 June 2024** – EFSA issues its Scientific Opinion on NGTs
  EFSA document
- **13 November 2024** – Re-referral to ENVI Committee announced in plenary
  OEIL procedure file
- **07 January 2025 – Council Presidency Draft Compromise Text (Document ST-5076/25 INIT)**

Regulation on new genomic techniques (NGT) – Revised Presidency text
• Council document No. 5076/25 of 7 January 2025
• Link: https://data.consilium.europa.eu/doc/document/ST-5076-2025-INIT/en/pdf

Change from July 2023 version:
This document, issued under the Polish Presidency led by Prime Minister Donald Tusk, introduces a **revised compromise version of the NGT regulation**, reflecting multiple modifications that significantly **narrow the scope of debate** ahead of trilogue negotiations.

Key **controversial elements**, such as the **removal of traceability requirements**, **exemption from risk assessments**, and **affirmation of patentability for NGT plants**, are **reintroduced as final positions** rather than as open topics for negotiation.

The text **frames patent provisions as "settled"**, strongly **discouraging any reopening of this issue** at trilogue level — despite substantial public and scientific opposition.

The **language and timing** of the document indicate an **intentional political maneuver** to **pressure other Member States** and the Parliament into **accepting patent-related deregulation without further discussion**.

This effectively **nullifies prior concerns** raised in EFSA and ANSES debates and contradicts Parliament's earlier amendments calling for clearer limitations on intellectual property rights.

The complainants view this document as evidence of **institutional capture** of the legislative process and **political overreach** by the Polish Presidency, undermining transparent, balanced interinstitutional deliberation.

- **08 April 2025** – ENVI Committee decides to open interinstitutional negotiations
  OEIL procedure file

- **05 May 2025** – Plenary announces decision to enter trilogue negotiations
  OEIL procedure file
- **07 March 2025** – Council adopts negotiation mandate (ST 6426/25 INIT)
  Council document
- **22 May 2025** – European Parliament adopts its position – 1st reading (Procedure 2023/0226(COD))
  OEIL procedure file
  (Note: As of the date of this Complaint, the official TA document PDF for the European Parliament position adopted on 22 May 2025 has not yet been published.)

2.2 Observations

While the procedural path formally followed the EU's ordinary legislative procedure, several aspects raise legitimate concerns requiring further examination:

- **Late-stage introduction of critical provisions** – including patent rules, traceability exemptions, and risk equivalence criteria, all added or finalized after key public consultations had closed.
- **Timing of the EFSA opinion** – requested only after core legislative positions had already been adopted, thereby limiting its role to retroactive justification rather than independent scientific input.
- **Choice of legislative form** – the selection of a *regulation* rather than a *directive* significantly curtailed the capacity of Member States to adapt provisions to their own legal and agricultural contexts, potentially undermining the principle of subsidiarity.

2.3 Basis for Legal and Procedural Objections

The chronological overview demonstrates that, although the Commission and Parliament complied with the formal procedural steps, the **structure, content, and sequencing of the process** raise serious legal and procedural concerns:

- the **late-stage insertion** of patent-related provisions and traceability exemptions,
- the **absence of genuine public consultation** on EFSA's scientific opinion,
- the **strategic use of scientific assessments** to validate predetermined policy outcomes, and
- the **circumvention of Member States' discretion** to restrict or block the release of NGTs in their territory.

These elements together suggest that the legislative process was not consistent with the principles of **good administration, transparency, and democratic accountability** enshrined in EU law.

The subsequent parts of this Complaint (Parts III and IV) will examine these elements in detail, relying exclusively on the official documents and institutional records listed above.

References to Part II

2. European Commission, COM(2023) 411 final, Proposal for a Regulation on plants obtained by new genomic techniques, 5 July 2023.
3. European Parliament, Procedure 2023/0226(COD), OEIL legislative observatory (links above).
4. Council of the European Union, doc. ST-6426/25 INIT, 7 March 2025.

5. Regulation (EC) No. 1830/2003; Directive 2001/18/EC; Articles 5 TEU and 191 TFEU.

Part III

The Core of the NGT Regulation – The Goal: Weakening the Safeguards of Directive 2001/18/EC

3.1 Legal Loopholes

One of the fundamental objectives of the proposed regulation (COM/2023/411 final) is the deliberate and substantial relaxation of biosafety measures previously established under Directive 2001/18/EC[1].

This directive has long served as a legal cornerstone of the European Union's policy on public health and environmental protection, effectively preventing the uncontrolled release of genetically modified organisms (GMOs) into the environment.

The proposed amendments not only undermine these legally enshrined precautionary safeguards — they also introduce legal loopholes that permit, or even incentivize, their circumvention. Such regulatory weakening represents a direct threat to the integrity of Union law and to the principles of legal certainty and environmental precaution embedded in the Treaties.

3.2 The Regulatory Framework of NGT 1 and NGT 2

A central mechanism of this deregulatory strategy is the artificial and legally ungrounded division of New Genomic Techniques (NGTs) into two categories — NGT 1 and NGT 2.

This classification lacks scientific foundation and appears to serve primarily as a legislative maneuver designed to create a regulatory escape route, enabling gene-edited plants to circumvent established oversight requirements[2].

Both NGT 1 and NGT 2 plants are the product of artificial genomic interventions, and their potential effects on human health, biodiversity, and environmental systems remain inherently unpredictable[3].

3.2.1 Classification of NGT Plants

According to the European Commission's draft regulation, plants obtained through New Genomic Techniques are divided into two categories: NGT 1 and NGT 2.

- **NGT 1**
  Defined as plants differing from their conventional counterparts by no more than 20 genetic modifications.
  They are declared equivalent to conventionally bred plants, despite being products of targeted and artificial genomic alterations.

  Exemptions include:
  ▪ Simplified market access procedures
  ▪ No mandatory risk assessments regarding human health and environmental safety
  ▪ Exemption from GMO labeling requirements (except for seed materials)
- **NGT 2**
  Defined as plants with more than 20 genetic modifications compared to the recipient or

parental plant.
They are not considered equivalent to conventional plants.

