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COMMISSION PROPOSAL FOR A REGULATION ON NEW GENOMIC TECHNIQUES (NGT): IN VIOLATION OF THE PRECAUTIONARY PRINCIPLE

Legal opinion

On behalf of the Bündnis 90/Die Grünen parliamentary group

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A. Summary

1. The EU Commission has proposed to completely exclude certain plants (category 1) obtained using new genomic techniques (NGT) and products obtained from them from the scope of EU genetic engineering law by means of an EU regulation (NGT Regulation), although they continue to be genetically modified organisms (GMOs) under the Commission proposal. They are only to be registered in a database. For other NGT plants and products derived from them, the approval procedure is to be simplified and shortened (category 2 NGT plants). Classification as an NGT plant and into one of the two categories is to be based on the type and number of DNA sequence changes. According to the Commission proposal, the resulting altered properties of the NGT plants, any associated risks for humans and the environment, and their possible contribution to sustainability are not a prerequisite for classification and privileging as NGT.

2. According to the case law of the European Court of Justice (ECJ), the precautionary principle enshrined in the EU Treaties entails that, where there is uncertainty as to the existence or extent of risks to human health or the environment, protective measures may be taken without having to wait until the reality and seriousness of those risks become fully apparent. Proper application of the precautionary principle requires, first, identification of the potentially negative consequences of potentially hazardous substances for health and the environment and, second, a comprehensive assessment of the risks to health and the environment based on the most reliable scientific data available and the most recent results of international research.

3. The Cartagena Protocol, which is binding under international and EU law, requires that case-by-case risk assessments be carried out before GMOs are placed on the market.

4. The Commission proposal contradicts the precautionary principle and the requirements of the Cartagena Protocol. Contrary to the Commission's claim that its proposal is coherent with existing GMO legislation and respects the precautionary principle, it provides for exemptions from the requirement for prior approval and risk assessment of GMOs, that are not justified on the basis of science either by per se lower risks or by per se greater benefits of NGT plants for the general public compared to other GMOs. It accepts that NGT plants, that later turn out to be harmful to humans or the environment, may reproduce in the environment so that their effects may be irreversible.

The new regulations are intended to apply to the latest genomic technologies, for which no experience is yet available regarding their possible harmful effects. These exceptions are to apply to the latest genomic technologies, which do not have a long safety record at all.

5. The Commission proposal is blind to the potential risks of category 1 NGT plants. Such plants are to be completely excluded from the scope of application of genetic engineering law solely on the basis of the type and number of changes to their DNA sequences. The resulting changes in the properties of the plants and any associated risks to humans or the environment are irrelevant. There is no case-by-case risk assessment. Such a privileged treatment of NGT plants compared to other GMOs is not justified because, both according to the findings of the ECJ and according to the Commission's own statement, NGT plants may pose risks comparable to those of other GMOs. Neither the Commission proposal nor other sources provide scientific evidence that category 1 NGT plants pose per se lower risks than category 2 NGT plants or other GMOs.

6. The Commission justifies the privileged status of NGT plants solely on the grounds that the type and number of changes in DNA sequences in NGT plants are comparable to the type and number of changes in DNA sequences in natural crosses. However, this does not infer a lower risk compared to the risks of other GMOs. In general, precautionary genetic engineering legislation has never been justified on the grounds that GMOs are more dangerous to humans or the environment than conventional organisms. Rather, GMOs are regulated because their release can have unintended and irreversible effects on humans or the environment, for example, when plants that are conventionally used for the production of food or feed have toxic effects due to genetic modifications, so that they themselves or similar plants, to which these traits outcross, can have unexpected adverse health effects when used as food or feed, or - similar to invasive conventional plants - can lead to significant changes in the ecosystem in the sense of displacement or even extinction of existing species. These effects can be caused by category 1 NGTs as well as by category 2 NGTs or other GMOs.

7. The Commission proposal contradicts the precautionary principle because the privileging of NGT plants over other GMOs cannot be justified by a generally higher benefit of NGT plants over other GMOs. The Commission emphasizes that NGT crops can have a particular benefit for sustainability, food security or autonomy. However, the Commission does not provide any evidence that the potential benefits of NGT plants are higher than those of other GMOs. Furthermore, such a benefit is not a prerequisite for the classification as and privilege of NGT plants. The privilege also benefits NGT plants that have adverse effects on the stated objectives.

8. The Commission proposal contradicts the precautionary principle and the requirements of the Cartagena Protocol because it does not provide for any case-by-case risk assessment for category 1 NGT plants.

9. The Commission proposal contradicts the precautionary principle because it wants to declare all risk management regulations of genetic engineering law inapplicable for category 1NGT plants. The omission of these regulations is also not to be compensated by other specific regulations that may ensure comparable risk management if a category 1 NGT plant has harmful effects on humans or the environment. It is true that the requirements of Novel Food Regulation 2015/2283 are to apply to novel foods. However, these require food businesses to be able to know whether the source materials they use are derived from NGT plants, which is not guaranteed without mandatory labelling. For other food and all feed, only the requirements of general food and feed law would apply. For other, e.g. industrially used NGT plants, not even the requirements for general product safety would apply. Under the Commission's proposal, for example, canola optimized by NGT for industrial purposes that is toxic to humans and animals could be grown without restriction, without its toxicity having to be assessed at all before it is placed on the market. If such NGT canola were to cross over into neighbouring canola fields during cultivation and this canola were to be used for food or feed purposes, this could lead to poisoning. Due to the lack of risk assessment of NGT canola, it would possibly take a long time before it was even determined that the poisonings originated from the NGT canola. Even after such a determination, the authorities responsible for genetic engineering would have no means of restricting the use of NGT canola. The food authority could only prohibit the owner of the affected conventional canola from using this canola for food or feed purposes.

10. The Commission proposal contradicts the precautionary principle because its scope of application is to be determined only on the basis of abstract specifications on the type and number of alterations of DNA. As a result, it remains unclear to members of the legislative bodies, to agri and food businesses, consumers and the general public what the range of modified properties and the associated risk potential of category 1 NGT plants may be. Furthermore, the criteria for determining the scope of application, in particular the required targeting precision of the so-called 'targeted mutagenesis', the necessary sequence similarity of the DNA of category 1 NGT plants to conventional plants, and the requirements for the bioinformatic predictability of these sequence changes are so indeterminate that the scope of application of the regulation is uncertain and can be interpreted in an indeterminately broad manner by the competent bodies. The enactment of the NGT Regulation would thus be practically equivalent to an abolition of genetic engineering law, because in the future all practice-relevant genetic modifications would presumably be concentrated on category 1 NGT plants exempted from genetic engineering law.

11. The Commission proposal contradicts the precautionary principle because products from category 1 NGT plants (with the exception of seeds) no longer have to be labelled in the future. This means that in the event that the products are found to be dangerous after they have been placed on the market, no effective protective measures can be taken in the form of segregation or recall because the products concerned are no longer recognizable due to the lack of labelling. Furthermore, companies in the food chain and consumers no longer have the possibility to refrain from using such category 1 NGT plants, the risks of which did not have to be tested before placing them on the market, on the basis of individual precautionary decisions.

12. The Commission proposal leaves open whether national coexistence measures such as a location register or minimum distance requirements are still permissible for the cultivation of category 1 NGT plants. This legal uncertainty alone will make it more difficult to introduce and maintain such coexistence measures and will thus stand in the way of effective protection against outcrossing and contamination.

13. The Commission proposal is incompatible with the precautionary principle. In implementing the precautionary principle, the Union legislator has regulatory discretion. The legislator can weigh the precautionary principle against other objectives and principles. Judicial review is therefore limited: Only manifest errors of assessment lead to the invalidity of a legal act.

However, if the Union legislator were to adopt the regulation as proposed by the Commission, it would make a manifest error of assessment on account of the contradictions described above, and exceed the limits of its regulatory discretion. An action for annulment against such a regulation before the ECJ would therefore have good prospects of success.

14. The lack of a risk identification and labelling obligation also leads to great legal uncertainties for companies. It raises the question both for the developers and distributors of category 1 NGT plants and products and for all companies in the food and feed chain whether and to what extent they are liable for damage that may result from the use of category 1 NGT plants and products. Is there a need for risk identification and assessment based on civil product liability? Who is responsible, those who develop and place category 1 NGT plants on the market or those who use them? Who must provide what information (classification, properties, risks) to their customers without being asked, or ask for it from their suppliers? Which risks are covered by which insurance?

