Forschungsstelle für Europäisches Umweltrecht

FEU RESEARCH PAPER NO. 18/2024

THE EUROPEAN UNION'S DEREGULATION OF PLANTS OBTAINED FROM NEW GENOMIC TECHNIQUES: A CRITIQUE AND AN ALTERNATIVE OPTION

Prof. Dr. Gerd Winter

Universität Bremen

Forschungsstelle für Europäisches Umweltrecht

Arbeitspapier Nr. 18

Impressum

Herausgeber/Redaktion: **Forschungsstelle für Europäisches Umweltrecht**

Universität Bremen

Universitätsallee, GW 1

28359 Bremen

Bildnachweis: **Universität Bremen**

Bremen, im Februar 2024

Preprint. Under review of Environmental Sciences Europe

The European Union's deregulation of plants obtained from new genomic techniques: a critique and an alternative option

Gerd Winter[1]

Abstract

The EU is about to relax its oversight of genetically modified organisms, focusing on plants and products that are obtained through certain new genomic techniques. The aim is to promote new genomic techniques as an innovative technology and employing it as a means to transform agriculture to sustainability. The present contribution describes and evaluates the planned reform. It discusses whether standards of legal certainty and legitimacy are met, how environmental side-effects are taken into account, how sustainability goals are integrated, what socio-economic effects are to be expected, and whether higher rank law is respected. As several shortcomings are found an alternative approach is submitted that combines a certain easing of administrative oversight with better integration of sustainability goals. Auspices for organic and conventional GMO-free agriculture are also sketched out.

Keywords: New genomic techniques, risks for human health and the environment, sustainability benefits, precaution, regulatory oversight

Introduction

Various legal acts of the European Union (EU) regulate contained uses and the release and bringing on the market of what is defined as genetically modified organisms (GMOs). The approach is to require a prior notification and, with exemptions, an authorization based on an assessment of risks for human health and the environment. The Member States are in principle responsible for the authorization procedure while for food and feed, including seeds, the EU Commission takes the final decision. Due to controversies about risk assessment and management the procedures have been costly and lengthy, in particular concerning genetically modified seeds. While many modified varieties of food and feed have been accepted for consumption none but one has by now been authorized for cultivation, with some Member States opting out. This has led many scientists and agricultural organizations to push for deregulation. The upcoming new genomic techniques were used as a leverage. While the existing regulation originated in the concern that artificial genetic engineering was different from natural and traditional breeding, especially if genes (called transgenes) were transferred between varieties, the new techniques were considered not to be different because (and if) modifying genomes within a variety. It was assumed that the resulting modified organisms could as well emerge from natural processes.

As a first move opponents strived to remove the new techniques from the scope of application of the established GMO regime. It was argued that the mutation exemption which was so far only reserved for untargeted techniques should also (and all the more) be applied to targeted mutations. However, the European Court of Justice (ECJ), referring to the precautionary principle, held that the risks linked to the new techniques are similar the those of transgenesis so that new techniques fall within the scope of application of the current GMO regime.**[21]**

As a second move opponents pleaded for establishing a special regime for plants and products derived from what is defined as new genomic techniques (NGT). As the rise of those techniques

[1] Professor em. for Public Law, Forschungsstelle für Europäisches Umweltrecht (FEU) University of Bremen. I would like to express my sincere thanks to the biologists Dr. Wolfram Reichenbecher, Federal Agency for Nature Conservation, and Christof Potthof for in-depth exchange and expert assistance. Of course, any remaining errors and misunderstandings are my own.

coincided with the climate crisis the deregulation could be framed as an opportunity and even imperative to promote the sustainability of agriculture. **[12]**

On this background the European Commission published a proposal that provides for certain easements of the current control regime for plants obtained by certain new genetic techniques (NGT). **[14]** The proposal was forwarded to the European Parliament (EP) and Council of the EU. The EP adopted its opinion **[17a]** on the basis of the report of its Committee on the Environment, Public Health and Food Safety (ENVI) **[17]**. The Council debated the proposal on the basis of a compromise paper **[4]** but has not yet formed the necessary qualified majority for it.

My comments will bear on the Commission proposal but include the main changes proposed by the EP. Articles, recitals and annexes cited without naming the source refer to the Commission Proposal.

NGT plants are defined as plants that have been modified by targeted mutagenesis or cisgenesis, targeted mutagenesis being defined as mutagenesis techniques resulting in modification(s) of the DNA sequence at precise locations, and cisgenesis as genetic modification techniques resulting in the insertion of genetic material already present in the breeder's gene pool (Art. 3 (4) and (5)). This implies that the use of CRISPR-Cas or other new techniques for the introduction of genetic material from a non-crossable species remains within the traditional GMO regime.

In newly established procedures it must be verified whether a plant is obtained by NGT. NGT are divided into two classes, one entailing less and the other more modifications, named category 1 NGT and category 2 NGT, respectively.

Category 1 NGT plants and products (here abbreviated as NGT 1 plants and NGT 1 products) are almost entirely exempted from further controls. They do not require authorization for deliberate release or the bringing on the market, risks for human health and the environment are not to be assessed, requirements of coexistence with non-GM agriculture are abandoned, as are opting out possibilities of Member States. Monitoring obligations are curtailed. Labelling as genetically modified is cut back. At least, a public data base listing NGT 1 plants is established.

Category 2 NGT plants and products (here abbreviated as NGT 2 plants and NGT 2 products) remain subject to the current regime for genetically modified organisms (GMOs), but with somewhat relaxed risk assessment, shortened timelines, reduced monitoring and certain incentives towards steering genetic modifications to more sustainability. Opting out by Member States is excluded also in relation to NGT 2 plants.

While the two aims of the proposal – simplification of procedures and sustainable agriculture - are commendable it is nevertheless useful to find out whether the aim will really be achieved, and whether it may come at the cost of other concerns. I will try such analysis taking different perspectives, including on legal certainty (I.), legitimacy and subsidiarity (II.), the avoidance of environmental risks (III.), the integration of sustainability criteria (IV.), concerns about socio-economic effects (V.), and compatibility with higher rank legal standards (VI.). In conclusion an alternative concept will be sketched out (VII.).