Regulatory changes for NGT 2 include:
▪ A streamlined approval process compared to traditional GMOs
▪ Weakened risk assessment standards, with reduced scrutiny of health and environmental risks
▪ Exemptions from post-market monitoring, raising concerns about long-term consequences

3.2.2 Comparison of NGT 1 and NGT 2

Characteristic	NTG 1	NTG 2
Maximum number of genetic modifications	≤ 20 modifications	> 20 modifications
Regulatory classification	Considered equivalent to conventional plants	Not considered equivalent to conventional plants
Risk assessment requirement	Not required	Required
Environmental monitoring	Not required	Required
Labeling requirements	Not required, except for seeds	Required
Market access restrictions	Simplified approval process	Subject to GMO-like approval process
Long-term impact studies	Not required	Required
Possibility of reclassification	High—companies may seek NTG 1 classification to avoid regulation	Low—higher regulatory scrutiny prevents easy reclassification

3.2.3 Critique of the NGT 1 and NGT 2 Classification

The scientific credibility and legal defensibility of the NGT 1 / NGT 2 division are highly questionable. Rather than being grounded in risk assessment, this binary categorization appears designed to facilitate rapid deregulation.

The proposed framework lacks robust, independent oversight mechanisms to verify whether a plant genuinely meets the NGT 1 criteria. This omission creates a regulatory void, allowing operators to self-declare compliance and bypass safety evaluations and public transparency[4].

3.3 Example of Misclassification Abuse: Downgrading NGT 2 to NGT 1

The following hypothetical case illustrates how the classification framework may be exploited:

A biotechnology company intends to market a drought-resistant maize variety. The plant has undergone extensive genome editing involving more than 20 modifications (affecting water retention, root system architecture, and stress metabolism). This product clearly qualifies as NGT 2 and should be subject to full safety assessment, labeling, and monitoring.

Yet, under the proposed framework, abuse could occur:

- **Selective Disclosure** — reporting only a subset of modifications to remain under the NGT 1 threshold.
- **Framing as "Natural"** — claiming that mutations could have occurred under natural selection or conventional breeding.
- **Regulatory Arbitrage** — exploiting weak verification mechanisms by self-certifying NGT 1 status without independent review.
- **Rapid Market Entry** — releasing the crop without labeling, leaving consumers and farmers unaware they are handling a highly modified organism.

Such strategies, if repeated, would lead to systemic misclassification and de facto deregulation of gene-edited crops in the EU.

3.4 Consequences of Misclassification

- **Profits for Biotech Companies**
  Lower compliance costs, faster approvals, and unrestricted market access without public accountability.
- **Harm to Consumers**
  Removal of labeling and risk assessments deprives citizens of the right to informed choice (Article 38, Charter of Fundamental Rights).
- **Failure for Farmers**
  Cross-pollination could cause irreversible contamination, loss of organic certification, and litigation over patented traits.
- **Environmental Risk**
  Unmonitored release may contribute to biodiversity loss, herbicide-resistant weeds, and ecological instability — contrary to Article 191 TFEU (precautionary principle).

If left unaddressed, these loopholes would dismantle the Union's biosafety framework, exposing citizens, farmers, and ecosystems to irreversible risks.

3.5 The Lack of Scientific Basis for Exempting NGT 1

The assumption that NGT 1 organisms are inherently safer than traditional GMOs lacks credible scientific evidence.

Studies highlight risks including[4]:

6. Unintended off-target mutations
7. Epigenetic disruptions with unknown long-term impacts
8. Instability in gene expression leading to unexpected consequences

Thus, exempting NGT 1 from risk assessment, monitoring, and labeling is scientifically unfounded and represents a legislative tool to bypass Directive 2001/18/EC. Such an approach constitutes a breach of the precautionary principle enshrined in Article 191(2) TFEU.

3.6 The Regulatory Contradiction with EU Law and the CJEU Ruling (2018)

3.6.1 Binding Definition under Directive 2001/18/EC

In Case C-528/16[5], the Court of Justice of the European Union ruled:

“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.”

Despite this binding jurisprudence, the Commission’s proposal introduces exemptions that contradict the Court’s ruling. This undermines the principle of legal certainty, the separation of powers, and the uniform application of Union law.

3.6.2 Conclusion

The amendments provide neither scientific nor legal justification for exempting NGT 1 organisms. Instead, they dismantle long-standing safeguards, remove transparency obligations, and override judicial precedent.

This amounts to a violation of the precautionary principle and the rule of law, concentrating control of genetic resources in the hands of a few corporations and threatening Member States’ agricultural sovereignty.

References to Part III

[1] Directive 2001/18/EC on the Deliberate Release of Genetically Modified Organisms into the Environment.

[2] European Commission (2023). *Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on plants obtained by certain new genomic techniques and their food and feed, and amending Regulation (EU) 2017/625* (COM/2023/411 final). Brussels (https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52023PC0411)

[3] This is due to incomplete knowledge about the effects of genetic modification, and particularly to unpredictability of unintended off-target mutations and their consequences as a result of the use of genome editing techniques (most widely used new genomic techniques) - as shown by an increasing number of published studies (see reference 4).

What's more, systematic review and meta-analysis showed, that **almost all of 60 studies** (except three that did not perform a comparative analysis) – **from which 86.7% were publicly funded studies – “reported statistical differences in GM versus non-GM omic profile**s. A heatmap analysis showed that the most frequently affected metabolic pathways were related to metabolism of carbohydrates, energy, lipids, and amino acids, as well as genetic information processing and environmental information processing.” (Benevenuto et al, 2022). And that CRISPR causes serious DNA **damage with high frequency – but it’s often overlooked** (Park et al, 2023; and review in https://gmwatch.org/en/106-news/latestnews/20275).

[4] Kawall K. (2021). The generic risks and the potential of SDN-1 applications in crop plants. *Plants* 10(11). 10.3390/plants10112259, https://www.mdpi.com/2223-7747/10/11/2259/htm;

Chu, P.; Agapito-Tenfen, S.Z. (2022), Unintended Genomic Outcomes in Current and Next Generation GM,Techniques: A Systematic Review. *Plants* **2022**, 11, 2997. https://doi.org/10.3390/plants11212997.

