Greenpeace European Unit

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The Commission proposal on the deregulation of “new GMO” plants: an attack on EU law, consumers and farmers’ rights, and on Member States’ right to regulate GMO cultivation.

This memo analyses the Commission proposal on the deregulation of plants obtained via certain new genomic techniques (the NGT proposal)[1] and outlines a number of ways in which the said proposal, if adopted, may be in conflict with the EU treaties and with the general principles of EU law. This memo also shows that the NGT proposal would have a negative impact on the rights of consumers, of farmers and of Member States, respectively by limiting their ability to choose whether or not to consume, produce or allow the cultivation of GMOs.

[1] 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 of 5 July 2023).

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1. The NGT proposal: main elements

The NGT proposal aims at creating a **special legal regime** for a range of **genetically modified plants** (NGT plants) that are obtained via two new **genetic modification techniques**: **targeted mutagenesis** and **cisgenesis**.[2]

As explained in section 2, below, **NGT plants are GMOs** and, therefore, are **currently subject to the provisions of the EU GMO framework**.[3]

There are significant differences between the rules that the NGT proposal would lay out for NGT plants and those contained in the EU GMO framework. If the EU legislators were to approve the NGT proposal as it stands, the GMOs included in its scope **would be significantly, when not entirely, deregulated**.

To fully appreciate the **extent of the proposed deregulation**, it is important to note at first that the NGT proposal divides NGT plants in two categories (*Category 1* and *Category 2*) and that the deregulation will vary depending on the category in which an NGT plant falls:

1. *Category 1* includes NGT plants that are deemed to meet "*criteria of equivalence*" with conventional plants and are therefore fully **excluded from the application of the rules which apply to GMOs in Union legislation.** *Category 1* plants are merely subject to a "*verification procedure*" that aims at establishing the equivalence with conventional plants. They are neither subject to risk assessment and authorisation in view of their deliberate release in the environment or placing on the market, nor they must fulfil labelling or tracking requirements, except for "*plant reproductive material*" (e.g. seeds).
2. *Category 2* includes NGT plants that are not deemed to be equivalent to conventional plants and that are therefore subject to a notification and authorisation procedure. However, the authorisation procedure is based on a **risk assessment** that is **significantly weaker than the one that currently applies under the EU GMO**

[2] This new special legal regime would also apply to:
1. Food containing, consisting of or produced from NGT plants, or containing ingredients produced from NGT plants;
2. Feed containing, consisting of or produced from NGT plants;
3. Products, other than food and feed containing or consisting of NGT plants.

[3] This framework includes: Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC (OJ L 106 of 17 April 2001); Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed (OJ L 268 of 18 October 2003); Regulation No 1830/2003 of the European Parliament and of the Council of 22 September 2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC (OJ L 268 of 18 October 2003), and Regulation (EC) No 1946/2003 of the European Parliament and of the Council of 15 July 2003 on transboundary movements of genetically modified organisms (OJ L 287 of 5 November 2003).

framework. Likewise, the rules on monitoring, traceability and labelling for *Category 2* plants are significantly weakened.

Sections 2 and 3 of this memo point out that NGT plants are GMOs and argue that it is appropriate that they remain submitted to EU GMO rules.

Sections 4 and 5 show that, by deregulating the conditions (i) for the release into the environment of NGT plants and (ii) for the placing on the market of food and feed and other products containing, consisting of or produced from such plants, the NGT proposal violates the precautionary principle as well as the requirements for internal market regulations set out in Article 114 of the Treaty on the Functioning of the European Union (TFEU).

In addition, sections 6, 7 and 8, argue that the NGT proposal:

- Potentially violates the principle of institutional balance, since it delegates to the Commission the power to make decisions on NGT plants that should be reserved to the European Parliament and to the EU Council;
- Impairs the right of farmers (in particular of those producing organic food, but also of conventional ones), to the extent that it does not provide for sufficient protection against the contamination of crops with NGT plants;
- Raises serious doubts on its compatibility with the Cartagena Protocol on Biosafety, an international agreement that regulates the circulation of GMOs across borders between EU and non-EU countries.[4] Indeed, the NGT proposal aims at excluding NGT plants from the application of Regulation No 1946/2003, implementing the Cartagena Protocol in the EU. This would make it possible to transfer GMOs plants from the EU to third countries, without complying with all the requirements laid out by the Protocol.