Being a policy brief the comments will be of a summary style.

I. Legal certainty

Legal certainty means that legal rules must be formulated so that the interested and concerned actors can know what they are required to do or omit.

1. Important terms are elusively defined.

- The distinction between GMOs and NGT plants is unclear. Art. 3 (2) defines NGT plants as genetically modified organisms (GMOs) such that NGT (targeted mutagenesis and cisgenesis) are subcategories. In contrast, Art. 3 (3) defines GMO excluding NGT from the term GMO which means that NGT are sui generis. The difference has formal consequences, i.e. whether the GMO legal acts are applicable with exceptions or not applicable from the outset, but it also has communicative effects, i.e. whether NGT plants can be called GMOs or not when brought to the market or discussed in public discourses.
- Mutagenesis, a core term delimiting the scope of the deregulation is left undefined although highly controversial in science and law.
- The term "New Genetic Techniques" (NGT) (Art. 3 (4)) is misleading, because "new" refers to a point in time, whereas it actually refers to something factual, namely techniques that differ from those techniques that belong to the scope of the existing GMO Regulation. A term that describes the substance of this difference would be better to comprehend.
- Although equivalence of NGT-plants to conventional plants is a major reason for the entire deregulation the term is nowhere defined. Annex I breaks it down to concrete criteria but a general rule giving guidance is lacking.
- While the proposal frequently invokes sustainability as a potential achievement of NGT (Recitals 3, 7, 10, 33, 37, 40, 43, 46) its operational rules refer to criteria listed in Annex IIII without establishing a rule that guides the choice. It seems this shall be sustainability but the term only appears as heading of Art. 22 and orientation for Commission delegated Regulations (Art. 22 (8)). Considering that sustainability has become a catch all for any interest legal certainty would require an appropriate term and comprehensible definition of the same.

2. There are inconsistencies of the new regime with other regulatory schemes and competences.
   - It is unclear whether the environmental risk assessment (e.r.a.) for NGT II plants that is sketched out in Annex II shall replace the much more elaborate e.r.a. in Annex II of Directive 2001/18/EC, or if it shall contain specifications (which however are not indicated). It is therefore unclear if the ambitious principle laid out in chapter A of Annex II of the Directive still applies. It reads: “The objective of an e.r.a. is, on a case by case basis, to identify and evaluate potential adverse effects of the GMO, either direct and indirect, immediate or delayed, on human health and the environment which the deliberate release or the placing on the market of GMOs may have.”
   - It is unclear whether the proposed Regulation shall contain an exhaustive harmonization leaving no space for national measures aiming at a higher level of health and environmental protection. ENVI proposed an Art. 11a that should make this explicit, but this was not subscribed by the EP.
   - According to the EP Opinion NGT plants and products shall have access to the EU market if they “meet the same standards as those laid down in this Regulation” (Art. 3 (1a of the EP Opinion). It is unclear if this means that such plants and products are freed from the verification requirement for EU internal plants and products.
   - Art. 4a of the EP Opinion provides that NGT plants and processes shall not be patentable. This is hardly compatible with Art. 53 (b) of the European Patent Convention which accepts as exception only “plant or animal varieties or essentially biological processes for the production of plants or animals”, a provision that is resounded by Art. 4 Directive 98/44/EC **[8a]**. NGT may have to be qualified as not being “essentially biological processes”. However, the issue is more fundamental touching also upon genetic modification techniques and products that are not covered by the proposed deregulation.

3. The administrative procedures are multiplied. Although aiming at simplification they may even further complicate the gene technology regime, possibly feeding lawyers rather than the people. The following procedures will have to be distinguished:
   - Verification of NGT 1 property of plants and products prior to a deliberate release

- Verification of NGT 1 property of plants and products prior to a placing on the market
- [No authorization of the deliberate release or placing on the market of NGT 1 plants and products needed]
- Verification of NGT 2 property of plants and products prior to deliberate release (integrated in authorization procedure for deliberate release)
- Verification of NGT 2 property of plants and products other than food and feed prior to placing on the market (integrated in the authorization procedure for the placing on the market)
- Verification of NGT 2 property of plants for food and feed and of food and feed (integrated in the authorization procedure for the placing on the market)

4. Tight procedural deadlines are set that disrespect the frequent lack of personal and technical administrative resources creating the risk of arbitrary or negligent verification of the NGT status.
   - The deadlines in pre-release verification procedures for NGT 1 plants are short: 30 working days for the review report (Art. 6 para 6), 20 days for comments by the Commission and other Member States (Art. 6 para 7), 10 days for the decision (Art. 6 para 8), 45 days for the Commission and EFSA, if MS made comments (Art. 6 (10). An extension is not foreseen.
   - In the pre-marketing verification procedure for NGT 1 plants EFSA has working 30 days to deliver its statement and the Commission 30 more working days for its draft decision with no possibility of prolongation (Art. 7 paras 5 and 6).
   - In the pre-marketing verification procedure for NGT 2 plants for food and feed EFSA must prepare its opinion within 6 months as from the receipt of a valid application. An extension is only possible if additional information is deemed necessary (Art. 20 para 1).

II. Legitimacy and subsidiarity

Legitimacy means that public authorities should exert powers entrusted to them in transparent, participatory and democratic ways. Subsidiarity means that good reasons must be given if a competence shall be levelled up from Member States to EU institutions.

1. In the NGT 1 plant verification procedures public participation is disabled.
   - In the pre-release verification procedure, no publication of application documents and review reports is foreseen. The EP at least proposes that any reasoned objections submitted by MS shall be made publicly available (Art. 6 (9) EP Opinion). According to the Commission Proposal only the decision of the competent national authority and the draft decision of the Commission are to be published (Art. 6 (11)).
   - While in the pre-market verification procedure the application and EFSA's opinion are published (Art. 7 (3) and (5)), this does not happen if the verification is omitted because it has already taken place before a release. It can therefore occur that an NGT 1 plant is brought to the market without prior publication of the verification documents.
   - Even insofar as the application and EFSA's opinion are to be published, the public is not given the opportunity to comment.

