

**Comment on the report “Compatibility of the EU proposal for a regulation on plants based on certain new genomic techniques with the Cartagena Protocol on Biosafety”  
Vöneky et al. (2025)**



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## Summary

Whilst we agree with the finding of Vöneky et al. (2025) that the proposed EU legislation for plants obtained from new genetic engineering (new genomic techniques, NGTs) does not meet the obligations under the Cartagena Protocol in regard to notification, information and labeling, we would argue that in regard to risk assessment, the findings of Vöneky et al. (2025) need to be re-examined.

As shown in this background paper, the EU Council proposal would allow the environmental release and marketing of NGT plants without mandatory risk assessment, simply on the basis of formal criteria without these being sufficiently scientifically justifiable.

Therefore, the proposal put forward by the EU Council and the EU Commission neither fulfill EU obligations under the Cartagena Protocol nor the requirements of its Annex III.

## 1. Introduction

In their report “*Compatibility of the EU proposal for a regulation on plants based on certain new genomic techniques with the Cartagena Protocol on Biosafety*”, Vöneky et al. (2025) argue that NGT plants cannot be exempted from the obligations under the Cartagena Protocol. It is shown that NGT plants meet the criteria provided by the Protocol regarding the definition of Living Modified

Organisms (LMOs), i.e. *“living organism[s] that [possess] a novel combination of genetic material through the use of modern biotechnology.”*

EU regulation of NGT plants therefore has to fulfill the obligations set out in the Cartagena Protocol in regard to notification and information, as well as labeling requirements, risk assessment and risk management.

Commenting on the ongoing debate around the future regulation of NGT plants, the report comes to the conclusion that the version put forward by the EU Council *“fails to comply with the Cartagena Protocol regarding the notification and information obligations as well as labeling requirements, as it removes NGT 1 plants from the scope of these obligations.”*

Nevertheless, according to the report, the EU Council version can be seen to comply with the obligations of the Cartagena Protocol on risk assessment, *“as it is scientifically justifiable to determine risks associated with NGT 1 plants as a group of cases and then to verify, on the basis of pre-determined criteria, whether a specific plant falls within this group.”*

## **2. The provisions of the Cartagena Protocol in regard to risk assessment of LMOs**

The Cartagena Protocol on Biosafety to the Convention on Biological Diversity is a binding international agreement regulating the transboundary movement of living modified organisms (LMOs) to protect biological diversity and human health.<sup>1</sup>

Article 15 of the Cartagena Protocol requires that risk assessment is undertaken *“in a scientifically sound manner, in accordance with Annex III and taking into account recognized risk assessment techniques. Such risk assessments shall be based, at a minimum, on information provided in accordance with Article 8 and other available scientific evidence in order to identify and evaluate the possible adverse effects of living modified organisms on the conservation and sustainable use of biological diversity, taking also into account risks to human health.”*

Annex III of the Cartagena Protocol reads as follows:

### *Objective*

*1. The objective of risk assessment, under this Protocol, is to identify and evaluate the potential adverse effects of living modified organisms on the conservation and sustainable use of biological diversity in the likely potential receiving environment, taking also into account risks to human health.*

### *Use of risk assessment*

*2. Risk assessment is, inter alia, used by competent authorities to make informed decisions regarding living modified organisms.*

### *General principles*

*3. Risk assessment should be carried out in a scientifically sound and transparent manner, and can take into account expert advice of, and guidelines developed by, relevant international organizations.*

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<sup>1</sup><https://bch.cbd.int/protocol/text>

4. *Lack of scientific knowledge or scientific consensus should not necessarily be interpreted as indicating a particular level of risk, an absence of risk, or an acceptable risk.*
5. *Risks associated with living modified organisms or products thereof, namely, processed materials that are of living modified organism origin, containing detectable novel combinations of replicable genetic material obtained through the use of modern biotechnology, should be considered in the context of the risks posed by the non-modified recipients or parental organisms in the likely potential receiving environment.*
6. *Risk assessment should be carried out on a case-by-case basis. The required information may vary in nature and level of detail from case to case, depending on the living modified organism concerned, its intended use and the likely potential receiving environment.*