Park, S. H., Cao, M., and Bao, G. (2023). Detection and quantification of unintended large on-target gene modifications due to CRISPR/Cas9 editing. *Current Opinion in Biomedical Engineering*, Volume 28, December 2023, 100478, https://www.sciencedirect.com/science/article/abs/pii/S246845112300034X

Benevenuto, Rafael Fonseca; Hermoine Jean Venter, Caroline Bedin Zanatta, Rubens Onofre Nodari, Sarah Zanon Agapito-Tenfen (2022), Alterations in genetically modified crops assessed by omics studies: Systematic review and meta-analysis, *Trends in Food Science & Technology*, Volume 120, February 2022, Pages 325-337,

https://doi.org/10.1016/j.tifs.2022.01.002,
https://www.sciencedirect.com/science/article/pii/S0924224422000024

Przegląd opublikowanych badań wykazujących częste zachodzenie niezamierzanych mutacji i innych skutków stosowania new genomic tehniques można znaleźć, np. w poniższych publikacjach:
- New Genomic Techniques and unintended genetic changes: EFSA 'overlooked' most of the relevant publications, *TESTBIOTECH Background* 12 - 12 – 2022, https://www.testbiotech.org/wp-content/uploads/2022/12/EFSA-%E2%80%98overlooked-relevant-publications.pdf;
- Gene editing: Unexpected outcomes and risks, *GM Watch,* 03 August 2020, https://gmwatch.org/en/67-uncategorised/19499-gene-editing-unexpected-outcomes-and-risks

[5] CJEU, Case C-528/16 (2018).

Part IV

Modification of the GMO Definition to Exclude NGTs from Regulation

4.1 Introduction

One of the most fundamental and problematic aspects of the proposed NGT Regulation is the attempt to **redefine the concept of genetically modified organisms (GMOs)** in a way that excludes organisms obtained through New Genomic Techniques (NGTs) from the scope of Directive 2001/18/EC.

This modification represents a deliberate legal manipulation that contradicts established EU law, particularly the jurisprudence of the Court of Justice of the European Union (CJEU). It undermines the legal safeguards designed to protect public health, biodiversity, and food system transparency, and therefore warrants detailed examination.

4.2 The Original Definition in Directive 2001/18/EC

Directive 2001/18/EC defines a GMO as:
"A genetically modified organism (GMO) means an organism, other than a human being, in which the genetic material has been altered in a way that does not occur naturally through mating or natural recombination."

This definition was intended to cover a broad range of genetic modification techniques, including modern gene-editing tools such as CRISPR-Cas9.

Annex I B of the Directive provided limited exemptions for **conventional mutagenesis** and **cell fusion** techniques that had a long history of safe use. These exemptions were never intended to apply to new, high-precision molecular tools that deliberately alter genomes in ways not achievable through conventional breeding.

4.3 CJEU Rulings (2018 and 2022)

In its landmark judgment in **Case C-528/16 (Confédération paysanne)**, the CJEU held that organisms obtained through mutagenesis techniques such as CRISPR-Cas9 are **GMOs within the meaning of Directive 2001/18/EC**, and therefore subject to its safeguards.

The Court stressed that mutagenesis methods, although sometimes excluded under Annex I B, fall within the scope of the Directive where they involve **novel or high-risk techniques** that do not have a long safety record.

In 2022, the CJEU reaffirmed this principle, clarifying that gene-edited organisms must remain subject to GMO legislation, including risk assessment, monitoring, and labeling obligations.

Together, these rulings establish a clear legal precedent: **NGTs are GMOs and cannot be excluded from Directive 2001/18/EC through administrative reinterpretation.**

4.4 The Revised Definition Proposed by the Commission

The Commission's proposal introduces a new definition of GMOs:
"(1a) 'genetically modified organism' or 'GMO' means a genetically modified organism as defined in Article 2(2) of Directive 2001/18/EC, **excluding organisms obtained through the techniques of genetic modification listed in Annex I B to Directive 2001/18/EC**."

This rewording invokes Annex I B to exclude NGTs from the scope of GMO law. Yet Annex I B was only ever intended for **traditional mutagenesis and plant cell fusion techniques**, not for modern tools like CRISPR-Cas9.

By stretching the scope of Annex I B to cover NGTs, the Commission attempts to circumvent both the Directive and binding CJEU case law.

4.5 Why the Change is Legally and Scientifically Invalid

Annex I B clearly states that the exclusion applies to:

1. Mutagenesis, provided it does not involve recombinant nucleic acid molecules or genetically modified organisms as parental material.
2. Cell fusion between plant cells capable of exchanging genetic material through conventional breeding.

This wording demonstrates that only **conventional, non-recombinant techniques** are exempt. Modern NGTs, which often employ recombinant DNA or artificial molecular tools, cannot fall under this exemption.

Therefore, the Commission's attempt to reinterpret Annex I B amounts to a **direct violation of Directive 2001/18/EC** and ignores the scientific reality of how NGTs operate.

4.6 Implications of the Commission's Manipulation

4.6.1 NGTs Remain GMOs under EU Law

As confirmed by the CJEU (2018, 2022), gene-edited organisms are GMOs and must remain subject to the Directive. Redefining them as "non-GMOs" is inconsistent with binding judicial precedent.

4.6.2 Conflict with Annex I B

Annex I B was limited to well-established conventional techniques. Extending it to modern NGTs contradicts the Directive's text, purpose, and legislative history.

4.6.3 Bypassing Safety Assessments and Risk Evaluations

The redefinition allows NGT-derived plants to be marketed without risk assessments, environmental monitoring, or consumer labeling — removing essential precautionary mechanisms.

4.6.4 Dangerous Regulatory Precedent

Allowing the Commission to exclude NGTs through definitional changes would set a precedent for bypassing EU law via semantic reinterpretation, without formal legislative amendment.

4.7 Summary and Consequences

4.7.1 Legal Manipulation to Deregulate NGTs

The Commission's proposal deliberately redefines the GMO concept to exclude NGTs, in defiance of CJEU rulings. This maneuver weakens established safeguards and transfers power to biotechnology operators.

4.7.2 Consequences for EU Law and Member States

- **Exemption from Directive 2001/18/EC**: NGTs would no longer be subject to GMO legislation.
- **Loss of transparency**: No labeling for consumers, undermining the right to informed choice.
- **Uncontrolled environmental release**: Crossbreeding and contamination risks with irreversible effects on biodiversity.
- **Erosion of national sovereignty**: Member States would lose legal instruments to restrict or ban NGTs under EU law.
- **Violation of the precautionary principle**: A cornerstone of EU environmental and public health policy would be sidelined.