Section 9 briefly mentions the fact that the NGT proposal also encroaches with the Member States' ability to impose restrictions or to ban the cultivation of GMOs in their territory, which is recognised by Article 26b of the GMO Directive, introduced by Directive (EU) 2015/412.[5]

2. NGT plants are GMOs

As mentioned in the previous section, it is important to bear in mind that **NGT plants are**, from a factual and legal standpoint, **genetically modified organisms** and that they are, at present, fully included in the EU regulatory framework applicable to GMOs.

This stems in absolutely clear terms from Article 3(2) of the NGT proposal, according to which:

[4] https://www.cbd.int/doc/legal/cartagena-protocol-en.pdf
[5] Directive (EU) 2015/412 of the European Parliament and of the Council of 11 March 2015 amending Directive 2001/18/EC as regards the possibility for the Member States to restrict or prohibit the cultivation of genetically modified organisms (GMOs) in their territory (OJ L 68 of 13 March 2015).

" '*NGT plant' means a* ***genetically modified plant*** *obtained by targeted mutagenesis of cisgenesis, or a combination thereof, on the condition that it does not contain any genetic material originating from outside the breeders' gene pool that temporarily may have been inserted during the development of NGT plant"* (emphasis added).

The NGT proposal also clarifies, at Article 3 (3), that the definition of "*genetically modified organism*" in the proposal coincides with the definition used in Article 2(2) of Directive 2001/18/EC (the GMO directive).

According to the first part of this definition,[6] " *'genetically modified organism' (GMO) means an organism, with the exception of human beings, in which the genetic material has been altered in a way that does not occur naturally by mating and/or natural recombination."*

For clarity, "*plants*" are "*organisms*" within the meaning of both the GMO directive (see Article 2(1)) and the NGT proposal, which adopts the same definition of organisms as the GMO directive).[7]

Therefore, when the NGT proposal says, at Article 3(2), that an NGT plant is a "*genetically modified plant*" **it also means that an NGT plant is a "*genetically modified organism*"** for the purposes of EU GMO law.

Notwithstanding this, the regime to which NGT plants are submitted under the NGT proposal radically differs from the EU rules that apply to all other GMOs. Indeed:

- Pursuant to Article 5(1) of the NGT proposal, "*The rules which apply to GMOs in Union legislation shall not apply to category 1 NGT plants*" (**full deregulation**).
- Pursuant to Article 12 of the NGT proposal, "*The rules which apply to GMOs in Union legislation* ***in so far as they are not derogated from by this Regulation****, shall apply to category 2 NGT plants and category 2 NGT products*" (**partial deregulation**).[8]

3. NGT plants, as GMOs, must be submitted to EU GMO rules

The Commission's decision to propose a full (for category 1) and partial (for category 2) deregulation for NGT plants goes against the jurisprudence of the Court of Justice of the European Union (the CJEU).

[6] The second part of the definition contains a reference to the list of techniques, the use of which results in GMOs, and that are listed in Annex IA, part 1 of the GMO Directive. It also contains a reference to the list of techniques, contained in Annex IA part 2 of the GMO Directive, whose use does not result in GMOs for the purpose of the Directive.

[7] In accordance with Article 2(1) of the GMO Directive, "'*organism' means any biological entity capable of replication or of transferring genetic material*". Unquestionably, the definition encompasses plants.

[8] For a short description of category 1 and 2 NGT plants, see Section 1, above.

In its landmark 2018 judgment in the *Confédération Paysanne* case,[9] the CJEU was asked to determine whether GMOs obtained via "targeted" mutagenesis (one of the techniques included in the scope of the NGT proposal) could be assimilated to GMOs obtained via "random" mutagenesis techniques, which are excluded from the scope of the the GMO Directive pursuant to its Annex IB.[10]

The CJEU clarified that plants obtained through "targeted" mutagenesis **are GMOs** and that their inclusion within the scope of the EU GMOs framework is fully justified in light of the characteristics of the techniques used to produce them.