#### *Methodology*

7. *The process of risk assessment may on the one hand give rise to a need for further information about specific subjects, which may be identified and requested during the assessment process, while on the other hand information on other subjects may not be relevant in some instances.*
8. *To fulfil its objective, risk assessment entails, as appropriate, the following steps:*
  - (a) *An identification of any novel genotypic and phenotypic characteristics associated with the living modified organism that may have adverse effects on biological diversity in the likely potential receiving environment, taking also into account risks to human health;*
  - (b) *An evaluation of the likelihood of these adverse effects being realized, taking into account the level and kind of exposure of the likely potential receiving environment to the living modified organism;*
  - (c) *An evaluation of the consequences should these adverse effects be realized;*
  - (d) *An estimation of the overall risk posed by the living modified organism based on the evaluation of the likelihood and consequences of the identified adverse effects being realized;*
  - (e) *A recommendation as to whether or not the risks are acceptable or manageable, including, where necessary, identification of strategies to manage these risks; and*
  - (f) *Where there is uncertainty regarding the level of risk, it may be addressed by requesting further information on the specific issues of concern or by implementing appropriate risk management strategies and/or monitoring the living modified organism in the receiving environment.”*

Specific points to consider are listed in Annex III.

In the EU, these requirements have been implemented by adopting the Directive 2001/18/EC (amended by Commission Directive (EU) 2018/350), which is the current the basis for the risk assessment of NGT plants as confirmed by the European Court of Justice.<sup>2</sup> As requested in the Protocol, this Directive foresees a case-by-case risk assessment, taking into account intended and unintended effects since “*intended and unintended changes can have either direct or indirect, and either immediate or delayed effects on human health and on the environment.*” Therefore, as introduced in Annex (C1) in the Commission Directive (EU) 2018/350, the risk assessment “*shall identify the intended and unintended changes resulting from the genetic modification and shall evaluate their potential to cause adverse effects on human health and on the environment.*”

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<sup>2</sup>European Court of Justice, Case C-528/16

### 3. The provisions in Annex I of the EU Council proposal for NGT plant regulation

Similarly to the EU Commission, the EU Council proposes a threshold of genetic modifications to establish equivalence with conventionally-bred plants. Additionally, the EU Council suggests extending the number of genetic changes per number of chromosomes. The text of the proposed Annex I reads<sup>3</sup>:

*“A NGT plant is considered equivalent to conventional plants when it differs from the recipient/parental plant by no more than 20 genetic modifications per monoploid genome of the types referred to in Points 1 to 4, in any DNA sequence sharing sequence similarity with the targeted site that can be predicted by bioinformatic tools.*

*Criteria specific to the use of targeted mutagenesis:*

- (1) substitution or insertion of no more than 20 nucleotides;*
- (2) deletion of any number of nucleotides;*

*Criteria specific to the use of cisgenesis:*

*(3) on the condition that the genetic modification does not interrupt an endogenous gene or that the resulting combination of DNA sequences in the recipient plant already occurs in a species from the breeders' gene pool:*

- (a) insertion of a continuous DNA sequence existing in the breeders's gene pool;*
- (b) substitution of an endogenous DNA sequence with a continuous DNA sequence existing in the breeders' gene pool;*

*(4) targeted inversion of a sequence of any number of nucleotides.”*

Article 6 and 7 of the EU Council proposal request a verification process to be conducted to examine whether the NGT plants meet the criteria in Annex 1. This verification process is to be carried out before they are placed on the market or released into the environment. This verification process is to be carried out by the national competent authorities. However, as Recital 20 explains, this process is of a formal nature and does not involve any risk assessment:

*(20) The verification of category 1 NGT plant status is of technical nature and does not involve any risk assessment or risk management considerations and the decision on the status is only declaratory. Therefore, when the procedure is conducted at Union level, such implementing decisions should be adopted by the advisory procedure, supported by scientific and technical assistance by the Authority.*

### 4. The justification of the Commission (and Council)

As stated by Vöneky et al. (2025), the criteria proposed for Category NGT 1 plants were not defined or proposed by EFSA. Instead, the EU Commission, when presenting its draft in 2023 (Commission 2023a), gave several reasons indicating political (or economic) assumptions that led to the proposal. In essence, the Commission (2023a) argues: *“As shown by the scientific literature analysis,*

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<sup>3</sup> Council of the European Union, 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 – (draft) Mandate for negotiations with the European Parliament, ST 16714 2023 INIT, available at <https://data.consilium.europa.eu/doc/document/ST-16714-2023-INIT/en/pdf>.