2. Access to information on whether the verification requirements of NGT plants are met is cut back in favor of trade secrets.
   - Confidentiality is enabled, among other items, with regard to DNA sequence information and breeding strategies (Art. 11 (3) (b) and (c)), although those are essential to be known by third parties intending to assess the verification.
   - It is commendable that a publicly accessible database listing the decisions about NGT 1 plant status is foreseen. However, it will not contain the relevant DNA sequences, but only a description of the traits and characteristics introduced or modified in the plant (Art. 9).

3. The Commission is empowered to set far-reaching sub-legislative standards.
   - The Commission is empowered to adopt delegated acts with regard to the criteria of equivalence of NGT plants with conventional plants (Art. 5 para. 3 with Annex I) as well as with regard to the sustainability characteristics that give rise to facilitated procedures (Art. 22 para. 8 with Annex III). These delegations of powers can lead to a far-reaching expansion of what is considered equivalent and sustainable.
   - The Commission may adopt implementing acts on the methodology and information requirements for the environmental risk assessment (e.r.a.) of NGT 2 plants and products, including food and feed (Art. 27 lit. c)). This e.r.a. can (but should not) be understood to replace the e.r.a. for traditional GMOs as laid down in Annex II Directive 2001/18/EC **[8]**. If so, it appears as very far-reaching that the EU and MS executive branches are empowered to design the core instrument of risk assessment.

4. Deviating measures or opinions of Member States are largely prevented or overruled.
   - The previous compromise line that Member States may prohibit the cultivation of authorized seed for certain reasons (so-called opting-out, Art. 26b Directive 2001/18) is abolished both for NGT 1 plants (Art. 5 para. 1) and NGT 2 plants (Art. 25).
   - The decision in the pre-release verification procedure of NGT 1 plants shall be taken by one Member State with binding effect for all Member States in which the applicant intends to release the plant. While this procedure is not unknown in EU regulatory schemes it is crucial that other Member States have the opportunity to submit their objections. This is indeed foreseen in Art. 6 (7) but according to the EP opinion the objection must include a scientific justification (Art. 6 (7) of the EP opinion) which may be interpreted to exclude evaluative arguments concerning equivalence or sustainability.
   - In case of objections in the NGT 1 verification procedure the decision on the NGT status moves up to the Commission with prior consultation of the EFSA (Art. 6 para 9, Art. 7 para 6). This decision is taken in the advisory committee procedure **[11]**, which means that the Commission can overrule any objection of Member States (Art. 6 para. 10, Art. 28 para. 2).
   - Such overruling is also enabled when the Commission decides in the pre-market verification procedure for NGT 1 plants and products.

III. Environmental risks

1. The deregulation of NGT 1 plants and products extends to an extremely broad range of organisms without requiring any assessment of risks to human health and the environment.
   - The term "breeders' gene pool" (Art. 3 No. 6, or "gene pool for conventional breeding purposes", as proposed by the EP (Art. 3 (6) of the EP opinion) is apparently intended to mark the realm of targeted mutagenesis/cisgenesis in distinction to transgenesis. This realm is broadly extended to include the entire genetic information of other taxonomic species with which cross-breeding can take place or be brought about by means of advanced techniques, including those that are invented in the future.
   - NGT 1 plants shall be distinguished from NGT 2 plants by being considered equivalent to conventional plants (Art. 3 No. 7 a with Annex I). "Equivalence" is not abstractly defined but broken down to specific criteria. The Commission and the EP have diverging suggestions in that regard:
     - According to the Commission Proposal equivalence is assumed if the NGT plant differs from conventional plants by no more than 20 genetic modifications. As genetic modifications are mentioned, among others: Substitution, insertion, deletion and inversion of nucleotides. In the case of substitution and insertion, the modification is limited to 20 nucleotides. However, it can occur 20 times, i.e. affect as many as 400 nucleotides. In the case of a deletion or inversion the number of affected nucleotides is even unlimited. (Annex I)

    - The EP proposes another limit for modifications which shall be three per any protein-coding sequence (Annex I of the EP Opinion). This is in reaction to the fact that an absolute limit across all species does not factor in the polyploidy of some. It is however unclear if the limit of 20 modifications still applies. The proposal has more criteria to offer but they are hard to understand. In any case the approach remains to be quantitative which does not reflect the different qualitative effects of genes.
- Equivalence is based on sequence similarity between the targeted site and the conventional plant, without defining what similarity means. Moreover, the similarity shall be predictable using bioinformatic tools, which is a constraint compared to a direct and comprehensive comparison of the genome sequences of the NGT plant with the recipient/parent plant.
- NGT 1 plants are defined as not only those that meet the equivalence criteria, but also their progeny, including the progeny derived from crossing with other NGT 1 plants (Art. 3 No. 7 b). This means that a few recognized NGT 1 plants can give rise to a large number of plants that are defined as NGT 1 without being further verified.
- The Regulation applies not only to annual arable plants but to all terrestrial plants, including trees, grasses, wild herbs and mosses, as well as various algae, which extends the scope to an enormous variety of plants and non-agricultural ecosystems (Art. 2 (1) and recital (9). A minority in ENVI proposed to confine the scope to arable plants but the majority rejected this. **[17]**

