A crack in creation?*

Release of NGT organisms may disrupt the ecosystems

* Title of a book from Jennifer Doudna and Samuel Sternberg (2017), Penguin Random House.

This report does not represent the position of JD and SS.

IN A NUTSHELL

This report provides a brief outline of some impacts that deregulation of NGT organisms could have on plants, animals and micro-organisms, particularly on the environment and ecosystems.

New genetic engineering (or new genomic techniques, NGTs) has progressed far beyond simply imitating naturally occurring gene variants. At present, the most important molecular NGT tools are so-called 'gene scissors', e.g. CRISPR/Cas, which can be used to overcome many of the constraints in conventional breeding (Koller, 2025). Gene scissors consist of recombinant enzymatic mutagens that can be used to insert new gene variants and combinations into the genome that were previously unknown and new to the environment.

Just a few genetic changes can be sufficient to achieve unique gene combinations that have never previously existed in nature, and which would be virtually impossible to achieve through conventional breeding (Mundorf et al., 2025; Koller, 2025). NGT organisms of this kind must be considered 'new-to-nature', and must consequently be subject to risk assessment requirements (ANSES, 2024).

On the whole, new genetic engineering techniques allow far deeper interventions into species characteristics and their ecosystems than could ever be expected from conventional breeding, or from evolutionary processes within limited periods of time. To put it bluntly, genetic engineering can make everything happen 'all at once' in all species, whereas evolutionary processes only allow a certain selection of characteristics to emerge and manifest in populations over very long periods of time. Natural processes thus enable mutual adaptation through co-evolution.

Further, NGTs make it possible to release large numbers of organisms from different species, which may be new-to-nature and not subjected to co-evolutionary processes. Thus possibly leading to new combinatorial, cumulated and potential cascading threats to ecosystems, all of which go far beyond the risks associated with individual NGT organisms. →

In comparison to transgenic plants, the use of NGT tools has hugely expanded the range of species that can be genetically engineered, including non-domesticated species (Testbiotech, 2026a). There are already many NGT plants with characteristics that differ significantly to those known in conventional breeding (Koller, 2025; ANSES, 2024). The new traits include, for example, changes in the composition of plant constituents, manipulated flowering, increased fitness, or changes in interactions between plants and microorganisms.

Several environmental risks associated with NGT organisms have already been described in scientific literature, e.g. the negative effects on pollinators and food webs, increased invasive potential, weakening of natural plant populations, yield depression, insect toxicity and unintended effects on soil organisms.

Inadequate regulation in regard to the release of organisms created with NGTs has the potential to endanger ecosystems. It may also become an underlying cause of species extinction and a threat to food security. All of the above can result in 'A Crack in Creation' as suggested by the title of a book by Jennifer Doudna, one of the inventors of the CRISPR/Cas gene scissors (Doudna & Sternberg, 2017).

As far as future legislation is concerned, it is important to extend risk research and amend approval processes to take account of the new characteristics in NGT organisms, including cumulated and combinatorial hazards.

However, overall EU policy in this respect appears to be moving in a completely different direction, in regard to NGT plants. According to EU plans, the environmental risk assessment of NGT plants will only rarely be mandatory. In particular, a proposed threshold of 20 genetic changes would become a central component of future regulation.[1] Based on current estimates, almost all NGT plants could be brought to market without mandatory environmental risk assessment. If this is agreed in the final decision, the planned deregulation would also apply to wild plant and crop species capable of spreading within natural populations. →

[1] https://data.consilium.europa.eu/doc/document/ST-16661-2025-INIT/en/pdf

The planned future regulation would also make it impossible to track, trace or monitor the NGT plants and their (hybrid) offspring in the environment. However, experience gained from large-scale and long-term cultivation of transgenic plants shows that the results of small field trials are completely inadequate in predicting real environmental risks.

The current proposal also fails to consider the convergence of artificial intelligence (AI) and NGTs, which will considerably accelerate developments and multiply the risks: the proposed new legal framework could intentionally incorporate AI to design NGT plants that are within the proposed thresholds, but which would nevertheless pose serious risks to the environment (Juhas et al., 2025; Mundorf et al., 2025).

Recent developments are very much in the interests of large companies, such as US-based Corteva, which is the most important player globally for patent applications claiming NGT plants. These companies broadly consider NGTs to be a disruptive technology (Testbiotech, 2021). However, this is fundamentally problematic from the perspective of health and environmental protection, as insufficiently controlled releases of genetically engineered organisms have the potential to disrupt ecosystems and endanger the future of biodiversity in Europe.