The CJEU stated, at paragraph 47 of the *Confédération Paysanne* judgement, that the techniques of directed mutagenesis "*appeared or have been mostly developed since Directive 2001/18 was adopted*" and that the related "***risks for the environment or for human health have not thus far been established with certainty***" (emphasis added).[11]

The Court went on to say, at paragraph 48, that "***the risks linked to the use of those new techniques/methods of mutagenesis might prove to be similar to those which result from the production and release of a GMO through transgenesis****. It thus follows from the material before the Court, first, that the direct modification of the genetic material of an organism through mutagenesis* ***makes it possible to obtain the same effects as the introduction of a foreign gene into that organism and, secondly, that the development of those new techniques/methods makes it possible to produce genetically modified varieties at a rate and in quantities quite unlike those resulting from the application of conventional methods of random mutagenesis***" (emphasis added).[12]

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[9] Judgement of the Court of 25 July 2018, Case C-528/16, *Confederation Paysanne*.

[10] "Targeted" mutagenesis is defined as a "*Technique that induces specific mutation(s) in targeted locations of the genome without inserting new genetic material*". https://www.efsa.europa.eu/en/glossary-taxonomy-terms. "Random" mutagenesis "*Random mutagenesis refers to the process of introducing mutations to organisms in a random fashion and thus is non-specific. Random mutagenesis involves exposing the organism into a mutagen for a period of time and selecting the mutant varieties. The mutagens can be either physical mutagens like UV radiation or chemical mutagens like alkylating agents*." https://www.differencebetween.com/difference-between-random-mutagenesis-and-vs-site-directed-mutagenesis/

[11] At paragraph 45 of the judgement, the Court recalled that in accordance with Recital 17 of Directive 2001/18/EC the directive "*should not apply to organisms obtained through certain techniques of genetic modification which have conventionally been used in a number of applications and have a long safety record*". These techniques are currently listed in Annex 1B of the GMO Directive.

[12] According to the German Federal Agency for Nature Conservation (BfN) plants produced by both directed mutagenesis and cisgenesis have a similar if not greater risk potential compared to the plants produced by genetic engineering to date. A group of experts and scientists working on the future EU regulation of NGT plants from the perspective of the protection goals of health, the environment and biodiversity issued a statement in December 2023 where they state that it is scientifically incorrect to assume that the risks to health or the environment from NGT plants are generally lower compared to transgenic plants.

Furthermore, continued the Court, "*as stated in recital 4 of Directive 2001/18, living organisms, whether released into the environment in large or small amounts for experimental purposes or as commercial products, may reproduce in the environment and cross national frontiers, thereby affecting other Member States.* ***The effects of such releases on the environment may be irreversible****. In the same vein, recital 5 of that Directive states that the protection of human health and the environment requires that due attention be given to controlling risks from such releases*." (paragraph 49).

In essence, according to the Court, **the risks (or scientific uncertainties) that are inherent in targeted mutagenesis techniques are such that they may not benefit from any derogation from EU GMO rules**, as those provided for by the NGT proposal**.** It is reasonable to assume that the reasoning of the Court can be applied to other NGT techniques, thus requiring that these techniques remain regulated under the current GMO framework.

4. The deregulation of NGT plants violates the precautionary principle

4.1 EU GMO rules and the precautionary principle according to the CJEU

The precautionary principle **is a general principle of EU law, which ensures the protection of the fundamental right to health and of the environment, and whose respect is a condition for the validity of EU secondary legislation** (such as the NGT proposal)**.**

The precautionary principle is expressly mentioned in Article 191(2) TFEU. It is a basic principle laying at the foundation of EU environmental legislation.[13]

The Court of Justice has extended its application beyond environmental law. Therefore, the precautionary principle also applies to all EU measures that can have an impact on public health and safety.[14] The Court also clarified that compliance with the precautionary principle is necessary in view of fulfilling the obligation that binds the EU institutions under Article 35 of the EU Charter of Fundamental Rights, whereby "*a high level of human health protection shall be ensured in the definition and implementation of all Union policies and activities*."[15]

[13] https://eur-lex.europa.eu/EN/legal-content/summary/the-precautionary-principle.html
[14] Judgment of the Court of First Instance of 26 November 2002, Case T-74/100, Artegodan, paragraphs 183 and 184.
[15] Judgement of the Court of Justice of 20 October 2019, Case C-616/17, *Blaise et al.*, paragraphs 41 and 42.