2. The Regulation is based on several untenable scientific assumptions about risks to human health and the environment.
    - The deregulation of NGT 1 plants is based on the assumption that a small quantity of changes poses little or no risk. However, a small number of sequence changes can modify entire genes and their functions and thus have significant intended and unintended effects. **[1]** This is particularly true if a regulator gene is modified. For instance, the nakedness of kernels, a major phenotype difference between maize and its origin, teosinte, was caused through the modification of a single acid. **[37] [34]** While in this case the modification resulted from natural breeding, genome editing was applied in the case of the monarch fly which developed resistance against toxic plants through the modification of just three nucleotides. **[28]**
    - "Targeted mutagenesis" (Art. 3 No. 4) is defined as a mutagenesis technique resulting in the modification(s) of the DNA sequence at precise locations in the genome of an organism. More correct would be the term sequence-specific mutagenesis, because the procedure is specific to DNA sequences and not to targeted locations in the genome. **[6]**
    - It is assumed that the targeted nature of NGT excludes the possibility that unintended traits are caused. This is incorrect for various reasons. **[30] [38]**
    - The distinction between NGT plants and plants from traditional breeding is based on differences at the level of nucleotides alone (Art. 3 No. 1). In fact, the properties of a plant, and thus also its risks and benefits, do not result from its genotype alone. Rather, the phenotype, as a totality of properties, is formed from the genotype in interaction with the environment in which a plant grows. **[29]**
    - The Commission proposal repeatedly contrasts genetic engineering interventions involving the transfer of genes foreign to the species (transgenesis) with targeted mutagenesis and cisgenesis in which no transgenes are transferred **[13]** (Recitals nos. 2, 3, 9 and 12). However, this difference of interventions does not result in any fundamental difference in relation to risks and benefits. Targeted mutations and cisgenesis can also generate harmful properties, while the introduction of transgenes may under circumstances pose negligible risks.
    - It is disregarded that new genetic engineering methods (such as CRISPR/Cas) are often combined with old genetic engineering methods. **[5]** This poses the question whether the resulting organism is then nevertheless to be classified as NGT.

- The recitals repeatedly express confidence that the application of NGT to plants is always directed towards sustainable goals (recitals 3, 7, 10 and 37). This ignores the fact that changes can also be arbitrary, abusive or deliberately harmful.

3. Allegedly, NGT plants cannot be distinguished from those resulting from natural mutations and therefore do not justify a specific control regime (recital 14). This must be refuted.
   - Certain areas in the genome of an organism can be protected against natural changes while with targeted mutagenesis such as CRISPR/Cas the entire genome becomes amenable to change on a larger scale compared to random genesis or conventional breeding. Inversely, some genome regions in organisms are naturally protected by mechanisms that cannot be overcome by certain NGT. **[29]**
   - Natural modifications have more potential for risk avoidance precisely because of their slower development. They may have already proven themselves or were eliminated in practice. **[6]**
   - Remarkably the ECJ stated in this regard "that the development of these new processes/methods makes possible the production of genetically modified varieties at a disproportionately greater pace and to a disproportionately greater extent than the application of traditional methods of random mutagenesis". **[21]**
   - It is not to be expected that in plants from conventional breeding all copies of a gene are altered and coupled genes are individually altered. NGT can therefore produce genotypes that are not to be expected in nature. **[6]**
   - It is a naturalistic fallacy to believe that no risks can arise from "targeted" mutations because they could also have arisen naturally. Natural mutations can also be associated with risks. **[24]**
   - Difficulties in detecting changes in the modified plant are not a sufficient reason for not imposing requirements. If the genetic modification cannot be detected in the product, risk hypotheses can only be formulated on the basis of the modifications themselves. After all, the equivalence of NGT plants with plants from conventional breeding is examined on the basis of the genetic engineering methods used rather than of the resulting plants and their products (Art. 6 and 7).

4. Powers of administrative bodies to intervene in cases of risks to human health and the environment are abolished with regard to NGT 1 plants.
   - During the verification procedure for NGT 1 plants no risk related information must be submitted, nor are any risks assessed. ENVI rejected a minority proposal suggesting that the verification procedure should also involve a – possibly somewhat limited - risk assessment (ENVI 2024 Art. 6 para 3 lit. ea).**[17]**
   - Administrative authorities are not required to intervene if - in ignorance of or in order to circumvent the law - NGT 1 plants or products are released or marketed without the NGT 1 or 2 status having been applied for and declared.
   - Administrative authorities are not empowered to intervene if - contrary to the assumption that NGT 1 plants are safe - risks to human health or the environment nevertheless arise. The EP proposes to empower the competent authorities to withdraw the decision on the NGT status (Art. 11a). However, more appropriate than removing the NGT status would be powers directed at abating the risks.
   - Powers to intervene do exist outside gene technology law, such as in seed, food and feed law, but without adequate focus on harmful environmental effects. **[36]** It could be argued that absent related harmonization the competence to regulate such intervention falls back to the Member States.
   - A safeguard procedure as provided for GMOs by Article 23 of Directive 2001/18 is excluded for NGT 1 plants and products (Art. 5).
   - If an NGT 1 plant has been determined to be equivalent in the pre-release verification

procedure according to Art. 6, no further verification is required for the placing on the market (cf. Art. 7 para 1). Any knowledge potentially gathered from the trials of deliberate release are not taken up although the plant may have had different effects in different regions or environments where it was released. In contrast, such learning potential is engaged by means of the "step-by-step principle" in the current GMO Regulation (Recitals 23, 24 of Directive 2001/18/EC).

5. Monitoring obligations of the operator are eliminated or reduced.
   - The release and placing on the market of NGT 1 plants and products is exempted from the submission and observance of monitoring plans that are required for GMOs according to Art. 14 and 19 Directive 2001/18/EC. In contrast, the EP proposes that in the pre-market verification procedure a monitoring plan must be submitted (Art. 7 (2) (da) EP Opinion). However, no provision is foreseen empowering the competent authority to make the plan obligatory.
   - The submission and ordering of a monitoring plan for the placing on the market of NGT 2 plants and products is largely based on the applicant's perceptions (Art. 14 para. 1 lit. h), Art. 19 para. 3 lit. b)).