B. Facts and question

In the field of molecular biology, a number of new genetic engineering methods have been developed in recent years and decades. The classification of the organisms produced by these methods as genetically modified organisms (GMOs), the classification of these breeding methods as mutagenesis, and thus the prerequisites for the applicability of genetic engineering law to the organisms produced by these techniques were controversial and not legally clarified.

The relevant genetic engineering legislation includes Directive 2001/18/EC of the European Parliament and of the Council on the deliberate release into the environment of genetically modified organisms (the Release Directive), Regulation (EC) No. 1829/2003 of the European Parliament and of the Council on genetically modified food and feed, and Regulation (EC) No. 1830/2003 of the European Parliament and of the Council concerning the traceability and labeling of genetically modified organisms and the traceability of food and feed products produced from them. The Directive is implemented into national law by the German Genetic Engineering Act (GenTG). Unlike EU directives, EC and EU regulations are directly applicable throughout the EU without the need for transposition into national law (Article 288 (2) and (3) of the Treaty on the Functioning of the European Union - TFEU).

At first, attempts were made to avoid the application of this genetic engineering law by classifying the techniques as mutagenesis. This is because, by way of exception, genetic engineering law does not apply to organisms in which a genetic change has been brought about by mutagenesis (mutagenesis exception).[1] The scope of application of genetic engineering law was to be limited to so-called transgenesis, i.e. the insertion of foreign ("transgenic") DNA sequences into an organism. Such transgenic techniques were the reason for the development of genetic engineering law. However, its scope of application was never limited to transgenic techniques.

The Grand Chamber of the European Court of Justice (ECJ) ruled on July 25, 2018, that the mutagenesis exception must be interpreted narrowly and applies only to methods that have been traditionally used in a range of applications and have long been considered safe.[2] This clarified that only classical methods of random mutagenesis are excluded from the scope of the Genetic Engineering.

[1] Art. 3 para. 1 in conjunction with. Annex I B No. 2 of the Release Directive 2001/18/EC.

[2] ECJ, judgment of 25.07.2018, case C-528/16, Confédération paysanne, confirmed by judgment of 07.02.2023, case C-688/21, Confédération paysanne II, para. 39 et seq.

The new genomic technologies are exempt from the provisions of the German Genetic Engineering Act, and the Genetic Engineering Act applies without restriction to new genomic technologies.

In response to this controversial ruling, the Council asked the Commission to conduct a study on the status of novel genomic techniques under Union law and, if appropriate, to submit a proposal.[3] The EU Commission first published a study on the status of NGT dated April 29, 2021.[4] On July 5, 2023, it published the proposal discussed here for a Regulation of the European Parliament and of the Council on plants produced using certain new genomic techniques a n d the food and feed products derived from them (NGT Regulation).[5]

A study commissioned by the Swiss Federal Office for the Environment (FOEN) lists 148 plant types that have been developed using new genetic engineering techniques. These include products typical of conventional GMOs, such as herbicide-tolerant and insect- or fungus-resistant rapeseed, corn and soybean plants, as well as potatoes, tomatoes, oats, tobacco, gold-of-pleasure and strawberries with a wide range of properties such as increased yields, altered composition, improved storage properties, longer shelf life on supermarket shelves and drought and salt tolerance.[6]

This opinion examines the compatibility of the Commission's proposal with the precautionary principle.

C. Legal appraisal

In order to examine the compatibility of the Commission proposal with the precautionary principle, the essential core elements of the Commission proposal are first presented (I.). The content and legal effects of the precautionary principle are then explained (II.). Subsequently, it is shown to what extent the Commission proposal contradicts the precautionary principle (III.).

[3] Council Decision (EU) 2019/1904 of 8 November 2019 requesting the Commission to undertake a study in the light of the judgment of the Court of Justice in Case C-528/16 on the status of novel genomic techniques under Union law and, if appropriate in the light of the results of the study, to submit a proposal.

[4] 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.

[5] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=COM:2023:411:FIN.

[6] Gelinsky, New Genetic Engineering Techniques: Commercialization Pipeline in Plant Breeding and Li- cence Agreements, 11.01.2022, evaluated in light of the Commission's proposal by Margret Engelhard, German Federal Agency for Nature Conservation, Where does the EUCommission's path lead to?, presentation of 07.09.2023.

I. The Commission's proposal for an NGT Regulation

According to the Commission proposal, the EU Commission concluded in its study of 29.04.2021 that the current GMO legislation was not suitable to regulate NGT plants. Authorization procedures and risk assessment requirements are not adapted to the diversity of potential NGT plants and products and may therefore be disproportionate or insufficient. Furthermore, the current GMO legislation is difficult to implement and enforce for certain NGT crops, especially if no specific detection method is available. The application of existing GMO legislation to NGTs would also not be conducive to the development of innovative and beneficial products that could contribute to the sustainability, food security and resilience of the food chain (recital 7 of the Commission proposal).[7]

The regulatory framework for NGT plants should be in line with the objectives of the Union's GMO legislation in order to ensure a high level of protection of human and animal health, the environment and the proper functioning of the internal market (recital 10).

In the explanatory memorandum of the proposal, the Commission emphasizes as a general objective the compliance with the precautionary principle and the coherence of the proposal with the existing GMO legislation.[8] However, it has not explicitly included the aspects of precaution and coherence with existing regulations in the recitals.

The regulation section of the ordinance is intended to clearly stipulate that NGT plants are genetically modified (GM) plants, i.e. GMOs within the meaning of genetic engineering law.[9] The economic background for this is likely to be that breeding processes based entirely on natural phenomena such as crossing or selection are not patentable.[10] Consequently, it should also be clearly regulated that NGTs may not be used as GMOs for the production of organic products.[11]

[7] Unless otherwise indicated, cited regulations refer to those in the Commission proposal.
[8] COM (2023) 411 final, p. 4 f.
[99] Art. 3 No. 2 in conjunction with. Art. 3 No. 1 and 3 of the Commission proposal.
[10] Article 4(1)(b) in conjunction with Article 2(2) of Directive 98/44/EC on biopatents.
[11] Art. 5(2) of the Commission's proposal in conjunction with Art. 5(f)(iii) and Art. 11 of the EU Basic Organic Regulation 2018/848.

The Regulation is to apply to NGT plants and products derived therefrom (NGT products), including food and feed (Art. 2). NGT plants are defined as GM plants obtained by directed mutagenesis or cisgenesis, if they contain only such genetic material that originates from the gene pool of the breeders (Art. 3 No. 2). The term 'mutagenesis' is not defined.[12] 'Targeted mutagenesis' is intended to denote mutagenesis procedures that result in changes at specific sites in the genome of an organism (Art. 3 No. 4).[13] Cisgenesis refers to genetic modification procedures that lead to the introduction of genetic material already present in the 'gene pool of breeders' into the genome of an organism (Art. 3 No. 5). The 'gene pool of breeders' includes the totality of genetic information of a species and other taxonomic species that can be crossed with it. This should also include species that are only crossable through the use of advanced techniques such as embryo rescue, induced polyploidy and bridge crossing (Art. 3 No. 6).

So-called NGT plants and products of category 1 are to be completely exempted from the existing regulations of genetic engineering law (Art. 5 para. 1). For NGT plants and products of category 2, the approval procedures are to be simplified and accelerated (Art. 12 ff.).
Category 1 NGT plants are defined in the recitals of the Commission proposal as those that also occur naturally or could be produced by conventional breeding techniques (recital 14). According to the proposed binding regulatory text, however, this is not a prerequisite for classification as a category 1 NGT plant; rather, only the equivalence criteria listed in Annex 1 of the Commission proposal must be met (Art. 3 No. 7). Equivalence with conventional plants is to be legally assumed ("deemed equivalent") if the NGT plant differs from the recipient or parent plant by no more than 20 specified types of genetic modification. The difference must also be present in a DNA sequence that has sequence similarity to the target site and must be predictable by bioinformatic tools (Annex I, first sentence). Permissible types of genetic modifications include, but are not limited to, the replacement or insertion of up to 20 nucleotides, the removal of any number of nucleotides, or other targeted modifications of any size if the resulting DNA sequences already occur in a species from the breeders' gene pool (Annex I Nos. 1 to 5).

[12] Cf. the definition in Annex A of the Commission's study of 29.04.2021, p. 61: "Creation of mutation(s) in an organism without insertion of foreign genetic material".
[13] Cf. in more detail below C.III.6.