*conventional breeding techniques can lead to a high number of modifications. However, certain combinations of modifications would be less likely to occur by conventional methods. To take this into account, following a conservative approach and considering the novelty of new genomic techniques, the criteria would be complemented by thresholds for both size and combination of modifications, also to ensure that plants obtained by complex modifications are excluded from the notification procedure.”*

It can be concluded that the EU Commission is aware that certain combinations of genetic changes in NGT plants are less likely to occur with conventional methods than with other methods. Therefore, the general aim of risk assessment should be to establish criteria with which to identify (case-by-case) NGT plants that cannot be obtained from conventional breeding, and to adapt the risk assessment accordingly. In this context, the number of mutations becomes the crucial criterion.

The Commission confirms its approach in another document (Commission, 2023b) which states: *“The criteria were developed to define type and number of mutations introduced by targeted mutagenesis and cisgenesis that could also be obtained by conventional breeding methods or could occur spontaneously. They were developed on the basis of a literature analysis of 90 scientific, peer-reviewed original studies and reviews (see Annex) on plants obtained by conventional breeding methods and on genetic variations in plants. The objective of the analysis was to explore:*

- Which type of mutations occur due to natural mutation or application of conventional breeding methods.*
- What size ranges these mutations span.*
- How many of these mutations do typically occur in a single plant.”*

It is interesting to know that none of the 90 publications deal with the question of whether safety can be concluded (or is more likely) by referring to a threshold of 20 genetic changes per plant. None of them suggest thresholds as proposed by the EU Commission and the EU Council.

## **5. The assessment of the category of NGT 1 plants by Vöneky et al.**

Vöneky et al. (2025) emphasise that risk assessments are a key requirement according to the regulatory framework of the Cartagena Protocol, and that the risk assessment is to be carried out in accordance with Annex III of the Cartagena Protocol. They explain that under the current EU GMO legislation, all NGT plants are subject to an environmental impact assessment that largely mirrors the requirements of Annex III Cartagena Protocol.

However, according to the proposal put forward by the EU Council, a large group of NGT 1 plants would be excluded from this process of risk assessment. Instead, NGT 1 plants could be placed on the market or released into the environment after successfully passing the verification process.

Vöneky et al. (2025) state: *“Hence, one must answer the question whether this proposed verification procedure for NGT 1 plants according to the Council version fulfils the requirements on risk assessments set out in Annex III Cartagena Protocol.”*

To answer this question, Vöneky et al. (2025) state that the Cartagena Protocol only *“frames the procedure but is silent on the evaluation of the results of the risk assessment or on the decisions to be taken based on these results.”* In regard to the procedure, it is mentioned that Annex III of the

Cartagena Protocol specifies that risk assessments should, as a general rule, be carried out on a case-by-case basis. They discuss whether the requirement of a case-by-case basis might not be fulfilled if such a procedure “*serves only to check that a NGT plant falls within a pre-determined group of cases, without requiring the identification and evaluation of risks specifically for that plant.*”

However, Vöneky et al. (2025) point out that the Cartagena Protocol offers considerable leeway when it comes to the depth of risk assessments when it states that “[t]he required information may vary in nature and level of detail from case to case, depending on the living modified organism concerned, its intended use and the likely potential receiving environment.”

Therefore, they conclude that “*the decisive factor is that the risk assessment is ‘carried out in a scientifically sound and transparent manner’ and is ‘appropriate’ to fulfil its objective.*” In this context, Vöneky et al. (2025) also mention the expert controversy about this approach, raising substantial doubts about whether the EU Council version is an appropriate and scientifically sound approach.