IV. Integration of sustainability criteria

1. Allegedly, the new genomic techniques would provide benefits for the environment and guarantee solutions for the mitigation of and adaptation to climate change (Recitals 3, 10, 43, and 46). However, although beneficial effects to that purpose have already been predicted for decades, this has by now not have convincing success.
   - The only current example in the EU is the modified maize MON 87427 × MON 87460 × MON 89034 ×MIR162 × NK603. Its producer, Monsanto, claimed that the GMO was drought tolerant. But the competent authority (ESA) did not require the firm to test it under extreme conditions. Upon recourse by the NGO TestBioTec the EU General Court accepted it to be sufficient to prove whether “the geographical locations, soil characteristics and meteorological conditions of the sites at issue were typical of receiving environments where the test materials could be grown.” **[23]**

2. Sustainability criteria are used as a reason for the further easing of control rather than for instigating related technology development.
   - The envisaged deregulation of NGT 1 plants (Art. 5) is not made conditional on sustainability objectives being pursued.
   - With regard to NGT 2 plants, there is no requirement that they actually pursue sustainability goals. Only certain procedural facilitations are provided for.
   - There is a lack of requirements for the submission of information on whether and how the sustainability criteria are met.

3. The sustainability criteria listed in Annex III are not entirely orientated towards ecological innovations.
   - Several criteria are fairly traditional, such as “yield”, “sustainability of storage, processing and distribution”, and “improved quality or nutritional characteristics”.
   - More reference to ecological concerns is visible in the criteria “yield under low input conditions”, “tolerance/resistance to abiotic stress factors, including those created or exacerbated by climate change”, “efficient use of resources”, “reduced need for external input such as plant protection products and fertilizers”, as well as – remarkably – the disqualification of tolerance to herbicides. However, it is sufficient that the applicant uses a single sustainability criterion, such as simply the least ecological one, namely the increase in yield. In contrast the EP proposes that yield shall only count if the modification

also contributes to the ecological criteria (Annex III Part I (1) point 1 EP Opinion).

- Furthermore, it remains open whether in the case of resistance to biotic and abiotic stresses a claimed ecological contribution is expected to be maintained in the long term.
- Insofar as the criteria, such as stress resistance, relate to climate change, they are only geared towards adaptation, not mitigation.
- Single stress resistances that are currently under development can hardly do justice to the multiple and simultaneous impacts of climate change such as storms, drought and floods.
- Overall, the modification objectives in Annex III refer to isolated/individual plant traits and are not geared towards innovative and organic land management.

V. Socio-economic effects

1. The proposal apparently assumes that only highly industrialized agriculture can satisfy the hunger of the growing world population (Recital 3). **[13]** In contrast, there is scientific evidence that such trajectory endangers natural resources in the long term. **[32]**

2. Allegedly, NGT plants could deliver benefits to farmers and consumers (Recital 3). In fact, however, the entire business model of the GMO-free agriculture is undermined. Farmers, traders and consumers who suspect that NGT 1 plants and products pose risks to human health or the environment are deprived of relevant information and access to GMO free products.
   - The coexistence of cultivation and products with and without GMOs as provided by Art. 26a Directive 2001/18/EC is abandoned for NGT 1 plants and products. Member States are not anymore entitled to take related measures. The supportive role the Commission was mandated to play is given up. In consequence, NGT 1 plants can be cultivated close to the fields of NGT-free agriculture, which entails the possible contamination of neighboring crops, and NGT 1 products can be mixed with non-NGT 1 products.
   - Plant reproductive material shall at least be labelled as "Cat. 1 NGT [identification number of the plant of origin]" (Art. 10), but this is uninformative because not informing about possible risks of the resulting plants and products.
   - Insofar as Member State law has introduced liability rules for damages or contamination by GMOs **[25]** these will be undermined. Contamination and possibly harmful effects of crops are defined out of existence because NGT 1 plants are assumed as being safe. In such situation the farmer will bear the burden of proof if suspecting that an NGT 1 plant or product is unsafe.
   - Moreover, according to the EP Opinion any adventitious or technically unavoidable presence of NGT 1 properties is assumed as being compliant (Art. 3 para 3 lit a EP Opinion). Disproving such assumption will be impossible.
   - Any traceability requirement is removed so that information about the origin of a plant or product is disregarded. In contrast, the EP does propose an obligation to transmit and hold related information (Art. 10 (1a) EP Opinion), although it is unclear how this obligation shall be supervised.
   - The entire aggravation of the burden of proof of non-NGT 1 agriculture should have been – but was not - analyzed by the Regulatory Scrutiny Board in its assessment of financial consequences of the NGT deregulation. **[16]**
   - Organic farming comes under additional pressure because it is forbidden to make use of NGT 1 plants (Art. 5 (f) (iii) of the Regulation 2018/848 on organic farming, Art. 5 (2)), although after close scrutiny the plants may be found to offer ecological/biological advantages while not causing significant risk (see below ch. VII.).

3. Consumer expectations and informed choice will be deprived of useful information.

- The status of NGT 1 products is not to be verified (Arts. 6 and 7).
- NGT 1 products are not to be labelled as such (Art. 5 (1)). In contrast the EP proposes that NGT 1 plants, products and reproductive material shall be labelled as "New genomic Techniques" (Art. 10 (1) EP Opinion).
- The data base (Art. 9) informs about the NGT 1 status of plants only, not of products (Art. 9).
- NGT 1 products do not have to be stored, transported or distributed separated from conventional or organic products. This means that consumers will be confronted with mixtures of GMO free and NGT 1 products.