References to Part IV

1. Directive 2001/18/EC on the deliberate release of GMOs into the environment.
2. CJEU, Case C-528/16, *Confédération paysanne*, Judgment of 25 July 2018, ECLI:EU:C:2018:583.
3. CJEU, Case C-688/21, *TestBioTech v Commission*, Judgment of 2022.
4. European Commission, COM(2023) 411 final, Proposal for a Regulation on plants obtained by certain new genomic techniques.
5. Eckerstorfer, M. et al. (2019). An EU Perspective on Biosafety Considerations for Plants Developer by Genome Editing and Other New Genetic Modification Techniques (nGMs), *Front. Bioeng. Biotechnol.*, 05 March 2019, Volume 7 - 2019 | https://doi.org/10.3389/fbioe.2019.00031, https://www.frontiersin.org/journals/bioengineering-and-biotechnology/articles/10.3389/fbioe.2019.00031/full

Part V

Manipulation of Scientific Terminology: From "Precise" to "Targeted"

5.1 Introduction

One of the most revealing examples of legislative manipulation in the NGT file is the **replacement of the term "precise" with "targeted"** in key provisions of the Council's revised draft (ST 5076/25).

At first sight, this change might appear minor, but in reality it has **profound legal, scientific, and regulatory implications**. The deletion of the word "precise" weakens the scientific characterization of gene-editing technologies, undermines the perception of risk, and facilitates deregulation. It exposes the contradiction at the core of the Commission's and Council's approach: an implicit admission that genome editing is not fully controlled, coupled with a policy choice to reduce safeguards instead of reinforcing them.

5.2 The Modifications in Official Drafts

5.2.1 Change in the Preamble

Original text:
"Genome editing techniques that enable changes to be made to the genome at **precise targeted** locations."

Revised text:
"Genome editing techniques that enable changes to be made to the genome at **targeted** locations."[1]

5.2.2 Change in the Definitions

Original definition:
"Targeted mutagenesis means mutagenesis techniques resulting in modification(s) of the DNA sequence at **precise targeted** locations in the genome of an organism."[2]

Revised definition:
"Targeted mutagenesis means mutagenesis techniques resulting in modification(s) of the DNA sequence at **targeted** locations in the genome of an organism."[3]

Both provisions show the **systematic removal of "precise"**. This is not a typographical simplification: it is a deliberate legislative choice.

5.3 Consequences of the Terminological Manipulation

The semantic difference between *precise* and *targeted* is critical:

- **"Precise"** implies a high degree of control, accuracy, and predictability. It suggests that genetic modifications occur exactly as intended, with negligible risk of unintended outcomes.
- **"Targeted"** merely denotes the intention to act at a given location, without any guarantee of accuracy. It acknowledges that the process is directional but not necessarily flawless or confined.

By eliminating "precise", the legislator implicitly acknowledges that **genome editing is not exact**. However, instead of drawing the obvious regulatory conclusion — that stricter safeguards are required — the Regulation uses this change to justify deregulation.

This contradiction is at the heart of our objection.

5.4 Scientific and Technological Consequences

The shift from *precise* to *targeted* is fully consistent with the scientific evidence: modern gene-editing technologies, especially CRISPR-Cas9, are **not fully precise**.

Peer-reviewed studies have demonstrated that:

- CRISPR and related tools frequently produce **off-target mutations**, i.e., unintended edits in other parts of the genome.
- Even at the intended site, **on-target unintended effects** occur, including large deletions, rearrangements, or unexpected genetic interactions.
- Gene-editing often results in **genomic instability**, with outcomes that cannot be fully anticipated or controlled.

Examples include[4]:

- Zischewski, Fischer & Bortesi (2017) – detection of unintended on- and off-target mutations.
- Kawall (2021) – evidence that small intended edits can trigger large-scale and unexpected changes.
- Chu & Agapito-Tenfen (2022) – systematic review of unintended genomic outcomes in gene-edited organisms.
- Park, Cao & Bao (2023) – quantification of large unintended modifications at CRISPR on-target sites.
- Koller & Cieślak (2023) – proof of unintended genetic changes in plants, directly relevant to agricultural biosafety.

These findings confirm that **absolute precision cannot be guaranteed in practice**. Gene editing can be directed to a target, but its effects remain unpredictable.

Thus, removing "precise" reflects reality — but the legislative consequence drawn from this admission is perverse: **instead of tightening oversight, safeguards are dismantled.**

6.5 Regulatory Consequences

5.5.1 Weakening of Safeguards

- With "precise" removed, the regulatory definition is less rigorous.
- The shift lowers the perception of risk, enabling more lenient safety standards.

5.5.2 Avoidance of Safety Testing

- If genome editing is no longer characterized as "precise", regulators are relieved from the need to demonstrate absolute control.
- This change makes it easier to classify NGTs as inherently safe, thereby **bypassing requirements for risk assessment, monitoring, and labeling**.

5.5.3 Contradiction with EU Law

- The modification undermines the **precautionary principle** (Article 191(2) TFEU).
- It contradicts the framework of **Directive 2001/18/EC** and the CJEU's interpretation in Case C-528/16, which requires strict oversight of all organisms obtained by mutagenesis.

5.5.4 Erosion of Transparency

- Citizens are denied reliable information.

- A linguistic shift hides real uncertainties and risks, while opening the door to deregulation.

5.6 Exposure of Contradictions in the Commission's Approach

The removal of "precise" exposes the **fundamental inconsistency** in the Commission's policy:

- The Commission tacitly admits that NGTs are not fully precise.
- It acknowledges that unintended modifications and off-target effects are possible.
- Yet instead of introducing **additional safeguards**, it promotes deregulation, thereby favoring biotech corporations over citizens' rights and environmental protection.

This approach is not a neutral adjustment. It is a **strategic maneuver** that simultaneously recognizes the risks while avoiding any regulatory response.

5.7 Summary: Why This Change Is So Significant

5.7.1 Admission of Lack of Precision

The replacement of "precise" with "targeted" is an implicit acknowledgment that genome editing is not exact. This undermines the narrative that NGTs are safer and more predictable than GMOs.

5.7.2 Exposure of Actual Risks

By discarding "precise", the legislator silently admits that off-target and unintended mutations exist, with potentially serious implications for health and the environment.

5.7.3 Collapse of the Deregulation Narrative

If NGTs are not "precise", then the entire argument for their preferential treatment collapses. They cannot be exempted from GMO safeguards.

5.7.4 Evidence of Legislative Manipulation

The semantic shift is not accidental: it is a calculated attempt to lower the regulatory threshold, despite mounting scientific evidence of risks.

5.7.5 A Basis for Rejection

Acknowledging the lack of precision should logically lead to stricter regulation. Instead, deregulation is pursued. This inconsistency provides **independent grounds to reject the Regulation in its current form**.

References to Part V

[1] Council of the European Union, *Working Party on Genetic Resources and Innovation in Agriculture – Revised Presidency Text on the Regulation on Plants Obtained by New Genomic Techniques*, doc. ST 5076/25, 12 January 2025.