However, in response to this debate they also state: “*Our legal opinion cannot offer a final assessment of these arguments, as these have to be based on scientific discourse. But, with all due caution, from a legal point of view, one can argue that a scientific consensus is not necessary concerning the approach taken in the risk assessment. As mentioned, the Cartagena Protocol itself provides only that it must be appropriate to fulfil its objective as well as that it is scientifically sound. If different scientific opinions exist, States Parties therefore have discretion on the approach taken, as long as it is scientifically justifiable.*”

Finally, Vöneky et al. (2025) suggest that the EU Council approach may be considered to be scientifically justifiable, as “*it includes a normative determination of the acceptable threshold of risks associated with NGT 1 plants by the COM, and the verification procedure under the Council version serves to verify that a NGT plant falls within that predetermined group of cases.*”

They conclude that the EU Council proposal “*carries with it the assertion that the potential adverse effects or risks associated with NGT 1 plants are the same for all intended use cases and for all potential receiving environments, and that any further differentiation is not scientifically necessary.*”

## **6. Facts and findings**

In the context of the Cartagena protocol, the following questions can be raised:

- 1) Can the formalistic verification process be regarded as a case-by-case risk assessment as set out in the Protocol?
- 2) Can the concept of a threshold for the number of genetic changes be seen as scientifically justifiable and sufficiently qualified to assess risks of NGT plants in a way that meets the objectives of the Protocol?
- 3) Is it correct to assume “*that the potential adverse effects or risks associated with NGT 1 plants are the same for all intended use cases and for all potential receiving environments, and that any further differentiation is not scientifically necessary*”?

### **The first question**

As far as the first question is concerned, it is possible to choose a similar approach to Vöneky et al. (2025) and apply the Vienna Convention on the Law of Treaties (VCLT). The VCLT is an international treaty that contains rules on, inter alia, the conclusion and interpretation of treaties under international law. Article 31 of the VCLT, which is about general rules for interpretation, states that:

*“1. A treaty shall be interpreted in good faith in accordance with the ordinary meaning to be given to the terms of the treaty in their context and in the light of its object and purpose.  
2. The context for the purpose of the interpretation of a treaty shall comprise, in addition to the text, including its preamble and annexes:  
(a) any agreement relating to the treaty which was made between all the parties in connection with the conclusion of the treaty;  
(b) any instrument which was made by one or more parties in connection with the conclusion of the treaty and accepted by the other parties as an instrument related to the treaty.  
[...]”*

In the context of the VCLT rules, it has to be concluded that that the approach of the EU Council and the EU Commission is not in accordance with the requirements of the Protocol:

(1) It would exempt a large group of LMOs from risk assessment (Bohle et al., 2024) by simply using a declaratory process based on formal criteria. This process cannot be considered to be a case-by-case risk assessment, which outlined by Vöneky et al. (2025), is essential to fulfill the obligations under the Protocol.

(2) The methodology on how to perform risk assessment would not be consistent with existing EU regulations based on the Protocol. Directive 2001/18/EC is generally seen as the correct implementation of the Protocol. Following the logic of the VCLT, it thus has to be taken into account in the interpretation of the Protocol. While Vöneky et al. (2025) may be correct in stating that *“the Cartagena Protocol itself does not determine the evaluation of the results of the risk assessment or on the decisions to be taken based on these results”*, the methodology on how to come to the results of the risk assessment has, nevertheless, to be consistent. This requirement to be consistent with the existing implementation of the Protocol is also necessary from the perspective of the European Court of Justice (Case C-528/16) decision.

The methodology as set in the Protocol is also binding for the future regulation of LMOs in the EU. In particular, it has to be taken into account that:

*“To fulfil its objective, risk assessment entails, as appropriate, the following steps:*

- (a) An identification of any novel genotypic and phenotypic characteristics associated with the living modified organism that may have adverse effects on biological diversity in the likely potential receiving environment, taking also into account risks to human health;*
- (b) An evaluation of the likelihood of these adverse effects being realized, taking into account the level and kind of exposure of the likely potential receiving environment to the living modified organism”.*

These requirements are fulfilled by the provisions of Directive 2001/18, but not by the Council proposal.

Therefore, the first question has to be answered with ‘No’.