On the basis of its case-law, the Court decided in 2018 that the implementation of the precautionary principle justifies the inclusion of **NGT plants in the EU GMO directive.** In the *Confédération paysanne* case, the CJEU stated as follows:

> *"50 Furthermore, it has been emphasised, in recital 8 of that directive, that **the precautionary principle was taken into account in the drafting of the directive and must also be taken into account in its implementation**. Emphasis is also placed, in recital 55 of Directive 2001/18, on the need to follow closely the development and use of GMOs.*
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> *51 In those circumstances, **Article 3(1) of Directive 2001/18**, read in conjunction with point 1 of Annex I B to that directive, **cannot be interpreted as excluding, from the scope of the directive, organisms obtained by means of new techniques/methods of mutagenesis which have appeared or have been mostly developed since Directive 2001/18 was adopted**. Such an interpretation would fail to have regard to the intention of the EU legislature, reflected in recital 17 of the directive, to exclude from the scope of the directive only organisms obtained by means of techniques/methods which have conventionally been used in a number of applications and have a long safety record[16].*
>
> *52 That finding is supported by **the objective of Directive 2001/18, which seeks, as is apparent from Article 1 thereof, in accordance with the precautionary principle, to protect human health and the environment** when, first, GMOs are deliberately released into the environment for any purpose other than placing on the market within the European Union and, secondly, when GMOs are placed on the market within the European Union as or in products.*
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> *53 As laid down in Article 4(1) of Directive 2001/18, **it is for the Member States to ensure, in accordance with the precautionary principle, that all appropriate measures are taken to avoid adverse effects on human health and the environment which might arise from the deliberate release or placing on the market of GMOs. This implies, in particular, that such deliberate release or the placing on the market may take place only on completion of procedures of assessment of the risks** referred to in part B and part C of that directive respectively. However, as set out in paragraph 48 of the present judgment, **the risks for the environment or human health linked to the use of new techniques/methods of mutagenesis to which the referring court refers might be similar to those which result from the production and release of a GMO through transgenesis**. It follows that an interpretation of the exemption in Article 3(1) of Directive 2001/18, read in conjunction with point 1 of Annex I B thereto, which **excludes organisms obtained by means of techniques/methods of mutagenesis from the scope of that directive,***

[16] It is important to point out, in this regard, that only few new GMOs have reached the market until present. Therefore, it is incorrect to assume that the NGT plants satisfy the requirement set out in recital 17 of Directive 2001/18/EC on the "*conventional use "in a number of applications*" and on the "long safety record".

> ***without any distinctions, would compromise the objective of protection pursued by the directive and would fail to respect the precautionary principle which it seeks to implement***."

Not only is the application of the GMO directive to NGT plants consistent with the Directive's wording and objectives, but, according to the Court, **it is also necessary in view of ensuring the respect of the precautionary principle, which is a general principle of EU law that the GMO directive seeks to implement**.

The Court highlighted, on the one hand, the analogy between the risk profile of NGT techniques (such as targeted mutagenesis) with that of transgenesis and, on the other hand, pointed out that there is a lack of evidence of the safety of those techniques, which is required for their assimilation to the random mutagenesis currently excluded from the GMO rules.

The Court also concluded that it is appropriate for organisms obtained from targeted mutagenesis techniques to be subject to the risk assessment procedures provided for by Directive 2001/18/EC.

4.2 The violation of the precautionary principle

Against the background of the *Confédération Paysanne* ruling, it looks clear that **the NGT proposal violates the precautionary principle,** since **it excludes, in full or in part, GM plants obtained from targeted mutagenesis and cisgenesis from the scope of EU GMO laws**.