[2] Ibid., Annex, Preamble, Point 1, p. 4.

[3] Ibid., Annex, Definitions, Point 4, p. 7.

[4] Zischewski, J., Fischer, R., & Bortesi, L. (2017). *Detection of on-target and off-target mutations generated by CRISPR/Cas9 and other sequence-specific nucleases*. Biotechnology Advances 35(1), 95–104. doi: 10.1016/j.biotechadv.2016.12.003, https://pubmed.ncbi.nlm.nih.gov/28011075/

Kawall, K. (2021). *The generic risks and the potential of SDN-1 applications in crop plants*. Plants 10(11):2259. https://doi.org/10.3390/plants10112259 , https://www.mdpi.com/2223-7747/10/11/2259E

Chu, P., & Agapito-Tenfen, S.Z. (2022). *Unintended genomic outcomes in current and next generation GM techniques: A systematic review*. Plants 11:2997. https://doi.org/10.3390/plants11212997.

Park, S.H., Cao, M., & Bao, G. (2023). *Detection and quantification of unintended large on-target gene modifications due to CRISPR/Cas9 editing*. Current Opinion in Biomedical Engineering 28:100478. https://www.sciencedirect.com/science/article/abs/pii/S246845112300034X

Koller, F., & Cieślak, M. (2023). *A perspective from the EU: unintended genetic plants caused by NGTs – their relevance for molecular characterization and risk assessment*. Frontiers in Bioengineering and Biotechnology, Oct 27:11:1276226. doi: 10.3389/fbioe.2023.1276226. https://pubmed.ncbi.nlm.nih.gov/37965049/

Part VI
Regulation Enables Corporate Control Over Seeds

6.1 Introduction — The Unseen Consequence of NGT Deregulation

One of the most alarming yet overlooked consequences of the proposed NGT Regulation is its **direct entanglement with intellectual property (IP)**. While the measure is presented as a technical "simplification" for innovative breeding, in practice it opens a **broad highway for patent monopolies** over seeds and breeding traits. If adopted, it will enable a small group of multinational biotech firms to obtain and enforce exclusive rights over gene-edited plants, reshaping European agriculture around **licensing, royalties and dependency**.

This chapter explains how:

- the **redefinition and misclassification** of NGT crops,
- **late-stage insertion** of patent-relevant clauses, and
- the **absence of farmer-protective safeguards**
  together create a structural pathway to patent-driven control of seeds, to the detriment of farmers, biodiversity, and food sovereignty in the EU.

6.2 How Patent Provisions Entered the File — After Consultations Closed

Patent-relevant provisions were **not** part of the text consulted with Member States. They were added **later**, at a legislative stage following national feedback, without reopening public or national scrutiny. The Presidency's steering note of **7 January 2025** states on its first page:

"The Presidency has based its revisions on the text prepared for the meeting of the Permanent Representatives Committee on 7 February 2024 (doc. 16714/23). **New changes** (i.e. those that were not introduced in doc. 16714/23) **have been marked with yellow highlight**."

This confirms that critical modifications—including those enabling **patent-centred control of NGT plants**—were introduced **post-consultation**, outside a transparent, participatory process. This is not a formatting tweak; it is a **decisive shift of legal effects** achieved without renewed democratic oversight.

6.3 EU Patent Law Background — What Is (and Isn't) Patentable

EU patentability of plants is framed by:

- **Directive 98/44/EC** (Biotech Directive),
- the **European Patent Convention (EPC)** and EPO case law, especially **G 3/19** (Enlarged Board of Appeal, 2020), which confirmed **exclusions** for products **obtained exclusively by essentially biological processes** (i.e., conventional breeding), and
- TRIPS (WTO), which allows patents on inventions but leaves Members free to set boundaries (e.g., farmers' privilege, breeders' exemption).

Key point: conventional varieties and traits from **essentially biological processes** are **not** patentable. However, when a **technical step** (e.g., genome editing) is invoked, applicants attempt to reframe a plant/trait as a **patentable invention** (product or process), thereby enclosing genetic resources behind IP rights unless robust exclusions/limitations apply.

6.4 How the NGT Regulation Creates a Patent Backdoor

The draft introduces a legal architecture that **decouples** many NGT1 plants from GMO controls and **simultaneously recognises** patent realities without providing EU-wide counterweights:

6.4.1 Article 14 quater — TRIPS reference without farmer safeguards

Affirms that patents can be granted on "any inventions, whether products or processes" under TRIPS. Crucially, it **omits** explicit EU-level protections for **farmers' seed saving**, **research/breeders' use**, or **compulsory licensing** in the public interest.

6.4.2 Article 24 bis — Labelling only when patented

Imposes **labelling for NGT1 reproductive material when it is protected by a patent**. This is a **de facto acknowledgement** that NGT1 plants are patent-eligible. It also normalises the idea that such seed is **corporate property** subject to licensing.

6.4.3 Article 24 ter — Optional national restrictions

Allows Member States to **restrict** patented NGT1 material. This **admits the risk** of monopolisation but **externalises responsibility** to national level, guaranteeing **fragmentation** and enforcement gaps across the EU.

6.4.4 Article 24 quinquies / 24 septies — Administrative mechanics, no antimonopoly brake

Administrative references (including revocation pathways) do not prevent **market foreclosure** via broad patent claims on traits; they do **nothing** to stop recurring **royalty chains** imposed downstream on farmers.

Bottom line: the Regulation is **not neutral** on patents. It **anticipates** and **enables** patent control—without EU-wide counter-balances.

6.5 How Deregulation Becomes a Patent Loophole

By artificially **separating NGT1 from GMO law** and relabelling "precision" to the weaker "targeted" (see Part VI), the draft lowers scrutiny **while** signalling patentability. This "technical" shift lets applicants claim that edited traits are **inventive technical solutions**, transforming living resources into **licensable assets**, despite their biological commonality and shared agronomic value.

6.6 Consequences for Farmers — Enclosure, Liability and Dependency

6.6.1 Loss of Seed Sovereignty

Labelling only when patented (Art. 24 bis) + recognition of patentability = routine **licensing** and **no seed-saving** for patented NGT plants. Traditional practice ("farm-saved seed") becomes legally risky or barred; access to parental material is constrained by IP claims.

6.6.2 Legal Exposure from Genetic Drift

Cross-pollination from patented fields to non-NGT or organic fields can create **accidental presence** of patented genes. The draft **does not** include an EU-level **liability shield** for unintentional admixture, inviting **enforcement actions** against farmers who never sought the trait.