The EU is on the verge of intentionally handing over its responsibilities for the safe use of the new technologies to free market forces. In fact, the planned future regulation of NGT plants would see the EU would give the biotech industry carte blanche to import and release their NGT plants via a fast-track approval process, with scant or no regard for health or environmental consequences. If the EU is to preserve its credibility, it must absolutely take a stand: As the recent example form the US shows, science must not be disregarded simply because it might hinder the deregulation demanded by the industry.[2]

[2] https://www.science.org/content/article/epa-sidesteps-science-repeal-u-s-greenhouse-gas-rules

EXAMPLES AND RISKS OF NGT ORGANISMS THAT ARE NEW TO THE ENVIRONMENT

To date, hardly any experimental risk research has been conducted with NGT organisms. However, several risk scenarios and reasoned opinions have been published showing that risk assessment must be conducted regardless of the number of genetic changes. The following section presents ten examples of NGT organisms with hazards and risks that need to be explored. No matter whether it is plants or animals, the NGT-induced genetic changes are often about as unlikely to occur as artificial gene constructs in transgenic organisms.

TASTING LESS PUNGENT:

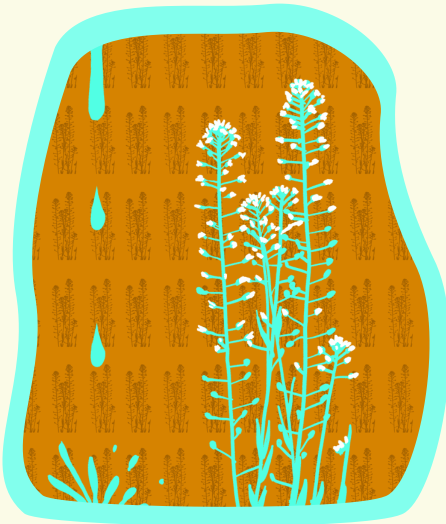
Weakening plant defence mechanisms

Brassica juncea is grown worldwide for use in oil and mustard production. The plants naturally produce substances known as glucosinolates, which act as a defence against pests and are known to be associated with health benefits after consumption. Pairwise used CRISPR/Cas to intervene in the metabolism of the glucosinolates and knock out specific gene functions. As a result, the leaves should taste less pungent (Karlson et al., 2022). The number and type of genetic changes that are necessary to achieve this trait in the NGT mustard fall within the proposed EU threshold for fast-track approvals. However, the specific genotype and phenotype are new to the environment.

This NGT intervention is associated with a reduction in compounds important to plant defence mechanisms. The NGT plants may consequently be more susceptible to plant pathogens or plant pests. Interactions with the environment may also be disturbed on several levels, thus possibly damaging other species associated with the plants (Barbour et al., 2022). Releases of these plants may become a major problem for the ecosystems, as the plants can persist and spread in the environment and hybridise with related species. The NGT plants were deregulated by the U.S. Department of Agriculture (USDA) without detailed in-depth risk assessment. Bayer is currently trying bring these plants to market.

CHANGES IN PLANT COMPOSITION:

Pollinators at risk



Several companies in the US and the EU are interested in genetically engineering oil producing *Brassica* plants such as camelina and oil seed rape. The aim is to alter the oil composition for specific purposes such as agrofuel production. Several of these plants exhibit a pattern of genetic changes that has resulted in significantly altered oil quality, which would have been almost impossible to achieve with conventional breeding methods (Kawall, 2021; Koller et al., 2024). In most cases, the number and type of genetic changes that are necessary to generate these NGT plants are within the proposed EU threshold for fast- track approval (see for example Bellec et al., 2024; Morineau et al., 2017).

Brassica plants such as camelina or oilseed rape originate from Europe. The plants can survive and propagate in the environment as well as hybridise with natural populations. Experts are warning that risks can arise from the cultivation of the NGT plants due to their altered oil quality and potential uncontrolled spread: interactions with beneficial insects and pollinators may be disturbed and defence responses to plant pathogens may be weakened (Kawall, 2021). In particular, changes in oil composition can affect the health of honey bees (Kawall, 2021; Koller et al., 2024).