### **The second question**

The EU Council and the EU Commission approach appears to suffer from severe scientific inconsistencies: the EU Commission is aware that certain combinations of genetic changes in NGT plants are less likely to occur with conventional methods than others. Therefore, the general outline for a case-by-case risk assessment should establish criteria allowing the identification of NGT plants less likely to result from conventional breeding and to adapt risk assessment accordingly. As yet, no such measures have been proposed.

Instead, it is the number of mutations (which is in essence no different to the number of combinations) that would be the crucial criterion to exempt NGT plants from risk assessment. This criterion has been introduced without any reference to specific scientific publications or other evidence based on relevant data that would indicate the viability of such a threshold.

Indeed, it is scientifically implausible that this criterion could enable reliable conclusions to be drawn on safety or equivalence to plants obtained from conventional breeding. As mentioned, none of the 90 publications referred to (Commission, 2023b) deal with the question of whether safety can be concluded from a threshold of 20 genetic changes per plant. Furthermore, none of the 90 publications even suggests any threshold at all. As several examples (see below) show, the approach of a threshold clearly ignores existing evidence.

Therefore, and also in the light of the answer to the third question, this question also has to be answered with 'No'.

### **The third question**

This question is closely related to the second question. If there is evidence that it is not correct to assume *“that the potential adverse effects or risks associated with NGT 1 plants are the same for all intended use cases and for all potential receiving environments, and that any further differentiation is not scientifically necessary”*, then the EU Council and the EU Commission concept falls apart.

Although a 'dire wolf'<sup>4</sup> is not a plant, it may be used to exemplify some basics, before discussing NGT plants: The US company Colossal Biosciences is claiming to have brought back the extinct species of the 'dire wolf'. Ultimately, however, Colossal has created nothing more than a NGT grey wolf whose genome has been altered at 20 target sites (that are reported to be endogenous regulatory genomic units). Among other things, the genetically engineered wolf is larger and has a modified coat. As a result, these animals may be considered to be 'transgenic' in a wider sense, i.e. their genetic material contains characteristics that are foreign to the species. They do not belong to an extinct species, but are completely new to existing ecosystems. If the genetically engineered wolves were to escape and mate with their wild counterparts, they could become a threat to the population of grey wolves. The genetically engineered wolves are said to be larger and stronger than their male competitors, and could therefore become dominant in the pack. Their offspring would be hybrids that could also possibly spread rapidly. Thus, a project claiming to have resurrected an extinct species would become a danger to existing species.

This example shows that the risks of a NGT wolf that inherits no more than 20 genetic changes, are not the same as those known from the grey wolf. Furthermore if a population of wild grey wolves were to be present, the risks would be considerably higher than in other environments. As a hypothetical case, if the EU Council and EU Commission proposal were to be applied to the NGT wolf, it might be released without mandatory risk assessment. This would be clearly against the

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<sup>4</sup><https://time.com/7274542/colossal-dire-wolf/>

obligations under the Protocol. It also should be taken into account that hybrid offspring of NGT wolves and grey wolves may be able to perform transboundary movements.

One may argue that in the case of the ‘dire wolf’, no national competent authority (if conducting the verification process) would come to the conclusion that these animals could enter the environment as NGT 1 organisms.

However, when we return to plants, there is a long list of examples of NGT plants that would all fulfill the EU Council criteria for NGT 1 plants, even though their genomes inherit characteristics that are not known in the existing species populations and are unlikely to be obtained from conventional breeding or random mutagenesis (see Kawall 2019; Kawall 2021; ANSES 2024). These plants may be considered to be the ‘dire wolves’ of the plant kingdom. The best plant examples to compare with the ‘dire wolf’ might be those NGT plants that result from *de novo* domestication of wild plants. For example, *de novo* domestication for a rapid conversion of wild relatives into crop plants was performed in tomatoes by Zsögön et al. (2018). The researcher simultaneously knocked out six genes in a wild species of the tomato plant (*Solanum pimpinellifolium*), whereby agronomically desirable traits were established in the genotype of the wild tomatoes that are new to the wild species. Therefore, the outcome is not equivalent to the one from conventional breeding. On the contrary, this NGT plant is a new tomato with a unique combination of genes that have to be assessed in detail. It could even be seen as a ‘transgenic’ version of *Solanum pimpinellifolium*, while according to the Council proposal, it would be considered as NGT 1.