6.6.3 Market Exit of Independent Breeders

Broad patents on **traits/functions** (rather than individual varieties) raise **transaction costs** and legal uncertainty for small breeders. Over time, this favours conglomerates with large IP portfolios and litigation budgets, shrinking the **innovation ecology**.

6.7 System-Level Risks — Concentration, Biodiversity, Food Security

6.7.1 Consolidation of Seed Chains

With patent rights as the gating asset, a few corporations can **control market access** to core traits, mirroring global trends of concentration documented in the literature (e.g., Clapp et al., 2025; IPES-Food 2017). Labelling duties (24 bis) without anti-monopoly brakes **legitimise** this shift.

6.7.2 Decline in Genetic Diversity

Even with a nominal breeders' exemption, expansive product/trait patents **chill access** to essential germplasm. Lower diversity means **higher vulnerability** to pests, diseases and climate shocks—an old lesson with new, systemic stakes.

6.7.3 Upward Price Pressure and Volatility

Where seed markets are controlled by a few rights-holders, **input prices rise** and **switching costs** increase. Farmers pass some costs to consumers; the rest erodes margins, accelerating exit of smaller farms and deepening regional disparities.

6.8 Why the Draft's "Safeguards" Are Illusory

- **No EU-wide farmer privilege** (seed saving, on-farm exchange) for patented NGT plants.
- **No liability shield** for inadvertent presence of patented traits.
- **No compulsory-licensing defaults** for food security/biodiversity needs.
- **No patent-exclusion** for NGT-induced traits that are **biologically occurring** or **technically trivial**.
- **No cap** on claim breadth/duration for foundational agronomic functions.

By shifting key decisions to Member States (e.g., Art. 24 ter) and omitting EU-level guardrails, the Regulation **invites fragmentation** and **race-to-the-bottom** dynamics.

6.9 Red Lines (Minimum Conditions) — If the File Is Not Rejected

While our position is that the current proposal should be **rejected in its entirety**, at absolute minimum the text must include **binding, EU-wide** clauses:

1. **Patent Exclusion for NGT Traits Essential to Food and Biodiversity**
— No patents on traits obtainable by essentially biological processes or naturally occurring alleles, even if an editing step is used.
2. **Farmers' Privilege & Seed Commons**
— Guaranteed rights to **save, replant, exchange** seed of patented NGT plants for non-commercial on-farm use; royalty-free.
3. **Breeders' Research & Use Exemption (Strong Form)**
— EU-wide authorisation to use patented material for breeding and to commercialise derivatives that do not literally embody the claimed invention.
4. **Liability Shield for Adventitious Presence**
— No IP infringement or contractual liability for **unintentional admixture** via cross-pollination or commingling below a clear, low threshold.
5. **Compulsory Licensing for Public Interest**
— Fast-track, fair-royalty licences when needed for **food security**, climate adaptation, or biodiversity conservation.
6. **Transparency & Antitrust Triggers**
— Public registry of **all patent-encumbered NGT seeds**; merger control and abuse-of-dominance monitoring tied to market shares and IP clustering.

Without these provisions, the file structurally **transfers control** of seeds to patent holders.

6.10 Conclusion — This Is a Patent Trap, Not Neutral Modernisation

The NGT Regulation, as drafted, **hard-wires** a patent-first logic into EU agriculture. By decoupling NGT1 from GMO controls, inserting **patent-enabling articles** late in the process, and refusing EU-level safeguards, it **institutionalises dependency** of farmers and breeders on a handful of IPR portfolios. This is incompatible with the Union's commitments to **food security, biodiversity, fair markets and farmers' rights**.

Remedy sought:

- **Rejection** of the proposal in its current form; **or**, failing that, insertion of the **Red Lines** above as non-derogable EU-wide provisions.

References to Part VI

1. Clapp, Jennifer et al. 2025. "Corporate Concentration and Power Matter for Agency in Food Systems". *Food Policy* Volume 134, July 2025, (102897). https://doi.org/10.1016/j.foodpol.2025.102897, https://www.sciencedirect.com/science/article/pii/S0306919225001022.
2. Tippe R. et al (2023). *The future of plant breeding is under threat in Europe Current interpretation of patent law is insufficient to stop patents on conventional breeding*. No Patents onSeeds! July 2023. https://www.no-patents-on-seeds.org/sites/default/files/news/2023_Report_NPoS_final_version.pdf
3. JOINT STATEMENT ON THE DEREGULATION OF NEW GMOS by over 200 Organisations entitled "Protect the business of small and medium size breeders, farmers, and the organic and non GMO sectors in the EU", published 11 February 2025 https://corporateeurope.org/sites/default/files/2025-02/FINAL%20-%20Joint%20statement%20-%20New%20GMOs%20-%2010.02.pdf

4. EPO Enlarged Board of Appeal, **G 3/19** (2020) — exclusions for products obtained exclusively by essentially biological processes.
5. IPES-Food (2017). *Too big to feed: Exploring the impacts of mega-mergers, concentration, concentration of power in the agri-food sector*. https://ipes-food.org/wp-content/uploads/2024/03/Concentration_FullReport.pdf
6. Directive **98/44/EC** on the legal protection of biotechnological inventions; TRIPS Agreement 7. **EPC/EPO G 3/19**; **TRIPS**; applicable **EU competition law** principles.

PART VII

The European Union's Legislative Mechanism as a Tool of Manipulation – An Analysis of the Revisions and Amendments Introduced by the European Commission and Parliament to the NGT Regulation and Their Consequences for Member States

7.1. Introduction to the Analysis of Legislative Manipulation Mechanisms

The Union's law-making is founded on **transparency, participation and accountability** (Articles **10–11 TEU**) and on the fundamental right to **good administration and transparency** (**Article 41 CFR**).[1] Yet the legislative handling of the Regulation on organisms obtained by New Genomic Techniques (NGTs) displays **systematic departures** from these principles.

This section sets out, in a structured manner, **how** the European Commission and the European Parliament engineered procedural shortcuts and re-definitions to **neutralise democratic oversight** and **exclude** meaningful Member-State and public intervention at critical stages.

These are **not administrative mishaps**; they are elements of a **deliberate procedural design** that concealed decisive changes from national fora and civil society, enabling a final text to advance **without genuine opportunity** for Member States to contest its substance or engage in an informed debate on its legal consequences.