VI. Compliance with constitutional law

1. The Regulation shall be based on the competences for agriculture (Art. 43 TFEU), the internal market (Art. 114 TFEU) and plant protection, which has the direct purpose of protecting health (Art. 168 (4) (b) TFEU). In contrast, the new genomic techniques are claimed to be primarily promoted for environmental and climate protection measures. At the same time, the Regulation shall control adverse side effects on human and animal health and on the environment at least in relation to NGT 2 plants. This shows, that the focus of the Regulation is on environmental protection, which means that Article 192 TFEU is the correct competence basis. This also corresponds to the opinion the ECJ rendered on the conclusion of the Cartagena Protocol, where the court finds Art. 175 TEC (now Art. 192 TFEU) to be apposite considering that the main objective of the Protocol is environmental protection. **[19] [31]**

2. There are reasonable doubts whether the planned deregulation of NGT 1 plants and products is compatible with EU fundamental rights of farmers and traders. Concentrating on the property right of farmers (Art. 17 EU Charter of Fundamental Rights (CFR)) the following should be considered:
   - While the property right does not protect mere commercial interests and opportunities against regulatory changes **[18]** it does provide protection of physical assets created for the commercial purposes in legitimate trust in the regulatory setting. **[20] [3]**
   - The investment of farmers in the GMO-free soil, storage, transport and sales infrastructure is frustrated by the deregulation of NGT 1 plants and products because of possible contamination of their land, mixing of goods and loss of their customer base.
   - Such interference could only be justified in view of preponderant interests of the public welfare or competing fundamental rights. However, preponderance can hardly be grounded considering that NGT 1 plants and products do pose risks and that those risks are neither assessed nor prevented.
3. The planned Regulation is in several respects incompatible with the precautionary principle (Art. 191 (1) TFEU). **[2]** This principle requires that, where there is uncertainty as to the existence or extent of risks to man or the environment, potentially adverse effects must be determined on the basis of the most reliable scientific data available and the most recent results of international research, and the risks must be fully assessed. **[22]** The principle is flanked by the principle that account must be taken of available scientific evidence (Art. 191(2) TFEU), and that a high level of protection must be ensured (Art. 114 (3) TFEU). As shown above environmental concerns are not sufficiently taken into account, including because
   - it is scientifically untenable to assume that there are no risks below the limit marked in Annex I
   - the definition of NGT only links to genetic differences, although properties - and risks - of plants are not only genetically determined
   - the scope of NGT 1 plants and products exempted from current genetic engineering law is enormously broad

- any risk assessment is excluded for NGT 1 plants
- when a marketed NGT 1 plant becomes known to be hazardous, no intervention by public authorities is foreseen
- the previous regulatory model of learning about uncertain risks through monitoring is largely abandoned.

Compatibility with precaution cannot be established by mere postulation, as Art. 1 in the EP Opinion's version does when positing that the new rules are "in accordance with the precautionary principle" and "ensuring a high level of protection of human and animal health and the environment". The legislator cannot by mere assertation exempt itself from the higher rank of precaution and high level of protection as established by Art. 191 TFEU.

4. The planned Regulation undermines EU nature conservation law and thus jeopardizes the principle of policy coherence (Art. 7 Treaty on the European Union (TEU)).

   - The obligation to examine the compatibility of projects with the conservation purposes of Natura 2000 areas **[7]** is undermined because it will usually be impossible to determine whether NGT 1 plants were released.
   - With regard to NGT 2-plants enforcement deficits concerning the Natura 2000 impact assessment are to be expected, because in practice it is questionable whether the release of plants constitutes a project within the meaning of Art. 6 (3) Habitats Directive. **[35]**

5. The duty of the EU legislator to ensure a high level of consumer protection is neglected (Art. 38 CFR).

   - Union law is based on the concept of the consumer as a responsible person. **[33]** However, this includes that the consumer is informed about the quality and manufacture of products and can choose between products accordingly. **[27]** This freedom of choice is abolished by the planned Regulation with regard to NGT 1 plants and products.
   - The envisaged database of NGT 1 plants and the labelling of seeds as "Cat. 1 NGT" cannot compensate for this deficiency.

6. The polluter pays principle (Art. 191 TFEU) is neglected.

   - In future, the effort and costs of maintaining GMO-free food production shall be borne by the GMO-free sector, not by the users and patent holders of NGTplants.
   - With the removal of NGT 1 plants and products from the scope of the GMO regime they will also be exempted from special liability rules Member States have established, such as no-fault liability for damage to health and property as well as compensation for market loss in the event of contamination of crops. **[25]**

7. The fact that the Commission receives powers to adopt delegated acts concerning the equivalence of NGT plants and concerning the sustainability criteria underrates the principle that the objectives, content, scope and duration of the delegation must be defined in the legislative act, and that the essential provisions must be laid out in legislative acts (Art. 290 TFEU).

8. As many core terms and provisions are elusive (see above I 1) legal certainty which is a crucial component of the rule of law is violated.

9. The planned Regulation disregards the provision of Art. 6 para. 11 of the Aarhus Convention, according to which the public must be involved in administrative procedures with regard to the release of GMOs. It also disregards Art. 2 para. 3 (a) of the same Convention, according to

which the presence of GMOs in the environment is to be regarded as environmental information. This also extends to the genome of genetically modified plants and products in the NGT 1-category.

VII. An alternative proposal

In preparing its proposal, the Commission identified five options.**[13]** These are:

(1) NGT plants continue to be subject to the current genetic engineering regime (risk assessment, authorization, traceability, labelling, co-existence Regulations, monitoring).
(2) NGT plants are subject to the current GMO regime, but the risk assessment caters for diverse risk profiles and detection challenges. Traceability and labelling are maintained.
(3) NGT plants are subject to the current GMO regime, but the risk assessment caters for diverse risk profiles and detection challenges. Measures are introduced to incentivize plant products that contribute to a sustainable agri-food system. While traceability is maintained, various labelling alternatives are considered, including a sustainability label.
(4) NGT plants are subject to the current GMO regime, but the risk assessment caters for diverse risk profiles and detection challenges. Traceability and labelling are maintained. Applicants are required to show that the introduced trait is not detrimental to sustainability.
(5) NGT plants are subject to a verification of whether they could occur naturally or by conventional breeding. Such plants are treated similarly to conventional plants and would not require authorization, risk assessment, traceability and labelling as GMOs. They are listed in a transparency register.

A combination of options (3) (incentive for sustainability) and (5) (exemption from the GM regime) was implemented, though differentiating between NGT 1 and NGT 2.