Indeed, the NGT proposal fails to address the concerns expressed by the Court on the risk profile of NGT plants. Furthermore, it oversteps the limit that the EU legislator previously agreed, in order to implement the precautionary principle, for the possible exclusion of GM techniques from the GMO directive, i.e. that these techniques *"have conventionally been used in a number of applications and have a long safety record".*[17]

The recitals of the NGT proposal **omit any credible references to the long safety record of applications of directed mutagenesis or cisgenesis**.[18] In recital 7 of the NGT proposal, the Commission justifies the attempt to deregulate GMOs by claiming that the current authorisation procedures and risk assessments would be inadequate and disproportionate for NGT plants[19].

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[17] See: GMO directive, recital 17.
[18] See the reference at footnote 15, above.
[19] This claim is disputed: according to BfN, only a case-by-case analysis as performed under the current legislation can ensure a high safety level. The group of experts and scientists, referred to at footnote 11, above, issued a statement in December 2023 where they expressed the view that the current GMO rules ensure adequate testing for new GMOs, and provide enough clarity and flexibility.

It refers to the difficulties in implementing and enforcing EU GMO law "*for plants obtained by targeted mutagenesis and cisgenesis and related products*" because "***in certain cases**, genetic modifications introduced by these techniques are indistinguishable with analytical methods from natural natural mutations or from genetic modifications introduced by conventional breeding techniques*".

It is clear, however, that removing legal safeguards on account of the difficulties in implementing or enforcing the law would be plainly absurd and unjust.

Further, still in recital 7, the Commission says that "*Union GMO legislation is not conducive to developing innovative and beneficial products that could contribute to sustainability, food security and resilience of the agri-food chain*".

Not only is this statement baseless and biased (EU law does not prohibit research and development: it only aims at ensuring that whatever is researched and developed does not breach EU citizens rights to health and environmental protection). It is also legally irrelevant: the protection of public health and environment cannot be sacrificed for the purpose of helping economic operators creating and marketing new products, particularly since the benefits for the public interest are merely hypothetical[20].

The NGT proposal mentions "*the amount of scientific evidence that is already available*" in particular on the safety of NGT plants[21]. However, the existence of scientific literature on a given subject cannot be used, in the context of the precautionary principle, **to deregulate *ex ante* an entire category of products** and to provide it with a blanket liberalisation measure.

EU law currently foresees that GMOs are authorised on a case by case basis, and after a proper risk assessment. The same approach is used for all other products that may be hazardous for health and the environment, such as pesticides, biocides, pharmaceuticals and chemicals.

This does not imply that pesticides, biocides, pharmaceuticals and chemicals are "banned". This simply means that, in accordance with the precautionary principle, the people and the environment can be exposed to a specific substance or product only when regulators at the EU and the national level have assessed and managed the relevant risks.

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[20] The few new GMOs that have reached the market have failed to deliver societal benefits. Moreover, according to BfN many new GM plants in the pipeline are not engineered for sustainability purposes but to enhance their market value for the agribusiness.

[21] The European Network of Scientists for Social and Environmental Responsibility (ENSSER) warns that older GMO (Bt plants) can in the end raise insecticide use instead of reducing it and that there is no scientifically plausible reason to believe that similar hazard processes may not also occur with the so-called new techniques, e.g. in the form of gene edited insecticidal RNAi plants that can silence genes in other organisms. A review of available data by Testbiotech shows that the cultivation of plants obtained with NGTs, notably camelina and oilseed rape, may put pollinators, such as bees, at risk. BfN has also warned of the potential risks of NGT plants, such as the GABA tomato, engineered for a change in composition for increased GABA content. Excessive accumulation of the GABA neurotransmitter could affect human health.

Recital 3 of the NGT proposal recognises that "*there is ongoing public and private research using NGTs on a* ***wider variety of crops and traits compared to those obtained through transgenic techniques authorised in the Union or globally***".

It is absolutely illogical for regulators to relax safeguards for products that they deem to be growing on the market, but whose implications are not fully clear from the perspective of public health and environmental protection. If the sector or NGT plants were really to be in rapid expansion, that would require an even closer regulatory scrutiny, not a softer one.

5. Potential violation of Articles 114 and 168 TFEU: environmental, health and consumer protection

5.1 The legal basis of the NGT proposal: duty to ensure health, environment and consumer protection

The proposal is based on the following TFEU provisions: Article 43, Article 114 and Article 168(4)(b).