For these NGT plants of category 1, the existing obligation for official testing and approval as a GMO prior to first release and first placing on the market is to be abolished[14] and replaced by a mere status check. This status check will only examine whether the NGT plant meets the requirements for classification as a category 1 NGT plant (Art. 6(2) and Art. 7(2)). If so, the Commission should classify the GMO as a Category 1 NGT plant by decision (Art. 6(10) and Art. 7(6)). The decisions are to be entered in a public database containing a summary description of the techniques used and a description of the characteristics and traits introduced or modified (Art. 9).

This status review does not include any risk assessment or risk management considerations (as explicitly stated in recital 20). Thus, it is not assessed whether the NGT plant or products derived from it may have harmful effects on human health or the environment. Furthermore, it is irrelevant for the status assessment whether the NGT plant or products derived from it contribute to the sustainability, food security or resilience of the food chain. Also irrelevant is the nature of the modified traits and properties and whether the modification could have been produced by natural crossing or conventional breeding methods.

The requirements for detectability and traceability, which must be fulfilled for GMOs and food and feed produced from them, are also no longer to apply to category 1 NGT plants. Thus, unlike other GMOs, no special identifier is to be assigned to Category 1 NGT plants and no detection methods or reference material need to be deposited in order to be able to verify, if necessary, whether a plant or a plant-derived food or feed product is a GMO product is a category 1 NGT plant or product and the required registration has been obtained.[15] Furthermore, category 1 NGT plants and food and feed produced from them - despite their continued classification as GMOs and the resulting ban on their use in organic products - will no longer have to be labeled as GMOs, containing GMOs or produced from GMOs.[16] For NGT plants of category 1, only seeds and other plant propagation material shall have to be labeled with the indication "Cat. 1 NGT" (Art. 10).

[14] Art. 5 para. 1 of the Commission proposal in conjunction with. Art. 4 para. 2 and Art. 16 para. 2 of Regulation (EC) 1829/2003 or Art. 4 para. 1 and 2, Art. 6 para. 1 and Art. 13 para. 1 of the Release Directive 2001/18/EC.

II. The Precautionary Principle in the TFEU and the Cartagena Protocol

The precautionary principle is a requirement of the Treaty on the Functioning of the European Union (TFEU, see 1.) that is binding on the Union legislator. Special requirements of the precautionary principle result from the Cartagena Protocol on Biosafety (2.).

1. TFEU

According to Article 191 (2) TFEU, the Union's environmental policy shall aim at a high level of protection taking into account the diversity of situations in the various regions of the Union. It is based on the precautionary principle and on the principle that preventive action should be taken, that environmental damage should as a priority be rectified at source and that the polluter should pay.

Furthermore, in its proposals for the approximation of the laws, regulations and administrative provisions of the Member States relating to the establishment and functioning of the internal market in the fields of health, safety, environment and consumer protection, the Commission assumes a high level of protection, taking particular account of any new developments based on scientific findings (Article 114(3) TFEU).

[15] Article 5 (1) of the Commission proposal in conjunction with Art. Art. 13 and Art. 25 of Regulation (EC) 1829/2003 or Art. 4 (1) and (6) and Art. 5 of Regulation (EC) 1830/2003.

[16] Art. 5 par. 1 of the Commission proposal in connection with. Art. 5(3)(i) and (j), Art. 6(5)(f), Art. 7(2), Art. 17(3)(i) and (j), Art. 18(5)(f) and Art. 19(2) of Regulation (EC) 1829/2003 and Art. 19(3) of the Release Directive, respectively, in conjunction with Art. 9(2) and (3) of Regulation (EC) 1830/2003.

According to the case law of the ECJ, the precautionary principle must therefore be applied not only in the context of environmental policy, but also in the context of other Union policies, in particular public health policy, and when the Union legislator adopts measures to protect human health on the basis of the common agricultural policy or the internal market policy.[17] It is thus incumbent on the Union legislator to follow the precautionary principle when adopting rules on the placing of products on the market, inter alia, in order to ensure a high level of protection of health and the environment.[18]

The precautionary principle entails that, where there is uncertainty as to the existence or extent of risks to human health or the environment, protective measures may be taken without having to wait until the reality and seriousness of those risks become fully apparent. Where it proves to be impossible to determine with certainty the existence or extent of the alleged risk because the results of the studies conducted are inconclusive, but the likelihood of real harm to public health persists should the risk materialize, the precautionary principle justifies the adoption of restrictive measures.[19]

The ECJ has repeatedly attached considerable importance to the precautionary principle in the interpretation and application of the respective legal provisions, in particular for genetic engineering law,[20] but also for plant protection product law[21] and other environmental law[22] . The precautionary principle has also been applied in the interpretation and application of the respective legal provisions.

[17] ECJ, Grand Chamber, Judgment of 01.10.2019, Case C-616/17, Blaise and others, para. 41 with further evidence, on Plant Protection Products Regulation (EC) 1107/2009.
[18] ECJ, Grand Chamber, Judgment of 01.10.2019, Case C-616/17, Blaise and others, para. 42 with further evidence, on Plant Protection Products Regulation (EC) 1107/2009.
[19] ECJ, Grand Chamber, Judgment of 01.10.2019, Case C-616/17, Blaise and others, para. 43 with further evidence, on Plant Protection Products Regulation (EC) 1107/2009.
[20] ECJ, Opinion 2/00 of 6.12.2001, Cartagena Protocol, para. 29; Judgment of 25.07.2018, Case C-528/16, Confédération paysanne, paras. 50 to 53; Judgment of 07.02.2023, Case C-688/21, Confédération paysanne II, para. 44 f.
[21] ECJ, Judgment of 19.01.2023, Case C-162/21, Pesticide Action Network, para. 47 et seq.; ECJ, Grand Com- mer, Judgment of 01.10.2019, Case C-616/17, Blaise and others, para. 41 et seq;
[22] Compare Calliess/Ruffert, EUV/AEUV, 6th ed. 2022, TFEU Art. 191 para. 30 with reference to ECJ, judgment of 10.10.2019, Case C-674/17, Tapiola, para. 66, and ECJ, judgment of 24.10.2019, Case C-212/18, Prato Nevoso Termo Energy, para. 58.

The ECJ had to examine the compatibility of the Plant Protection Products Regulation (EC) No. 1107/2009 with the precautionary principle, among other things, because the approval procedure for active substances provided for therein did not examine the cumulative effects of active substances with other components of plant protection products.

In this regard, the ECJ stated that it is not sufficient for the determination of the compatibility of a regulation with the precautionary principle if this principle is mentioned in a recital of the regulation. Rather, a correct application of the precautionary principle in the area of the Plant Protection Products Regulation requires, first, identification of the potentially negative consequences for health of the use of the active substances and plant protection products falling within its scope and, second, a comprehensive assessment of the risks to health based on the most reliable scientific data available and the most recent results of international research. Since the purpose of the Plant Protection Products Regulation is to lay down provisions on the authorisation of plant protection products and the approval of the active substances contained therein with a view to their being placed on the market, the Union legislature must establish a normative framework which enables the competent authorities, when they are informed of that authorisation and of the active substances contained therein, to take the necessary measures, when deciding on that authorisation and that approval, to have sufficient information to assess satisfactorily the risks to health arising from the use of those active substances and those plant protection products, taking account of the precautionary principle.[23]

Since several objectives and principles must be weighed against each other and the application of the relevant criteria is complex, a judicial review must necessarily be limited to the question whether the Union legislature committed a manifest error of assessment in adopting a regulation.[24]

[23] ECJ, Grand Chamber, Judgment of 01.10.2019, Case C-616/17, Blaise and others, paras 44 to 47 with further evidence, on Plant Protection Products Regulation (EC) 1107/2009.

[24] ECJ, Grand Chamber, Judgment of 01.10.2019, Case C-616/17, Blaise and others, para. 50 with further evidence, on Plant Protection Products Regulation (EC) 1107/2009.

As far as can be seen, the ECJ has not yet found in any case that the Union legislator made such a manifest error of assessment when adopting a Union act, that a directive or regulation of the European Parliament and of the Council is invalid because of a violation of the precautionary principle.

There is also no apparent case in which the ECJ would have declared a Union law provision null and void because the application of the precautionary principle would have led to a disproportionate impairment of other legal goods or interests.