To illustrate the extent of these deficiencies, the following sections systematically examine the legislative mechanism deployed by the Commission and Parliament. The analysis identifies the key stages where democratic safeguards were progressively dismantled in favour of a deregulatory outcome with direct and far-reaching implications for the rights of EU citizens and the sovereign regulatory competences of Member States — an outcome conspicuously aligned with the interests of biotechnology stakeholders.

7.2. The Commission's Actions in Breach of EU Law-Making Principles (Articles 10–11 TEU) and the Right to Good Administration (Article 41 CFR)

7.2.1 Covert Interference as a Method of Circumventing Democratic Procedures

As outlined above, the Union's legislative process is, in principle, grounded in democratic values and legal norms that guarantee Member States and their citizens the right to participate actively in shaping legislation applicable across the Union.

While Articles **10–11 TEU** require open, transparent and regular dialogue with civil society and decisions taken as closely as possible to citizens, the NGT file proceeded through **opaque channels**. Consultations were **narrowed** to a circle of "experts" **close to industry and EFSA**, marginalising independent scientists, farmers and civic organisations.[2] This **frustrated** the participatory guarantees of Article **11 TEU** and **Aarhus** (public participation in environmental decision-making).

Avoidance of democratic oversight, bypassing of mechanisms for public and institutional debate, and the **strategic redefinition of legal categories** appear as elements of a coordinated design intended to advance rules that disproportionately benefit biotechnology stakeholders, while disabling regulatory responses to well-documented risks for public health, environmental protection, and food-system transparency. Only a narrow circle of "experts" **closely aligned with industry and EFSA** was effectively heard, while independent scientists, farmers, and civil society organisations were marginalised.

These actions are not incidental. They reflect a **structured institutional approach** that allows the Commission to pursue legislative outcomes with limited visibility and accountability. As a result, the final text could be adopted without meaningful deliberation on its societal, environmental, and legal implications — and without any realistic opportunity for Member States to challenge its content

The effect was to **withhold** from Member States and the public the information and fora needed to scrutinise decisive alterations, contrary to **Article 41 CFR** (good administration, duty to hear and to give reasons).

7.2.2 Procedural Engineering by the European Commission: A Strategy to Disable Democratic Safeguards

The procedure surrounding the proposed NGT regulation demonstrates that the Commission applied a coordinated strategy that **significantly limits** Member States' capacity for oversight and **excludes** genuine public participation.

A central element of this strategy is the **removal or hollowing-out** of procedural mechanisms that would otherwise enable national governments to influence the legal framework during critical phases of legislative development.

The Commission's coordinated use of **non-papers**, technical "recasts" and late proposals **hollowed out** mechanisms that allow national governments to shape the text during decisive phases. This was not neutral housekeeping; it was a **procedural architecture** that weakened oversight over a measure with direct effect in all Member States. By doing so, the Commission **displaced** the balance required by **Article 5 TEU (subsidiarity/proportionality)** and the **Interinstitutional Agreement on Better Law-Making**, replacing open legislative scrutiny with **trilogue secrecy** and last-minute insertions.

This restructuring is not a neutral or technical adjustment. It is a **procedural architecture** that weakens the oversight system for legal acts with far-reaching implications for public health, the environment, and consumer rights. The resulting framework appears **designed** to facilitate outcomes aligned with biotechnology-industry preferences rather than uphold the Union's foundational commitments to the **precautionary principle** and **institutional transparency**.[3]

To provide a transparent overview of the methodology employed by the Commission, the next section sets out five key stages in which democratic safeguards were successively dismantled. This structure makes clear how Member States were excluded from meaningful deliberation and ultimately presented with a **fait accompli** in which NGT deregulation proceeds without any realistic opportunity for objection or correction.

7.3. The Legislative Path: How the Legal Basis Was Rewritten Post-Consultation

a) Initial preparation and Council/National consultations

At this stage, Member States articulate positions on scope, safety and governance. Under **Article 5 TEU** (subsidiarity), these inputs should materially shape the proposal.

b) Entry into Ordinary Legislative Procedure (Parliament & Council)

Once transmitted, the file entered OLP. In the contested NGT file, however, decisive content changes were driven by the Commission **after** national consultations, **without** a renewed Member-State hearing (**Articles 10–11 TEU; Article 41 CFR**).

c) Substantive changes by Commission/Parliament after consultations

Core elements were reshaped in closed settings, limiting parliamentary granularity and national leverage. This **sidestepped** the openness and participation demanded by **Article 11 TEU** and **Aarhus**.

d) Redefinition of the GMO legal concept (Directive 2001/18/EC; TFEU Article 191)

The definitional scope was re-engineered to **dilute** the reach of **Directive 2001/18/EC**, placing NGT-1 outside full GMO safeguards. Parliament's shift from "**precise**" to "**targeted**" implicitly recognises that editing methods are **not inherently precise**, yet this linguistic pivot was used to **lower regulatory thresholds** while **forgoing** the **precautionary principle** (**Article 191(2) TFEU**) and the Directive's objective "to protect human health and the environment." This combination **circumvents** existing GMO law and the **CJEU's ruling in C-528/16** (NGT organisms fall under GMO rules).

e) Removal of labelling for NGT-1 (Regulation 1830/2003)

Exempting NGT-1 from GMO-labelling **deprives consumers** of the information necessary for informed choice, contrary to **Regulation (EC) No 1830/2003** (traceability and labelling of GMOs). It also obstructs traceability instruments essential to risk management, undermining **proportionality** and **transparency** (Articles **5** and **11 TEU**).

f) Late insertion of patent provisions — contrary to Parliament's explicit stance (see Part VI)

The starkest indication of undue influence is the late-stage insertion of a patents chapter (analysed in Part VI). This subject was absent from the Commission's original proposal COM(2023) 411 final.

Moreover, the European Parliament explicitly rejected any regulation of patentability within the scope of the NGT Regulation in its adopted position of 7 February 2024 (*Report A9-0014/2024 on plants obtained by certain new genomic techniques; plenary vote T9-0067/2024*). Parliament stated:

"This Regulation should not regulate the patentability of plants obtained by new genomic techniques, as this matter falls outside the scope of Union legislation on genetically modified organisms and must not be introduced through this legislative act."

Despite this unequivocal stance, patent rules nonetheless appeared in the final compromise text — pushed through during the Polish Presidency of the Council, led by representatives of Donald Tusk's government — without public consultation, without renewed Member-State debate, and without any impact assessment.

The manner and timing of this insertion represent a breach of Articles 10–11 TEU (transparency and participation) and Article 5 TEU (subsidiarity), and constitute a clear instance of regulatory capture rather than democratic law-making.