These provisions are also the legal basis for the existing GMO framework. It follows that all the primary law provisions and principles that apply to the general GMO framework are also applicable to the NGT proposal and therefore determine the conditions for its validity.

For the purpose of this briefing, Articles 114 and 168(4)(b) TFEU are particularly relevant:

- Article 114 TFEU is the legal basis for the harmonisation of rules that affect the good functioning of the internal market. This article requires, in particular, that in its proposals the Commission takes as a base "***a high level of protection for health, safety, the environment and for consumers*****"**. Likewise, it mandates the Parliament and the Council to seek to achieve this objective.

- Article 168(4)(b) TFEU is the legal basis for "*measures in the veterinary and phytosanitary fields which have as their direct objective the protection of public health*". Measures adopted on this basis of the article must contribute to the achievement of a "***high level of human health protection***", as foreseen by Article 168(1) TFEU.

These provisions form part of a broader body of EU constitutional law which aims at ensuring that human health and the environment are protected in the implementation of all EU policies.

In particular, Article 35 of the EU Charter of Fundamental Rights requires that "*A high level of human health protection shall be ensured in the definition and implementation of all Union policies and activities*."[22]

5.2. The lowering of health, environment and consumer protection in the NGT proposal

Against this background, it is striking that the Commission is attempting, with the NGT proposal, to **significantly lower the level of protection for the environment and human health** currently provided for by the EU GMO framework, by **removing the obligations of risk assessment and authorisation** (for category 1 NGT plants) and by **minimising the risk assessment** (for category 2 NGT plants).

Under current EU GMO law, the risks for human health and the environment **must be verified on a case by case basis** and the Commission does not make a clear case, from a scientific standpoint, for this safeguard to be reduced.

As the European Network of Scientists for Social and Environmental Responsibility (ENSSER) pointed out in its analysis statement, the equivalence criteria for category 1 plants are scientifically questionable.

ENSSER also points out that the Commission did not properly assess the problem of **unintended genetic modifications**: "*Unintended modifications that are all well documented in the scientific literature and, thus, widely known to occur throughout the genome due to the various processes of genetic modifications (such as transformation processes involved in the insertion of the transgene for CRISPR/Cas DNA cutters) are explicitly excluded from any requirements for detection and analysis. They have become invisible to the regulatory process, despite their known high risk potential*."[23]

It stems clearly from the text of the proposal that the Commission **pursues an objective of administrative simplification for businesses**. Such an objective, however, should not be allowed to prevail over the general interest of the public to health and environmental protection and to justify **lowering of health and environmental safeguards.**

Whereas the CJEU recognises to the legislator a broad margin of discretion when it has to decide on matters that require a complex assessment, **this margin of discretion is not without boundaries**. Indeed, the EU legislator is still required to base its decision on evidence that is "*factually accurate, reliable and consistent*" and that evidence must contain "*all the*

[22] Judgement of the Court of Justice of 20 October 2019, Case C-616/17, *Blaise et al.*, paragraphs 41 and 42.

[23] https://ensser.org/press_release/analysis-statement-by-ensser-on-the-eu-commissions-new-gm-proposal-here-for-annex-1-on-ngt-equivalence-criteria/

information which must be taken into account in order to assess a complex situation" and must be capable "*of substantiating the conclusions drawn from it*".[24]

In particular, it must be noted that decisions based on the precautionary principle must be based on a ***"scientific risk assessment carried out as thoroughly as possible on the basis of scientific advice founded on the principles of excellence, transparency and independence***" in order to "*ensure the scientific objectivity of the measures adopted and preclude any arbitrary measures*".[25]

This must necessarily mean that **excellent, objective and solid scientific evidence is necessary to back the decision of the EU legislator to allow the release of entire categories of GMOs plants into the environment** without risk assessment, or on the basis of a reduced one.

As ENSSER made it clear, the **evidence presented by the Commission in support of the NGT proposal is plainly inadequate**.[26] This means that, if they were to approve such a proposal, the European Parliament and the Council would breach the requirements of Article 114 and 168(4)(b) TFEU and that the new NGT regulation may be found invalid.