With regard to the Plant Protection Products Regulation, it was criticized that it allowed the approval of active substances without examining their interaction with other components of a plant protection product. However, the ECJ did not consider this to be a manifest error of assessment because the Regulation also provides for a separate approval procedure for plant protection products in which cumulative effects of active substances and other components of the plant protection product must be examined. [25]

However, the ECJ has confirmed on many occasions that the Union legislator is entitled, on the basis of the precautionary principle, to require approval procedures and risk assessments in advance of identified hazards, in order to be able to prevent and, if necessary, effectively combat adverse effects on the environment and health in advance.

In 2007, the European Court of First Instance also annulled the Commission's inclusion of the active ingredient paraquat in the list of approved plant protection active ingredients on the basis of the precautionary principle.[26]

[25] ECJ, Grand Chamber, Judgment of 01.10.2019, Case C-616/17, Blaise and others, paras 62 to 76, on the Plant Protection Products Regulation (EC) 1107/2009.
[26] ECJ, judgment of 11.7.2007, Case T-229/04, Paraquat, paragraphs 224 et seq., 262.

2. Cartagena Protocol

According to Article 216 (2) TFEU, international agreements concluded by the Union bind the institutions of the Union and the Member States. According to the established case law of the ECJ, agreements under international law therefore take precedence over secondary Union law. Secondary Union law, such as the NGT Regulation in the case of its adoption by Parliament and Council, is therefore invalid if it
is inconsistent with an international agreement and it is not possible to interpret the secondary legislation in accordance with the agreement.[27]

The relevant international agreement governing the handling of GMOs, including NGT, is the Cartagena Protocol on Biosafety (CPB) to the Convention on Biological Diversity (CBD).[28]

According to its Art. 1, the Cartagena Protocol aims at adequate protection in the field of the use of living modified organisms produced by modern biotechnology, which may have adverse effects on the conservation and sustainable use of biological diversity, as well as risks to human health, in accordance with the precautionary approach as set out in Principle 15 of the Rio Declaration on Environment and Development.

The Cartagena Protocol applies, inter alia, to the handling and treatment of living modified organisms (Art. 4 CPB). Living modified organisms (LMOs) are living organisms that contain a new combination of genetic material through the application of modern biotechnology (Art. 3(h) CPB). Modern biotechnology is the application of in vitro nucleic acid techniques which overcome natural physiological barriers to reproduction or recombination and which are not techniques used in conventional breeding and selection (Art. 3 letter i CPB).

Thereafter, the Cartagena Protocol applies not only to organisms modified by transgenesis, but also to those modified by novel mutagenesis and cisgenesis techniques.

[27] Thus Schmalenbach, in: Calliess/Ruffert, EUV/AEUV, 6th ed. 2022, TFEU Art. 216 para. 50 with reference to ECJ, Case C-265, ECLI:EU:C:2020677, para. 62 (Recorded Artists Actors Performers Ltd.) and ECJ, Case C-366/10, Collection 2011, I-13755, para. 51 (Air Transport Association of America).
[28] https://bch.cbd.int/protocol/text/.

According to Art. 16 para. 3 of the Cartagena Protocol, each Party shall take appropriate measures to prevent unintentional transboundary movements of LMOs, including measures to measures such as the requirement to conduct a risk assessment prior to the first release of an LMO.

According to Art. 15 of the Cartagena Protocol, risk assessments shall be carried out in a scientifically sound manner, in accordance with Annex III of the Cartagena Protocol. According to Annex III No. 6 of the Cartagena Protocol, risk assessments should be carried out "on a case-by-case basis".

III. Precautionary principle and NGT regulation

Although the precautionary principle is of great importance in EU genetic engineering law and, according to the Commission, should also apply to the NGT Regulation, it is not mentioned in the text of the Regulation, including the recitals (see 1.). In fact, the Commission proposal is characterized by a risk blindness, which contradicts the precautionary principle, because the privileging of NGT plants compared to other GMOs cannot be justified by a lower risk of NGT plants compared to the risks of other GMOs (2.). The privileging of NGT plants is also not justified by a greater societal benefit of NGT plants compared to other GMOs (3.). It is contrary to the requirements of the Cartagena Protocol and the precautionary principle that the Commission proposal foregoes a case-by-case risk assessment for NGT plants of category 1 (4.). The precautionary principle is also contradicted by the fact that all risk management measures of genetic engineering law for NGT plants of category 1 are omitted without replacement (5.). In addition, the scope of application of the exemption regulations, in particular for NGT plants of category 1, is indefinite (6.). The exemption from labeling requirements and the resulting loss of freedom of choice for companies in the food chain and consumers also contradicts the precautionary principle (7.). Whether national coexistence measures will continue to be permissible for NGT of category 1 is an open question; the legal uncertainty associated with this alone will make national coexistence measures and the protection of companies in the food chain and consumers made possible by them more difficult (8.). Overall, the Commission proposal contradicts the precautionary principle to such an extent that the regulatory scope of the Union legislator would be exceeded if it were to adopt the proposal as it stands (9.).

1. Precautionary principle in release directive and NGT regulation

The precautionary principle is the central guiding principle of the Deliberate Release Directive. It is prominently mentioned in Art. 1 and Recital 8 of the Release Directive.

According to Article 1 of the Release Directive, in line with the precautionary principle, the objective of the Directive is the approximation of the laws, regulations and administrative provisions of the Member States and the protection of human health and the environment in the case of deliberate release of GMOs into the environment and their placing on the market as or in products.

According to recital 8 of the Release Directive, the precautionary principle was taken into account in the drafting of the Directive and must be taken into account in its implementation.

The Release Directive is designed as a cross-sectional standard that sets minimum requirements for all GMOs. It is true that sectoral legislation may contain special regulations that supersede the provisions of the Deliberate Release Directive. However, their requirements must be at least equivalent to the requirements of the Deliberate Release Directive (Article 12(1) of the Deliberate Release Directive). Such sectoral legislation is contained in Regulation (EC) No. 1829/2003 for genetically modified food and feed.

In accordance with the Release Directive, the Commission, in the Explanatory Memorandum to its NGT Regulation proposal, identifies the maintenance of a high level of protection of human and animal health and the environment, in accordance with the precautionary principle, as the first general objective of the proposal.[29] It claims that its proposal is coherent with existing regulations in the field. It pursues the same objectives as the GMO legislation, namely to ensure a high level of protection of human health and the environment in line with the precautionary principle and the functioning of the internal market, while taking into account the specificities of NGT plants.[30] The proposal is in line with the precautionary principle and contributes to the achievement of a high level of protection of human health and the environment of a high level of health protection.

[29] COM (2023) 411 final, p. 4.
[30] COM (2023) 411 final, p. 5.

The labeling of products subject to the requirements of risk assessment and authorization remains in place to ensure consumers' right to information.[31]

However, the Commission has not included these seemingly fundamental justification considerations in the recitals of its proposal. The recitals serve to fulfill the obligation to give reasons for Union legal acts pursuant to Article 296 (2) TFEU. They are an important basis for the application and interpretation of the legal acts.[32]

The Commission proposal is therefore contradictory because, on the one hand, it claims to take into account the precautionary principle and to want to be coherent with the Release Directive, but, on the other hand, does not include this objective in the recitals of the Regulation.

2. Risk blindness and lack of justification for an exception

In fact, the Commission proposal is characterized by a risk-blindness that contradicts the precautionary principle, in complete contrast to the Release Directive.

According to the recitals of the Release Directive, living organisms released into the environment in large or small quantities can reproduce in the environment and spread beyond national borders, affecting other member states. The effects of such releases may be irreversible.[33] The protection of human health and the environment requires due control of the risks resulting from the deliberate release of GMOs into the environment.[34]

These central risks of a potentially irreversible release of GMOs with negative effects on health or the environment are not addressed at all in the Commission proposal. Thereby it is obvious that NGT plants - like all other GMOs - can reproduce and spread in the environment as living organisms.

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[31] COM (2023) 411 final, p. 15.

[32] Compare on the importance of recitals Willand/Buchholz, Environmental risk assessment of GMO: Lawfulness of a recital of a draft Commission Directive to adapt the Annexes to Directive 2001/18/EC of the Parliament and of the Council to technical progress, 2017, p. 11 ff; Calliess, in: Calliess/Ruffert, EUV/AEUV, 6th ed. 2022, TFEU Art. 296 Rn. 7 ff.

[33] Recital 4 of the Release Directive 2001/18/EC.

[34] Recital 5 of the Release Directive 2001/18/EC.