The critical comments compiled here suggest that the proposal should be rejected as a whole. It then stands to reason to recommend a return to the first variant - status quo. However, since admittedly with some techniques the risks can be negligible, and genetic engineering has the potential to contribute to a more sustainable agriculture, a change of approach is apposite.

There are two basic options that may be discussed. One transcends gene technology and addresses plant reproduction material in general, cross-cutting modification techniques. Considering that also traditional breeding can contribute to varieties that are incompatible with truly sustainable agriculture the variety law itself may be changed in order to better ensure environmental protection. **[39]** Remarkably, the new Commission Proposal on plant reproductive material **[15]** adds sustainability as a criterion to the traditional three requirements of variety registration - distinctness, uniformity and stability. However, if this approach was undertaken the new Regulation on plant reproductive material would have to be thoroughly rethought to also provide for the protection of human and animal health and of the environment.

The other option remains within the genetic engineering realm. It would be a sixth option beyond the five considered by the Commission. Its core would be to allow for a cautious and controlled loosening of the regulatory regime, while at the same time requiring a verifiable contribution to sustainability. The two components would entail a reorientation of the risk assessment and the introduction of a sustainability assessment.

Concerning risk assessment: a screening stage should be introduced on the basis of which it is decided whether a comprehensive risk assessment is necessary. That the plant is derived from NGT should be an indication, but not a conclusive feature, because, as stated above, NGT 1 plants can also pose risks, while on the other hand it is possible that transgenes don't do so. The methodology of the screening should be predetermined at the Regulation level and be standardized by Commission Delegated or Implementing Act.

Concerning sustainability assessment: since risks can never ultimately be ruled out, but also in order

to exploit the potential of NGT, it should additionally have to be demonstrated that the genetic modification serves defined sustainability goals. Several legal orders foresee such requirements **[26] [39]**, including the Norwegian Genetic Engineering Act of 2 April 1993 No. 38, § 10 of which reads: "The deliberate release of genetically modified organisms may only be approved when there is no risk of adverse effects on health or the environment. In deciding whether or not to grant an application, considerable weight shall also be given to whether the deliberate release will be of benefit to society and is likely to promote sustainable development."

The two components should be linked as follows. If there are significant risks after preliminary or full testing, authorization must be refused as before, notwithstanding if sustainability criteria are met. If, on the other hand, the risks can be regarded as residual, it must additionally be demonstrated that the plant makes a verifiable contribution to sustainability. Traceability and labelling are retained, whereby the labelling should be linked to sustainability criteria, for example by stating that the product has been genetically modified for agro-ecological purposes.

Consumers can then decide whether to accept the product or not. GMO-free farmers could maintain their business model and continue to decide not to bring GMOs on the market. Alternatively, they could accept the proposed regulatory change and work for its improvement, in particular by insisting that the sustainability criteria be formulated more ambitiously than as contained in the current Annex III of the Commission proposal. They could also develop their own label.

An innovative path would also open up space for organic farming. While at present organic farming is categorically excluded from the use of GMOs **[10]** and also from the use of NGT plants (Art. 5 (2)), an exemption could be allowed if the plant was modified in a way that even better serves organic goals. In that line the principle “no use of GMOs” could be replaced by a principle reading as follows: “the use of organisms or products derived from them which have been genetically modified is only allowed if risks to human health and the environment are practically excluded and agro-ecological advantages are to be expected in comparison to usual organic methods”. This qualification could also be communicated by a corresponding label.

References

1 Arpaia S, Birch ANE, Kiss J, van Loon JJA, Messéan A, Nuti M, Perry JN, Sweet JB, Tebbe CC (2017), Assessing environmental impacts of genetically modified plants on non-target organisms: The relevance of in planta studies. Sci Total Environ. 2017 Apr 1;583:123-132. doi: 10.1016/j.scitotenv.2017.01.039. Epub 2017 Jan 15. PMID: 28095991.

2 Buchholz G (2023), Kommissionsvorschlag einer Verordnung über Neue Genomische Techniken (NGT): Zur Verletzung des Vorsorgeprinzips, Legal expertise commissioned by the Green group in the Bundestag, 2023. https://www.gruene-bundestag.de/fileadmin/media/gruenebundestag_de/themen_az/gentechnik/pdf/Gruene_im_Bundestag_Gutachten__Vereinbarkeit_des_Kommissionsvorschlags_zu_NGT_mit_dem_Vorsorgeprinzip.pdf

3 Calliess C (2023) Schutz des Eigentums nach der Grundrechtcharta, in Ehlers D, Germelmann C F, Europäische Grundrechte und Grundfreiheiten (De Gruyter 5th ed) p. 693

4 Council of the European Union (2023) Interinstitutional File 2023/0226(COD) 16443/23, 07.12.2023 https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CONSIL:ST_16443_2023_INIT

5 Eckerstorfer MF, Dolezel M, Heissenberger A, Miklau M, Reichenbecher W, Steinbrecher RA and

Waßmann F (2019) Corrigendum: An EU Perspective on Biosafety Considerations for Plants Developed by Genome Editing and Other New Genetic Modification Techniques (nGMs). Front. Bioeng. Biotechnol. 7:90. doi: 10.3389/fbioe.2019.00090

6 Eckerstorfer, M.F., Dolezel, M., Engelhard, M., Giovannelli, V., Grabowski, M., Heissenberger, A., Lener, M., Reichenbecher, W., Simon, S., Staiano, G., et al. (2023) Recommendations for the assessment of potential environmental effects of genome-editing applications in plants in the EU. Plants, 12, 1764. https://doi.org/10.3390/plants12091764

7 European Union, Council Directive 92/43/EEC of 21 May 1992 on the conservation of natural habitats and of wild fauna and flora, OJ L 206, 7, Art. 6 (3) with Art. 7

8 European Union, Directive 2001/18 of the European Parliament and of the Council on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC, OJ L 106, 1

8a European Union, Directive 98/44/EC of the European Parliament and of the Council on the legal protection of biotechnological inventions, OJ 213/13