In addition to lowering the protection for health and the environment, the NGT proposal undermines consumer protection. Indeed, Article 19(3)(e) of the GMO directive requires products containing GMOs to carry a label clearly stating that a GMO is present ("*This product contains genetically modified organisms*").

Instead, Article 10 of the NGT proposal limits labelling requirements for category 1 NGT plants to "*reproductive material*" (e.g. seeds, roots or tubers).

Removing labelling requirements for products containing category 1 NGT plants has, beyond doubt, a negative impact on consumers' right to know what they are buying and to choose what to consume.

At no point does the NGT proposal bring clarity on how this removal of safeguards for consumers can be justified, except with supposed difficulties in implementation or enforcement (which cannot be, in any case, used as an excuse to lower public health and environmental protection standards).

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[24] Judgement of the Court of 15 February 2005, Case C-12/03 P, *Commission v Tetra Laval*, para. 39. This case refers to the limits of discretion in the decision of competition cases However, its reasoning related to the institutions' margin of appreciation can be (and has been) applied to matters governed by the precautionary principle and involving the regulation of risk.

[25] Judgement of the Court of First Instance of 11 September 2002, *Pfizer Animal Health*, T-13/99, paragraph 172

[26] See footnote 23, above.

What is clear, instead, **is that the NGT proposal lowers the level of consumer protection**, in breach of the requirements laid out in Article 114 TFEU.

6. Violation of the principle of institutional balance

Not only does the NGT proposal remove, for category 1 NGT plants, the many important safeguards that EU law imposes on the release of GMOs into the environment. It also attempts **to devolve to the Commission the decision on the criteria for NGT plants to be considered "equivalent" to conventional ones.**

Indeed, according to Article 5(3) of the NGT proposal, the Commission would be "*empowered to adopt delegated acts (...) amending the criteria of equivalence of NGT plants to conventional plants (...) in order to adapt them to scientific and technological progress as regards the types and extent of modifications which can occur naturally or through conventional breeding.*"

This provision means that the Commission could, via delegated act, decide on further deregulation of GMOs by extending the scope of category 1. This is highly problematic, taking into account that the current criteria of equivalence are far from scientifically sound.

In addition, it is **also an issue from the perspective of the EU institutional balance**.

Indeed, in accordance with Article 290(1) TFEU:

> *"A legislative act may delegate to the Commission the power to adopt non-legislative acts of general application* ***to supplement or amend certain non-essential elements of the legislative act****.*
>
> *The objectives, content, scope and duration of the delegation of power shall be explicitly defined in the legislative acts.* ***The essential elements of an area shall be reserved for the legislative act and accordingly shall not be the subject of a delegation of power****.*"

It is absolutely clear that **the criteria under which a GMO plant may be deemed to be equivalent to a conventional plant do not qualify as "*non-essential elements"*** of the NGT proposal. Indeed, they directly determine the scope of the GMOs deregulation and are therefore essential elements of that proposal.

As discussed in the previous sections, removing entire categories of NGT plants from the scope of EU GMO law poses serious issues of compatibility with the precautionary principle and with Articles 114 and 168 TFEU.

In addition, as seen in this section, the principle of the EU institutional balance of the EU, as reflected in Article 290(1) TFEU, is also breached by Article 5(3) of the NGT proposal, insofar as it aims at empowering the Commission to make decisions that should only be reserved to the European Parliament and to the EU Council.

7. Violation of the right to property and to the freedom to conduct a business

The use of NGT plants and products is incompatible with organic production. Articles 5(f)(iii) and 11 of the Organic regulation apply to both category 1 and 2 NGT plants.[27] This emerges clearly from Article 5(2) of the NGT proposal, as regards category 1 NGT plants, and is implicit in the fact that no rule, in the proposal, excludes category 2 NGT plants from the provisions of the Organic regulation.

In practice, however, the absence of labelling and traceability requirements for category 1 plants means that the rights of consumers and of producers of organic food to know that organic food is not contaminated by NGT plants is severely impaired.