Therefore, just like all other GMOs, they can displace natural conventional plant species due to deliberate or adventitious selection advantages, thereby affecting existing food chains. Herbicide-tolerant NGT plants can transfer their herbicide tolerance to related wild plants through outcrossing, so that the corresponding herbicides lose their effect on such wild plants.[35] Plants previously used for nutritional purposes may be optimized by NGT for other purposes and thus lose their suitability for nutritional purposes or even lead to health hazards without this being apparent to farmers and consumers. Regulation 1829/2003 on genetically modified food and feed therefore requires that genetically modified food and feed must not be misleading and must not differ from the food and feed they are intended to replace to such an extent that their normal consumption would cause nutritional deficiencies.[36] According to the Commission proposal, this requirement shall no longer apply to food and feed from NGT plants of category 1 (Art. 5 para. 1).

[35] Cf. on herbicide tolerance the possibility of establishing growing conditions in the variety approval procedure for all herbicide-tolerant varieties, irrespective of whether they are GMOs, NGTs or conventional plants, as provided for in Article 47(1)(f) of the Commission proposal for a new Regulation on the production and marketing of plant propagating material [COM(2023) 414 final].

[36] Thus, the general requirements Art. 4(1)(b) and (c) and Art. 16(1)(b) and (c) of Regulation 1829/2003 on genetically modified food and feed.

[37] The ECJ- case of Confédération Paysanne concerned so-called in vitro mutagenesis, which was used to produce herbicide-tolerant Clearfield canola. In the first judgment, the ECJ essentially distinguished between targeted mutagenesis and conventional random mutagenesis (ECJ, judgment of 25.07.2018, Case C 528/16, Confédération paysanne, para. 47). The term targeted mutagenesis used there is likely to be consistent with the corresponding term in Article 3(4) of the Commission proposal (see C.I. above and C.III.6. below). In the second judgment in the Confédération Paysanne case, on the other hand, the focus was on the difference between in vitro random mutagenesis and targeted mutagenesis. In this regard, the ECJ stated that in vitro mutagenesis is also subject to genetic engineering law if it differs from conventional random mutagenesis by characteristics that are capable of leading to changes in the genetic material of this organism that differ from those of conventional random mutagenesis in their nature or in the rate at which they occur. However, the effects associated with in vitro cultures as such do not alone lead to the applicability of the Release Directive (ECJ, judgment of 07.02.2023, Case C-688/21, Confédération paysanne II, para. 34 and operative part). Accordingly, the procedure of in vitro random mutagenesis does not seem to be subject to the Release Directive, which, however, has to be examined again in factual terms by the referring court, the French Conseil d'Etat. It is unlikely to be classified as a procedure of targeted mutagenesis within the meaning of Art. 3 No. 4 of the Commission proposal.

In its judgment of July 25, 2018, the Grand Chamber of the ECJ, based on the findings of the French Constitutional Court Conseil d'État, pointed out that the risks associated with the use of new processes and methods of 'targeted mutagenesis' (i.e., NGT)[37] for a distinction of the risk potential of NGT plant - there is obviously also no scientific basis for the classification of NGT plants in category 1 and NGT plants in category 2.[38]

NGT plants can therefore be just as harmless, but also just as risky for the environment and health as other GMOs.

Furthermore, the Commission points out that NGTs, in contrast to established techniques, have a higher speed of introduction of genetic modifications.[39] According to the jurisprudence of the ECJ, a higher speed of introduction and release of GMOs does not speak for, but against a deregulation of corresponding techniques.[40] This is because a higher speed of introduction of novel organisms into agro-ecosystems can both overtax the adaptive capacity of the ecosystems surrounding them and limit the possibilities of reaction in the event of risks and hazards subsequently identified.

Precisely because the Commission emphasizes that the NGT Regulation should be coherent with the regulations of the Deliberate Release Directive and consistent with the precautionary principle, an exemption from the regulations of the Deliberate Release Directive could only be justified if it could be demonstrated that NGT plants always pose lower risks than other GMOs.

However, there is no evidence or even scientific proof for this.
Therefore, the Commission does not base its proposed exemption for NGT plants on a comparison of the risks of NGT plants with other GMOs, but on a comparison with risks of conventional plants. Category 1 NGT plants are just as safe as plants that occur naturally or have been produced by conventional breeding techniques, and are therefore not subject to regulation.[41]

[38] Cf. GABA tomato and agrofuel linseed as examples of modified traits that were produced by significantly fewer than 20 modified nucleotides (per gene locus) and could not have been obtained from conventional breeding: Testbiotech, New genetic engineering: EU Commission's legislative proposal endangers nature, the environment and the future of our livelihoods, Testbiotech Background 31.08.2023, p. 4 f.

[39] COM (2023) 411 final, p. 1.

[40] ECJ, Judgment of 25.07.2018, Case C 528/16, Confédération paysanne, para. 48 on the difference between targeted and random mutagenesis; also confirmed to that extent by Judgment of 07.02.2023, Case C-688/21, Confédération paysanne II, para. 52.

This comparison cannot justify the exemption from the Deliberate Release Directive. Conventional GMOs are not regulated because they are or could be more dangerous than conventionally bred or non-GM organisms resulting from natural reproduction processes. It is obvious that such conventional organisms can also be and are indeed dangerous to humans or the environment. However, these dangers are widely known. Both nature and humans have developed strategies to avoid or control these natural risks. Moreover, natural processes cannot be changed by regulation.

The main reason for regulating GMOs has therefore never been that they could be more dangerous than conventional organisms. Rather, the focus has always been on the fact that they can have negative effects on human health or the environment. These can also be negative effects that conventional organisms could also have, e.g. the alteration of ecosystems by invasive conventional species.

In 1987, the Enquete Commission of the German Bundestag on the opportunities and risks of genetic engineering identified, for example, a possible toxic effect on humans or farm animals and an undesirable transfer of genes to other plant species as significant risks of GM plants.[42]

In the explanatory memorandum to the first Genetic Engineering Act of 1990, it is pointed out that the deliberate or unintentional introduction of GMOs into the environment can have a variety of interactions of an organism that are difficult to predict in advance, making predictions on a hypothetical basis difficult. The eco- logical consequences of introducing new organisms into regions where they had not previously been present would demonstrate how sustainable change in the environment by introducing an organism that is new to them and what far-reaching consequences this could have.[43]

[41] Cf. recital 14 of the Commission proposal and the explanatory memorandum in COM (2 023), 11 final, p. 12.
[42] Report of the Enquete Commission "Opportunities and Risks of Genetic Engineering," Bundestag Printed Paper 10/6775, January 6, 1987, p. XXI.

The recitals of the 1990 and 2001 Release Directives emphasize that living organisms released into the environment in large or small quantities for experimental purposes or in the form of commercial products may propagate in the environment and spread beyond national borders, affecting other Member States. The effects of such releases could be irreversible. Furthermore, the protection of human health and the environment requires due control of the risks resulting from the deliberate release of GMOs into the environment.[44]

The recitals of the Cartagena Protocol on Biosafety state that the transboundary movement of any living modified organism produced by modern biotechnology may have adverse effects on the conservation and sustainable use of biodiversity.[45]

According to recital 3 of Regulation (EC) 1829/2003 on genetically modified food and feed, genetically modified food and feed should undergo a safety assessment before being placed on the market in the Community in order to protect human and animal health.

Accordingly, none of these regulations has ever been justified on the grounds that GMOs or products made from them would be associated with greater or different risks than conventional organisms or products. On the contrary, the comparison of the risks of the release of GMOs with the risks of invasive conventional species used in the explanatory memorandum to the Genetic Engineering Act confirms that genetic engineering law is also intended to counter risks that are comparable to the risks posed by conventional organisms.
These justifications further show that potential risks of GMOs are not solely based on the properties of the GMO itself, but also on may be based on the usual uses of the respective organisms and their interactions with the environment.

[43] Draft Law of the Federal Government, Bundestag Printed Paper 11/5622 of November 9, 1989, p. 20.
[44] This was already the case in the first two recitals of the first release directive 90/220/EEC of the Council of 23.04.1990; recitals 4 and 5 of the current release directive 2001/18/EC are identical.
[45] Recital 3 of the Cartagena Protocol.

For example, the specific risk of genetic modification of plants used for food or feed may be that the genetic modification of such a plant, making it accessible or optimized for other uses, may render the use of such plants for food or feed useless or even dangerous. Furthermore, such traits may outcross to related crops or wild plants and lead to consequences that are difficult to foresee, such as the displacement or even extinction of existing species. The danger is not that the GMO itself is more dangerous than conventional organisms, but that the established culture and ecosystems do not recognize such changes and are not able to adapt to them or not in time.