As Kawall (2021) explains: “Plants (...) which contain traits that are known from cultivated varieties, but are expressed in a new genetic background, cannot be equated to their conventional or natural counterparts, as the corresponding target gene(s) might have divergent functions or interactions in different species. *De novo* domesticated plants generated using CRISPR/Cas9 are interesting examples in that regard. (...) Comprehensive environmental and health risk assessments will be needed to ensure that no effects with negative impacts have occurred.”

In its 2022 report, EFSA highlighted the challenges for risk assessment in this case. EFSA even considers these tomatoes to have been obtained from synthetic biology (SynBio), thus underlining the complexity of this new genotype (EFSA, 2022). They come to the conclusion that current EU guidance may not be sufficient to assess these risks: “*This case study highlighted potential issues for the applicability of the existing comparative analysis guidelines with respect to the availability of the conventional counterpart and non-GM reference varieties. The parental line used to obtain this SynBio product (S. pimpinellifolium) is not commonly consumed (...). The selection of reference varieties would also be challenging: wild tomato varieties of commercial use as food and feed might not be available. Tomatoes cultivated for food and feed purposes could be of interest for comparison, considering the intended use of the SynBio tomato, but would be genetically far from the SynBio plant. As a consequence of the lack of an appropriate comparator (...), the comparative analysis for this SynBio case may not be carried out as described in the existing guidelines.*”

The list of known examples of NGT 1 plants inheriting new genotypes that were previously absent in these species (and are unlikely to be obtained from previous methods of breeding) includes plant species, such as tomatoes (Nonaka et al., 2017), wheat (Sánchez-León et al., 2018), rice (Wakasa et al., 2024), camelina (Morineau et al., 2017) and poplar trees (Ortega et al., 2023). Each of them, as well as the ‘dire wolf’ are inheriting what the Protocol calls a “novel combination of genetic material” that needs to be risk assessed on a case-by-case basis. Furthermore, the risks also depend on the receiving environment: for example, the potential spread of its new characteristics in the

environment depends on the presence of wild relative species in the receiving environment. However, the criteria proposed by the EU Council and the EU Commission would not enable the identification needed to distinguish these ‘dire wolves’ of the plant kingdom. Furthermore, all unintended effects resulting from the NGT processes that only could be assessed case-by-case basis, would be set aside completely.

In conclusion, it is evident that the potential adverse effects or risks associated with these NGT 1 plants are not generally equal to those of conventionally-bred plants nor for all intended uses of NGT plants, and that these risks also depend on the receiving environment.

Therefore, also the third question has to be answered with ‘No’.

## 7. Conclusions

We agree with the finding of Vöneky et al. (2025) that NGT plants are LMOs in the sense of the Cartagena Protocol. We also agree that the proposal of the EU Council for the future regulation of NGT plants does not fulfill obligations under the Cartagena Protocol in regard to the notification, information or labeling requirements.

However, the Vöneky et al. (2025) findings need to be re-examined in regard to risk assessment. As shown in this background, the EU Council proposal would allow the NGT plants to be released into the environment or marketed without mandatory risk assessment, simply by applying formal criteria that lack sufficient scientific justification.

It is known that far fewer than 20 genetic changes can be sufficient to generate new characteristics that go beyond the spectrum of known characteristics of the species, e.g. in poplars, tomatoes, rice, wheat and camelina. The fact that these plants are not regarded as ‘transgenic’ in the classical sense does not imply that the risks can be considered equivalent to those of conventionally-bred plants. Furthermore, their actual risks will depend on the biodiversity in the receiving environments. There is no doubt that these plants need to be risk-assessed on a case-by-case basis.

Therefore, in regard to risk assessment, the EU Council and the EU Commission proposals are not in accordance with the obligations of the EU under the Cartagena Protocol. In addition, they do not fulfill the requirements of Annex III of the Protocol. More specifically, the proposal and its Category 1 for NGT plants is not scientifically justifiable.

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