Besides the evident disruption of the framework for organic agriculture, the NGT proposal risks also to entail a violation of the individual rights of organic farmers, notably their fundamental rights to property and the freedom to conduct a business, which are respectively protected by Articles 16 and 17 of the EU Charter of fundamental rights and by Article1 of Protocol 1 of the European Convention on Human Rights.[28]

Indeed, unless labelling and traceability are imposed on **all GMO plants**, organic farmers are unduly burdened with additional significant costs, in order to demonstrate to regulators and to consumers that their production is entirely GMO-free.

This, in turns, determines an important loss in the value of their investments and activities, as well as a potential loss in terms of market value for their products. All of this takes place in the absence of compensation and of any clear public interest that would support the limitation of the property right.

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[27] In accordance with Article 11(1) of Regulation (EU) 2018/848, "*GMOs, products produced from GMOs, and products produced by GMOs shall not be used in food or feed, or as food, feed, processing aids, plant protection products, fertilisers, soil conditioners, plant reproductive material, micro-organisms or animals in organic production*".

[28] Article 16 of the Charter states that "*The freedom to conduct a business in accordance with Union law and national laws and practices is recognised*". In accordance with Article 17 of the Charter *"No one may be deprived of his or her possessions, except in the public interest and in the cases and under the conditions provided for by law, subject to fair compensation being paid in good time for their loss. The use of property may be regulated by law in so far as is necessary for the general interest.*" Under Article 1 of Protocol 1 to the ECHR, "*Everyone has the right to own property and use its possessions. No-one shall be deprived of his property unless public necessity so demands. If so, the State must guarantee fair compensation.*"

The same problem affects also conventional farmers and food producers that, in order to gain consumers' trust, commit to avoid the use of GMOs in their products.

8. Violation of the Cartagena Protocol

The EU is a party to the Cartagena Protocol of 29 January 2000. The Cartagena Protocol "*is an international agreement which aims to ensure the safe handling, transport and use of living modified organisms (LMOs) resulting from modern biotechnology that may have adverse effects on biological diversity, taking also into account risks to human health*".[29]

It establishes "*an advance informed agreement (AIA) procedure for ensuring that **countries are provided with the information** necessary to make informed decisions before **agreeing to the import of such organisms into their territory***". Hence, the Cartagena Protocol protects the right of a country to decide whether GMOs may, or may not, be imported in their territory, in accordance with a precautionary approach.[30]

Pursuant to Article 216(2) TFEU, the Cartagena Protocol is binding on the EU and, as all international agreements to which the EU is a party, it prevails over EU internal legislation.[31] This means that a piece of EU legislation that breaches international agreements would also also be in breach of Article 216(2) TFEU. This would be the case for the NGT proposal, if approved.

The EU has implemented the Cartagena Protocol in the EU legal system by adopting Regulation (EC) No 1946/2003. This regulation sets out the rules and the procedures that allow for the "AIA procedure" to take place when GMOs are exported from, or imported into, the EU.

The **NGT proposal entirely excludes Category 1 NGT plants from the scope of Regulation (EC) 1946/2003**. Not only this means that the circulation of new GMOs would be deregulated within the EU, but also that GMOs could be exported and released in the environment of third countries without the safeguards provided for by the Cartagena Protocol.

This would put the EU in breach of its international obligations, and determine the invalidity of the NGT proposal, if approved in its current state.

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[29] https://bch.cbd.int/protocol/background/

[30] https://bch.cbd.int/protocol/background/

[31] Article 216(2) TFEU says: "*Agreements concluded by the Union are binding upon the institutions of the Union and on its Member States*".

9. Limitation of Member States' freedom of choice on the cultivation of GMOs in their territories.

A final aspect of the NGT proposal that needs appropriate consideration is the fact that it makes Article 26b of the GMO directive inapplicable to both Category 1 and Category 2 NGT plants.

Article 26b was introduced in the GMO directive by Directive (EU) 2015/412. It establishes a procedure that allows Member States to restrict or ban the cultivation of GMOs in their territory.

The NGT proposal would deprive Member States of an essential right to decide on the use of their land and on the development of their agricultural policies, forcing them to accept the cultivation of GMOs on their territory even if, since almost ten years, EU law has established the principle that national authorities must be left free to decide.