All these risks apply equally to NGTs as to other GMOs. They also apply equally to category 1 NGTs as to category 2 NGTs and other GMOs.

There is thus no objective justification for exempting category 1 NGT plants from the requirements for other GMOs and for privileging category 2 NGT plants over other GMOs. The regulatory proposals of the Commission are therefore simply arbitrary.

The Commission justifies the criteria for the classification of Category 1 NGT plants solely on the grounds that these criteria should be objective and based on scientific evidence. They are intended to cover the nature and extent of genetic changes that can be observed in nature or in organisms obtained by conventional breeding techniques, and to include thresholds for both the size and the number of genetic changes in the genome of NGT plants.[46]

In other words, the NGT exemption is justified solely on the basis that the nature and number of DNA sequence changes are for category 1 NGT plants, the type and number of DNA sequence changes are similar in a natural cross.

[46] Recital 14 of the Commission proposal.

The fact that there may also be changes in the genome which, in terms of their nature and in terms of their number, meet the criteria of Annex 1 of the Commission proposal, but which nevertheless cannot arise naturally, and which may also lead to other risks for humans or the environment, is irrelevant. The Commission proposal is blind to such risks.

This applies in particular to so-called protected areas in the DNA. These are characterized by the fact that the DNA in these areas is protected against changes caused by natural crossing. Genetic engineering methods make it possible to overcome such natural barriers.[47] For classification as an NGT plant of category 1, on the other hand, it is irrelevant whether the type and extent of the modification of the genetic information takes place within or outside such a protected area.

Furthermore, it is irrelevant for the classification as a category 1 NGT plant what effects the molecular genetic modifications have on the properties of the plant. If the formal classification criteria are met, it is completely irrelevant whether an NGT plant is toxic to humans or animals, invasive to certain ecosystems or herbicide resistant due to the genetic modification.

Furthermore, there is not only a lack of scientific evidence per se of lower risks of NGT compared to conventional GMOs, but also a lack of sufficient experience with NGT crops.

For example, the Release Directive excludes GMOs produced by mutagenesis from its scope because they are obtained by genetic modification techniques that have been traditionally used in a number of applications and have long been considered safe.[48]

[47] Cf: Kawall, K. (2019): New Possibilities on the Horizon: Genome editing makes the whole genome accessible for changes. Frontiers in Plant Science 10, 525; Monroe, J.G., Srikant, T., Carbonell-Bejerano, P. et al. (2022): Mutation bias reflects natural selection in Arabidopsis thaliana. Nature 602, 101-105. with Fig. 1.

[48] Recital 17 of the Release Directive 2001/18/EC, cf. in this regard ECJ, judgment of 25.07.2018, case C-528/16.

This is contradicted by the fact that the EU Commission, with its proposal for an NGT regulation, wants to exclude from the scope of the release directive precisely those GMOs for which the least experience is yet available.

As a result, there is no objective justification for an exemption of NGT plants from the requirements of the Deliberate Release Directive. There is neither scientific evidence nor experience that NGT plants pose lower risks to the environment or human health than other GMOs. Rather, this depends on the individual case. The comparability of the risks of NGT plants with conventional plants does not justify an exemption from the Deliberate Release Directive, because the Deliberate Release Directive is not based on the assumption that GMOs per se are more dangerous than conventional organisms. Rather, the regulation of GMOs and the case-by-case assessment prior to their release also served from the outset as a precaution against risks with irreversible consequences that can also emanate from conventional organisms.

3. Inconsiderability of the benefits of NGT

The precautionary principle is not a strict precautionary requirement, but a principle that must be weighed against other objectives and principles.[49] The Union legislator therefore has regulatory leeway when adopting a regulation.

Therefore, in addition to the potential risks of NGT plants, the Union legislator may also consider the benefits of NGT plants.
In this sense, the Commission justifies its proposal by arguing that the relatively simple and rapid use of NGT crops could bring benefits to farmers, consumers and the environment. NGT has the potential to contribute to the innovation and sustainability goals of the European Green Deal and the Farm-to-Fork strategy, the biodiversity strategy and the climate change adaptation strategy, and to global food security, contribute to the bioeconomy strategy and the strategic autonomy of the Union (recital 3).

[49] ECJ, Grand Chamber, Judgment of 01.10.2019, Case C-616/17, Blaise and others, para. 50 with further evidence, on the Plant Protection Products Regulation (EC) 1107/2009, on this already above II.1.

According to the Commission's regulatory proposals, however, the sustainability benefit of an NGT plant is to be taken into account only to the extent that, in addition to the simplifications in the approval procedure applicable to all NGT plants in category 2, further privileges are to apply to NGT plants in category 2 if certain sustainability criteria are met (Art. 22 in conjunction with Annex III).

As with the risks, however, there is also a lack of comprehensible justification for the benefits as to whether and, if so, why the corresponding benefits of NGT plants should be greater than those of other GMOs that are to remain within the scope of the Deliberate Release Directive. If NGT plants do not pose a lower risk than conventional GM plants, then at least another justification, such as a special benefit of NGT plants, would be required to justify an exemption from the provisions of the Deliberate Release Directive.

According to the Commission proposal, the benefit of an NGT plant should not be a prerequisite for an exemption from the scope of the Deliberate Release Directive, nor should a low risk.

Rather, the complete exemption of NGT plants of category 1 from the requirements of genetic engineering law should also benefit, without restriction, those NGT plants that are recognizably harmful to other Union objectives such as sustainability or bio-diversity.

For example, a herbicide-tolerant category 1 NGT plant is to be exempted from the requirements of genetic engineering law in the same way as any other category 1 NGT plant, although herbicide tolerance is explicitly mentioned in Annex III, Part 2 of the Commission proposal as a characteristic that precludes the privileging of category 2 NGT plants on the basis of their benefit for sustainability.

As a result, even a potential benefit of NGT plants cannot justify the Commission's planned exemptions for NGT plants from the requirements of the Release Directive.

4. Lack of risk identification in individual cases

It is contrary to the precautionary principle of the TFEU and the requirements of the Cartagena Protocol that no case-by-case assessment is provided for NGT plants of category 1.

First of all, it can be deduced from the Cartagena Protocol that risk assessments for GMOs should always be carried out on a case-by-case basis.[50] This is contradicted by the Commission's general exclusion of category 1 NGT plants from the scope of the Deliberate Release Directive on the basis of purely formal, non-risk-related criteria such as the type and number of DNA sequence modifications.

Furthermore, the waiver of case-by-case examinations contradicts the requirements established by the ECJ for the application of the precautionary principle in the area of plant protection product law. Accordingly, a correct application of the precautionary principle in the area of the Plant Protection Products Regulation requires, firstly, the determination of the possible negative health effects of the use of the active substances and plant protection products falling within its scope and, secondly, a comprehensive assessment of the health risk on the basis of the most reliable scientific data available and the latest findings of international research. The Union legislator must therefore establish a normative framework enabling the competent authorities, when they decide on that authorization and that approval, to have sufficient information to assess satisfactorily the risks to health arising from the use of those active substances and those plant protection products, taking into account the precautionary principle.[51]

These requirements can also be applied to NGT plants. This applies in any case if an NGT plant has similar properties as a plant protection product, as is the case with conventional insect-resistant GMOs such as maize MON 810, which, due to its genetic modification, produces an active ingredient that is subject to plant protection product legislation.

[50] Annex III No. 6 of the Cartagena Protocol, see II. 2. above.

[51] ECJ, Grand Chamber, Judgment of 01.10.2019, Case C-616/17, Blaise and others, paras 44 to 47 with further evidence, on Plant Protection Products Regulation (EC) 1107/2009. On this point, already above C.II.1.

However, other possible properties of a NGT plant, just like those of any other GMO, also require a case-by-case risk assessment. As explained above, there is apparently no scientific evidence that NGT plants pose lower risks than other GM plants (see C.III.2. above).

5. Lack of risk management

It is also contrary to the precautionary principle that all risk management measures of the Deliberate Release Directive and Regulation (EC) No 1829/2003 on genetically modified food and feed are overridden for category 1 NGT plants and not replaced by alternative risk management measures.