9 European Union, Regulation (EC) 2100/94 on Community plant variety rights, OJ L 227, 1

10 European Union, Regulation (EU) 2018/848 on organic production and labelling of organic products, OJ L 150, 1

11 European Union, Regulation (EU) No 182/2011 of the European Parliament and of the Council laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers, OJ L 55, 13

12 European Commission (2021) Commission Staff Working Document, Study on the status of new genomic techniques under Union law and in light of the Court of Justice ruling in Case C-528/16, SWD(2021) p. 92

13 European Commission, 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. Explanatory Memorandum (pp. 1-16)

14 European Commission, 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. Proposal (pp. 16-24)

15 European Commission, Proposal for a Regulation of the European Parliament and of the Council on the production and marketing of plant reproductive material in the Union, COM(2023) 414

16 European Commission, Regulatory Scrutiny Board, Opinion of 26 May 2023, SWD(2023) 412, p. 7

17 European Parliament, Committee on the Environment, Public Health and Food Safety (ENVI report 2024), Compromise Amendment 2023/0226(COD)

17a European Parliament, Amendments adopted on 7 February 2024 , P9_TA(2024)0067

18 European Court of Justice, Case C-280/93, judgment of 05.10.1994 (Federal Republic of Germany v Council) para 79

19 European Court of Justice, opinion 2/00 of 6.12.2001

20 European Court of Justice, Case C-283/11 judgment of 22.01.2013 (Sky Österreich) para 34

21 European Court of Justice, Case C- 528/16 (Conféderation Paysanne), para. 48

22 European Court of Justice, Case C-616/17 (Blaise), paras. 43-46

23 European General Court, Case T-605/21 (TestBioTec v Commission), 18.10.2023, ECLI:EU:T:2023:648, paras 46-50

24 Federal Agency for Nature Conservation (2017) Background Paper on New Genetic Technologies, p. 9. https://www.bfn.de/sites/default/files/2021-04/17-07-

25 Gesetz zur Regelung der Gentechnik, Bundesgesetzblatt I p. 2066, §§ 33 and 36a

26 Greiter A, Heissenberger A (2021) Sozioökonomische Überlegungen gemäß Gentechnologierecht, https://www.umweltbundesamt.at/fileadmin/site/publikationen/rep0779.pdf

27 Jarass H D (2016) Grundrechtecharta (C H Beck 3rd ed), Art. 38 para 4.

28 Karageorgi M, Groen SC, Sumbul F, Pelaez JN, Verster KI, Aguilar JM, Hastings AP, Bernstein SL, Matsunaga T, Astourian M, Guerra G, Rico F, Dobler S, Agrawal AA, Whiteman NK. Genome editing retraces the evolution of toxin resistance in the monarch butterfly (2019), Nature 574(7778):409-412. doi: 10.1038/s41586-019-1610-8.

29 Kawall K (2019) New Possibilities on the Horizon: Genome Editing Makes the Whole Genome Accessible for Changes. Front. Plant Sci. 10:525. doi: 10.3389/fpls.2019.00525

30 Koller F and Cieslak M (2023), A perspective from the EU: unintended genetic changes in plants caused by NGT—their relevance for a comprehensive molecular characterisation and risk assessment. Front. Bioeng. Biotechnol. 11:1276226. doi: 10.3389/fbioe.2023.1276226

31 Krämer L (2013) Genetically modified living organisms and the precautionary principle. Legal dossier commissioned by Test Biotec. https://www.testbiotech.org/sites/default/files/GMO%20and%20precaution.pdf

32 McIntyre BD, Herren HR, Wakhungu J, Watson RT (2009) (eds) International assessment of agricultural knowledge, science and technology for development (IAASTD): global report. https://wedocs.unep.org/handle/20.500.11822/8590

33 Micklitz HW, Rott P, in Dauses MA, Ludwigs M (eds) Handbuch des EU-Wirtschaftsrechts, Werkstand: 58. EL April 2023, paras 63-65

34 Pflanzenforschung.de (2015) Punktmutationen schaffen Nahrungspflanzen, Bundesministerium für Bildung und Forschung https://www.pflanzenforschung.de/de/pflanzenwissen/journal/punktmutationen-schaffen-nahrungspflanzen-minimale-vera-10462

35 Potthof C et al, Expert Opinion: Evaluation of the European Commission's study on new genomic techniques, 2023, S. 204-206. https://www.bfn.de/sites/default/files/2023-03/bng_finalreport_COMstudy_Feb2023.pdf

36 Spranger T M, In-depth analysis of various European directives and regulations with regard to their potential to regulate environmental effects of New Technologies besides Genetic Engineering Law, 2017. Legal expertise commissioned by the german Federal Agency for Nature Conservation (BfN). file:///C:/Users/winter/Downloads/NT_Auffangrechte_RGutachten_Spranger_en.pdf

37 Wang H, Studer AJ, Zhao Q, Meeley R, Doebley JF (2015), Evidence That the Origin of Naked Kernels During Maize Domestication Was Caused by a Single Amino Acid Substitution in tga1. Genetics 200(3):965-74. doi: 10.1534/genetics.115.175752.

38 Wilson AK (2021) Will gene-edited and other GM crops fail sustainable food systems? In: Kassam A, Kassam L (eds) Rethinking food and agriculture. Woodhead Publishing, pp 247–284, ch. 13.6. https://www.google.com/url?sa=t&rct=j&q=&esrc=s&source=web&cd=&ved=2ahUKEwip69KF_v-DAxVj_bsIHSAEDOIQFnoECA8QAQ&url=https%3A%2F%2Fdownloads.regulations.gov%2FAPHIS-2020-0030-4093%2Fattachment_11.pdf&usg=AOvVaw29NroRtYVkkJotjB9BCuDq&opi=89978449

39 Zetterberg Ch, Björnberg K E (2017), Time for a New EU Regulatory Framework for GM Crops? J Agric Environ Ethics 30:325–347. DOI 10.1007/s10806-017-9664-9