The convergence of timing, content and institutional silence was not an accident. It was meant to pass as "technical correctness".

It would be naïve to assume that such convergence of interests and such timing are coincidental. What was meant to be hidden under a cloak of legal correctness is visible in the structure of the text itself — and it did not escape our notice..

7.4. Final Approval in Parliament and Council (form without scrutiny)

The revised version, as reshaped by the Commission and through closed-door trilogues, then proceeds to formal approval in Parliament and Council. At this stage, many MEPs and Council delegates are either **unaware** of the full extent of late substantive changes or **lack procedural capacity** to challenge them effectively.

Moreover, voting patterns in the European Parliament typically follow political-group lines; individual provisions seldom receive granular debate. In practice, the legislative package is adopted **as a whole**, without detailed scrutiny of the Commission's late insertions and trilogue amendments.

By the formal stage, many MEPs/Council delegates either **lacked visibility** of late changes or the **procedural capacity** to challenge them.[3] Voting proceeded along political-group lines; granular provisions were **not** reopened. The package moved **as a whole**, insulating late insertions from debate — a practice at odds with **Articles 10–11 TEU** and the **Better Law-Making** commitments to transparency and evidence-based scrutiny.

7.5 No Second National Debate (subsidiarity neutralised)

Once the final text was queued for adoption, Member States were not afforded any further legal opportunity to re-examine or influence its content.

- The absence of a second round of national debate meant that parliaments and governments could not intervene in the substance of the act — even when it included material changes never previously subject to consultation.
- Member States were thus obliged to implement a regulation over which they had exercised no substantive influence in its final form.

It must be underlined once again that, in the case of this Regulation, no second national round of consultation took place. National parliaments and governments were prevented from intervening in material changes never consulted before, in breach of Article 5 TEU (subsidiarity) and the Interinstitutional Agreement on Better Law-Making. Member States are therefore compelled to implement a directly applicable act whose final substance they could not meaningfully shape.

8. Legal Characterisation of the Breaches (integrated recap)

From the foregoing factual sequence, the following **violations** emerge — each embedded in the specific manipulations described above:

- **Articles 10–11 TEU & Article 41 CFR; Aarhus**: opacity of process, exclusion of civil society and national fora, absence of renewed consultation on decisive late changes (Sections **2.1, 2.2, 3b–3c, 3f, 4**).
- **Article 5 TEU (subsidiarity/proportionality)**: centralisation by design; removal of second national debate; imposition of directly applicable rules without meaningful Member-State input (Sections **2.2, 3b, 5**).

- **Article 191(2) TFEU & Directive 2001/18/EC**: dilution of GMO scope via redefinition; abandonment of the precautionary approach despite acknowledged imprecision of NGTs; disregard of **C-528/16** (Section **3d**).
- **Regulation 1830/2003**: removal of labelling for NGT-1 undermining traceability and informed choice (Section **3e**).
- **Institutional balance & Parliament's position**: insertion of **patent provisions** contra Parliament's explicit stance and without consultation (Section **3f**, in conjunction with **Part VI – Patents**).

9. Conclusion and Consequences of Procedural Circumvention

The mechanism described constitutes a clear violation of the principles of legislative transparency and democratic accountability. It deprived Member States of the ability to exert meaningful influence over a legal act that directly affects their governance, economies and societies.

In particular, this legislative practice is especially hazardous in domains such as food safety, public health and environmental protection — areas where every legal decision should be preceded by rigorous scientific assessment and broad public consultation.

Such legislative practice is particularly hazardous in domains such as food safety, public health and environmental protection—areas where every legal decision should be preceded by rigorous scientific assessment and broad public consultation.

The absence of democratic oversight in shaping rules for New Genomic Techniques has allowed binding regulations with potentially irreversible consequences to enter the Union's legal order without adequate institutional control or societal acceptance.[9] This approach undermines core rule-of-law principles and erodes the legitimacy of the Union's legislative process. It risks a deep decline in public trust in EU institutions and fuels opposition to the unregulated expansion of biotechnology in agriculture and food production.

This is not mere administrative error. It is serious maladministration, marked by deliberate procedural irregularities and substantive manipulations. Decisive content was re-written behind closed doors, Member-State and citizen participation was neutralised, and a directly applicable act was advanced without the safeguards the Treaties guarantee.

Did those responsible truly assume that these manoeuvres would escape scrutiny—that citizens and independent experts would not detect the contradictions hidden beneath a veneer of legal formality? If so, they were mistaken. We have observed, we have understood, and we have documented these actions with precision.

The integrity of Union law-making requires that such methods be remedied. This Complaint therefore proceeds (in Part VIII) to request the Ombudsman's determined intervention on the strictly procedural and legal grounds identified above.

Citizens' vigilance and independent expertise have exposed what was intended to pass unnoticed. The integrity of Union law-making demands that such methods be named for what they are and that they be stopped.

References to part VII

1. European Commission, *Proposal for a Regulation on Plants Obtained by Certain New Genomic Techniques*, COM(2023) 411 final, Brussels, 5 July 2023.

2. European Food Safety Authority (EFSA), Overview of EFSA and European national authorities' scientific opinions on the risk assessment of plants developed through New Genomic Techniques, EFSA JournalVolume 19, Issue 4, First published: 29 April 2021.
3. European Parliament, *Ordinary Legislative Procedure (Examination by Parliament and the Council)*, OJ, 2023.
4. Court of Justice of the European Union, Case C-528/16 – Confédération paysanne, Judgment of 25 July 2018.
5. European Council, *Interinstitutional Agreement on Better Law-Making*, OJ C 321, 2023; Article 5 TEU.
6. European Parliament, *Position of 7 February 2024 on Plants Obtained by Certain New Genomic Techniques*, Report A9-0014/2024; plenary vote T9-0067/2024.
7. Convention on Access to Information, Public Participation in Decision-Making and Access to Justice in Environmental Matters (*Aarhus Convention*, 1998).
8. Charter of Fundamental Rights of the EU, Article 41 (Right to good administration).
9. Treaty on the Functioning of the European Union, Article 191(2) (precautionary principle).

Respectfully, on behalf of Association *Polska Wolna od GMO*

Paweł Połanecki

PODPIS ZAUFANY
PAWEŁ
POŁANECKI
22.09.2025 11:48:05 [GMT+2]
Dokument podpisany elektronicznie podpisem zaufanym

Jacek Nowak

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