The overridden measures include:

- Risk identification and assessment in an authorization procedure with risk-based preventive decision on release and placing on the market, if necessary specifying release conditions,[52]
- Requirements for traceability and labeling of GMOs and derived products, in particular establishment of detection methods, collection of reference materials and allocation of unique identifiers to enable and facilitate monitoring,[53]
- Monitoring of releases and placing on the market by the responsible person according to an officially tested and approved monitoring plan,[54]
- regulatory monitoring of releases and placing on the market and ordering of measures, [55]
- Amendment procedure in case of new information,[56]
- Safeguard clause for emergency action by member states, [57]
- Cultivation ban by member states (opt out), e.g. due to environmental policy objectives.[58]

[52] Art. 6 et seq. and 13 et seq. of the Release Directive.
[53] Articles 4 to 9 of Regulation (EC) 1830/2003.
[54] Art. 13(2), Art. 19(3), Art. 20 and Annex VII of the Release Directive.
[55] Art. 4(5) and Art. 20 of the Release Directive.
[56] Art. 8 and Art. 20 of the Release Directive.

These risk management measures would be completely eliminated for Category 1 NGT plants under the commission proposal, nor are they to be replaced by alternative measures. There are not even general requirements that those responsible for the release and placing on the market of Category 1 NGT plants must take all appropriate measures to ensure that the deliberate release or placing on the market of NGT plants and products does not have any adverse effects on human health and the environment.[59] Furthermore, unlike food and feed derived from Category 2 NGT plants and other GMOs, food and feed derived from Category 1 NGT plants should not be required to be misleading or to differ from the food and feed they are intended to replace to such an extent that their normal consumption would result in nutritional deficiencies.[60]

According to recital 22 of the Commission proposal, only the requirements of Novel Food Regulation (EU) 2015/2283 shall apply to foods produced from NGT category 1 plants. Accordingly, novel foods may only be placed on the market as such or used in and on foods in accordance with the conditions and labeling requirements laid down in a Union list (Article 6(2) of Regulation 2015/2283). However, foods derived from NGT plants are novel foods only if they bring about significant changes in the composition or structure of the food that affect its nutritional value, its metabolism or its level of undesirable substances (Art. 3(2)(a)(iv) of Regulation 2015/2283). Furthermore, it is the responsibility of the food business operators to check whether the food they place on the market is safe in the applications fall within the scope of the Novel Food Regulation (Art. 4(1) of Regulation 2015/2283).

[57] Art. 23 of the Release Directive.
[58] Art. 26b of the Release Directive.
[59] Thus, the basic general obligation in Art. 4(1) of the Deliberate Release Directive, similar to Art. 4(1)(a) and Art. 16(1)(a) of Regulation 1829/2003 on genetically modified food and feed.
[60] Thus, the general requirements Art. 4(1)(b) and (c) and Art. 16(1)(b) and (c) of Regulation 1829/2003 on genetically modified food and feed.

However, the status check of category 1 NGT plants does not examine whether foods produced from them would fall within the scope of the Novel Food Regulation as novel foods. Furthermore, Category 1 NGT products (except seeds) do not have to be labeled as such. Therefore, it can often happen that food companies do not even know whether and to what extent the food they produce has been produced from category 1 NGT plants.

Only the general requirements of food and feed law would then apply to food from category 1 NGT plants, which are not novel foods, and to all feed, including feed with novel properties.

For products made from NGT plants that are not food or feed, not even the requirements for general product safety would apply. Accordingly, economic operators may only place or make available on the market safe products.[61] Products for which no special requirements apply are subject to market surveillance; special information and recall obligations apply to them in the event of safety defects. However, living plants and GMOs will be exempt from these requirements in the future.[62]

Category 1 NGT plants, which are not food or feed, would then probably be the only category of products for which no specific producer responsibility applies. Only the general regulations on hazard prevention would then apply, even if specific risks arise that are based on the genetic modification.

[61] Thus the general safety requirement under Article 5 of Regulation (EU) 2023/988 on general product safety, which applies from 13 December 2023; until then, Article 3(1) of Directive 2001/95/EC on general product safety.
[62] Article 5(2)(d) of Regulation (EU) 2023/988 on general product safety, applicable from 13.12.2023; until then, Article 3(1) of Directive 2001/95/EC on general product safety.

For example, a Category 1 NGT canola could be developed that is suitable for industrial uses but is toxic when used in food or feed. Such NGT canola would be toxic at presence of the conditions of category 1 to be classified as a category 1 NGT plant, without any further regulations on its cultivation. [63]

If such NGT canola were to cross over into neighboring fields where canola is grown for food or feed purposes, it could affect the neighboring canola crop and lead to poisoning when the neighboring canola is used.

Since the Commission proposal does not require any risk assessment, it is conceivable that the toxicity of NGT canola is not even known at first. It may therefore take months or years before symptoms of poisoning can even be attributed to the crossbred NGT oilseed rape as the causative agent.

If so, the food authority may prohibit the affected neighbor from using the impacted canola for food purposes. The police or the general regulatory authority would presumably be responsible for issuing orders regarding the NGT canola.[64] In any case, the genetic engineering authority would have no power to issue measures on the basis of genetic engineering law, because its regulations would no longer apply to category 1 NGT plants.

As a result, the Commission proposal would not only lack preventive risk management measures, but also suitable instruments to adequately address subsequently identified NGT-specific risks.

[63] Cf. on gold of pleasure as an example of an NGT crop optimized for industrial purposes https://doi.org/10.1186/s12302-021-00482-2. .

[64] It is possible that in the future, according to Art. 47(1)(g) of the Commission proposal for a new Regulation on the production and marketing of plant propagating material [COM(2023) 414 final], growing conditions for varieties that have undesirable agronomic effects may be established in the variety approval procedure by the competent authority. However, this is only possible after such risks have become known.

6. Indefinite breadth of the exemption

Furthermore, the indeterminate breadth of the exceptions in the Commission's proposal violates the precautionary principle. The Commission's proposal is undefined because its scope is only defined on the basis of abstract specifications on the type and number of DNA modifications. As a result, it remains unclear, at least for laypersons in molecular biology such as members of the legislative bodies, for agricultural and food companies, consumers and the general public, what range of modified properties and what associated risk potential would be covered by the exemption. The Commission does not describe, either in the Commission's proposal itself or in its explanatory memorandum or elsewhere, what changes the DNA modifications subject to the exemptions for category 1 and 2 NGT plants may have. Also the study of 29.04.2021 commissioned by the Commission, which does not deal with the determination of the scope of a possible new regulation, does not show anything in this respect.[65] Therefore, it must be assumed that the spectrum of possible changes in properties and associated risks has not been scientifically clarified. This underscores the risk blindness of the proposed regulation (see C III.2. above).

The Commission justifies the criteria for the classification of Category 1 NGT plants by stating that these criteria are objective and should be based on scientific evidence. They are intended to cover the type and extent of genetic changes that can be observed in nature or in organisms obtained by conventional breeding methods, and to include thresholds for both the size and the number of genetic changes in the genome of NGT plants.[66]

Thus, the Commission does not intend to limit the scope of the NGT Regulation to the modification of properties that can be achieved by conventional breeding techniques, but only to a type and number of DNA modifications comparable to such modifications. Whether a type and number of DNA changes comparable to such changes also lead to completely different changes in properties and risks that cannot be achieved by conventional breeding methods is not a matter for the Commission remains uncertain.

[65] 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,.

[66] Recital 14 of the Commission proposal.

This does not prevent classification as an NGT plant of category 1. If the criteria of Annex I are met, the equivalence of the NGT plant with conventional plants is assumed by law, even if modified properties speak against equivalence.

The definition of the scope of application by determining NGT plants on the basis of the concept of targeted mutagenesis (Art. 3 Nos. 2 and 4) is also indeterminate.

First, there is a lack of definition of the term "mutagenesis."

Targeted mutagenesis is intended to refer to mutagenesis procedures that lead to changes at specific locations in the genome of an organism (English version: modifications "at precise locations in the genome", Art. 3 No. 4). This definition is already linguistically unsuccessful, because even classical random mutagenesis can only lead to modifications "at precise locations in the genome". From the term "targeted" mutagenesis it can be deduced that it is probably meant that targeted mutagenesis leads to changes in the genome specified in advance by the procedure, whereas this is not the case with classical random mutagenesis. Here, it could also be linked to the fact that the sequence change at the target site according to Annex I should be predictable by bioinformatic tools.

Here, however, much is unclear. Is targeted mutagenesis already present if only one of several changes was predictable by bioinformatic tools? Do all the genetic changes that actually occur have to have been predicted? Is mutagenesis therefore already no longer targeted if even one unintended change has occurred at the target site or at a site other than the target site?
The Commission study of 29.04.2021 proposes to define 'targeted mutagenesis' as a generic term to describe newer techniques to induce mutations at selected target sites of the genome without using genetic material to be inserted. [67] This suggests that by using this term, the Commission does not intend to establish legal minimum standards for target accuracy. Rather, all newer techniques mentioned in the study (ODM, RdDM, SDN-1 to SDN-3, CRISPR/Cas)[68] are apparently to be summarized under this generic term, irrespective of their respective target accuracy.

Accordingly, the required target accuracy would not result from the requirements of the Commission proposal. Rather, the target accuracy achieved in practice with the respective procedures would probably be sufficient. However, it is likely that new procedures or procedure variants will be developed that were not considered in the study. They will also want to claim the target accuracy required for classification as NGT. However, if they are not as precise as the known procedures, it remains open how they should be classified.

Furthermore, the only seemingly objective regulation on the type and number of changes in DNA, which according to Annex I of the Commission proposal should lead to the classification of an NGT plant in category 1, is undefined.[69]

Thus, the central criterion for the equivalence of NGT plants with conventional plants, and thus for classification in category 1, is that the genetic modifications have a sequence similarity with the target site that can be predicted by bioinformatic tools (Annex I, sentence 1).

It is thus clear that only the sequence similarity, i.e. only the similarity of the DNA sequences, is important and not, for example, the properties and risks caused by genetic modifications and their similarities with those of conventional plants.

[67] Thus Annex A of the Commission's study of 29.04.2021, p. 62: "An umbrella term used to describe newer techniques of mutagenesis that induce mutation(s) in selected target locations of the genome without insertion of genetic material."

[68] See the definitions of these techniques in Annex A of the Commission's study of April 29, 2021, p. 61 f.

[69] Cf. European Networks of Scientists for Social and Environmental Responsibility (ENSSER), Analysis statement on the EU Commission's new GM Proposal, 07.07.2023. and Testbiotech, New genetic engineering: EU Commission's legislative proposal endangers nature, the environment and the future of our livelihoods, Testbiotech Background 31.08.2023, p. 5.

However, it is completely unclear when sequence similarity should exist. It is obvious that the degree of similarity between the DNA sequences of the conventional and the NGT plant is important. It is unclear how high this degree of similarity must be for the required sequence similarity to exist. It is also unclear how long the DNA sequences that are compared must be. Is sequence similarity already present if 10, 15, 18 or 19 base pairs of a DNA sequence match 20 base pairs, is the relevant length of the DNA sequence to be determined differently or does the degree of similarity of the complete DNA sequence of the plant matter?

The requirement that the sequence similarity must be able to be predicted by bioinformatic tools is comparably indeterminate. For here, too, it remains open how precise the prediction and how high the agreement of the sequence change with the prediction must be. Furthermore, it seems that only the predicted changes matter. According to this, it would be irrelevant if the genetical change led to further, unpredicted and possibly surprising changes in addition to the predicted changes. Above all, it is apparently not at all necessary to examine and determine whether there have been unpredicted changes in addition to the predicted changes.

The significance of the vagueness of this provision is exacerbated by the proposed empowerment of the Commission to adopt implementing rules on the information required to demonstrate the classification of an NGT plant [Art. 27(a)]. The determination of the required information would indirectly place the interpretation and application of the undefined criteria for determining the scope practically in the hands of the Commission, since the competent authority could and would have to decide on the basis of the information provided. In this way, the Commission would have an even greater influence on the determination of the scope than through the authorization to adapt the criteria of Annex I to technical progress. This can only be done by means of delegated acts, so that the European Parliament and the Council still have a veto right.[70]

As a result, it is very uncertain how many GM plants will be classified as category 1 and 2 NGT plants in the future and which characteristics will distinguish these NGT from conventional plants. Due to the high attractiveness of deregulating category 1 NGT plants, it must be expected that well over 90% of GM plants will be classified as category 1 NGT plants in the future.[71] This would practically reverse the theoretical rule-exception relationship between the Deliberate Release Directive and the NGT Regulation and abolish genetic engineering legislation for more than 90% of GMOs.

7. Labeling and freedom of choice

The precautionary principle is also violated by not labeling category 1 NGT plants and the products derived from them (with the exception of the remaining labeling for seeds).

On the one hand, the labeling of products of NGT category 1 plants is particularly necessary precisely because no risk assessment takes place prior to marketing. Particularly when risks can only be identified retrospectively, the identifiability of category 1 NGT plants is of central importance. After the fact, effective protective measures, such as the elimination or recall of products made from category 1 NGT plants that are identified as hazardous only after they have been placed on the market, can only be taken if the products concerned can be easily and quickly identified on the basis of their labeling.

Furthermore, only labeling allows downstream companies in the production chain and consumers to make individual precautionary decisions by avoiding the use of category 1 NGT plants and plants derived from them products. This individual freedom of choice is also particularly relevant from a precautionary point of view in the case of category 1 NGT plants, because companies and consumers cannot rely on them due to the lack of official risk identification and assessment.

[70] Art. 5(3) in conjunction with Art. 26 of the Commission proposal.

71 According [to] evaluations by the German Federal Agency for Nature Conservation (BfN), approx. 94% of 86 currently developed NGT plants are likely to fall into category 1: Cf. presentation by Margret Engelhard at the GMO free Europe confe- rence on 07.09.2023:

8. Admissibility of coexistence measures?

It remains open whether and to what extent the member states should be allowed to continue to require mandatory coexistence measures for category 1 NGT plants.

Such measures include the publication of cultivation areas of GM plants in a location register (§ 16a GenTG) and requirements for good professional practice in the cultivation of GM plants, e.g. compliance with minimum distances to conventional crops (§ 16b GenTG in conjunction with the Genetic Engineering Plant Production Ordinance).

The admissibility of such national coexistence regulations also for NGT plants of category 1 is supported by the fact that, according to the Commission proposal, only the legal provisions of the Union applicable to GMOs are not to apply to NGT plants of category 1 (Art. 5 para. 1). According to this, the regulatory competence of the Member States to enact coexistence regulations remains unaffected (cf. Art. 26a of the Release Directive).

The declared aim of the Commission proposal to put Category 1 NGT plants on an equal footing with conventional plants speaks against the admissibility of such national coexistence regulations.

In this respect, the Commission proposal will lead to legal uncertainty. The very doubts about the permissibility of national coexistence measures for category 1 NGT plants, justified by an NGT regulation, are likely to pose a considerable hurdle in the political debate about the enactment or maintenance of such coexistence regulations.

9. Conclusion

The Commission's proposal for an NGT regulation contradicts the precautionary principle in key aspects. In particular for NGT- Category 1 plants, it repeals all precautionary provisions of the Release Directive, although the Commission claims its proposal is consistent with the Release Directive.

The Commission proposal is blind to potential risks of NGT crops. Its privileges are not justified by any particular benefit. For NGT plants of category 1, any risk assessment is to be dispensed with in future, contrary to the requirements of the Cartagena Protocol. The risk management regulations of the Release Directive are to be deleted without replacement, so that even in the case of subsequently identified risks and hazards, no appropriate measures can be created by authorities specializing in this area. Moreover, the scope of the NGT Ordinance is so vague that it is not clear which properties and risks of NGT plants are to be removed from the control of genetic engineering law. Furthermore, it must be feared that the precautionary genetic engineering law will no longer have any practical relevance in the future, because almost all practical applications will be concentrated on the regulations of such an NGT regulation, which are excluded from the scope of the genetic engineering law.

If the Union legislator were to adopt the regulation as proposed by the Commission, it would exceed the limits of its regulatory leeway in the application of the precautionary principle due to the contradictions described above and in view of the binding requirements of the Cartagena Protocol and the case law of the ECJ on the precautionary principle under primary law. An action for annulment against such a regulation would therefore have good prospects of success.

The lack of a risk identification and labeling obligation also leads to great legal uncertainties for companies. It raises the question for developers and distributors of NGT plants and NGT products of category 1 as well as for all companies in the food and feed chain whether and to what extent they are liable for damage that may result from the use of NGT plants and NGT products of category 1.

Is risk identification and assessment required due to product responsibility under civil law? Who is responsible - those who develop and market category 1 NGT plants or those who use them?

Who has to pass on which information (classification, properties, risks) to his customers without being asked or who has to ask his suppliers for it? Which risks are covered by which or whose insurance?