GENETICALLY ENGINEERED WILD LIFE:

A threat to natural populations

According to a number of published studies and filed patent applications, the US company Colossal Biosciences, wants to 'bring back to life' extinct vertebrates, such as woolly mammoths, dire wolves, dodos and Tasmanian tigers. However, what the company is in reality trying to create are genetically engineered versions of existing wild life species, e.g. Asian elephants, grey wolves, South American running birds and marsupial mice (Testbiotech, 2026b). The intended effects largely depend on changes in gene regulation (as is the case with many NGT plants) and do not necessarily include the insertion of additional genes. Studies published so far indicate that the resulting NGT animals exhibit genetic changes previously unknown in these species (Chen et al., 2025).

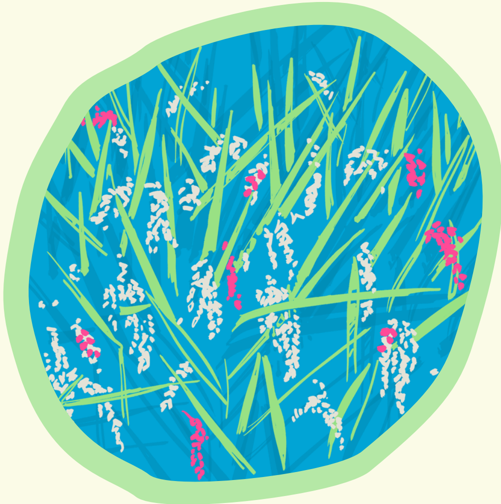
Interestingly, the number and types of genetic changes introduced to create a genetically engineered 'dire wolf' appear to be within the proposed EU threshold for fast-track release and market approval of NGT plants. This comparison with NGT animals exemplifies the huge potential of even just a limited number of small genetic changes. ⟶

If genetically engineered wildlife, such as the 'dire wolf', were to escape into natural populations of grey wolves, it is possible that they could reproduce. As these animals are larger and stronger than their natural counterparts, the genetically engineered grey wolves and their offspring would have a fitness advantage, and thus be capable of displacing natural populations. Significant consequences would ensue – not only for the protected wolf species, but also for ecosystems, and possibly humans if the genetic changes resulted in changed hunting behaviour.

As there is currently no proposal for a deregulation regrading NGT animals in the EU, it is not clear if the NGT wolves described would require mandatory risk assessment in future.

CHANGES IN YIELD AND EARLY FLOWERING:

Increased spread of weeds



In 2026, India approved the first NGT rice for commercial production (Solanki et al., 2026). The combination of small changes in regulatory units of the rice genome resulted in higher yields, altered architecture and early flowering in the NGT plants. The specific pheno- and genotype are new to the environment. However, the number and type of genetic changes that are necessary to generate this trait are within the proposed EU threshold for fast-track release and market approval.

If the NGT rice is grown in the fields, hybridisation with weedy rice found in all regions where rice is grown commercially is highly likely. It is also known that (hybrid) weedy rice can back-cross into fields where conventionally bred varieties are grown (Bauer-Panskus et al., 2013). In this case, the traits ‘higher yield’ and ‘early flowering’ are likely to increase the potential of (hybrid) weedy rice to spread in and around the fields, to lower yields and increase herbicide applications.

HORNLESS CATTLE:

Endangering the breeders' gene pool

Gene scissors were used in 2016 to genetically engineer cattle and make them 'hornless'. Scientists used a gene from a hornless breed as a template for this purpose. The resulting genotype may thus be considered as not new to the environment. However, in 2019 scientists found that genetic material from the bacteria used in the genetic engineering process had been introduced into the genome of the NGT cattle. They found, amongst other things, complete DNA-fragments able to confer resistance to antibiotics in the genomes of the NGT cattle shortly before they were due to be brought to the market (Norris et al., 2020). Consequently, the animals had to be slaughtered.

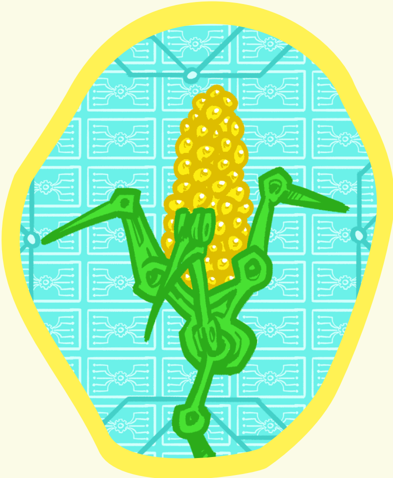
The use of gene scissors is not as simple as frequently suggested. In a first step, gene scissors mostly introduce the DNA into the cells by using tools which often involve bacterial genes. In many cases, these processes result in additional genes being unintentionally inserted into the genomes of the plants and animals. If overlooked, these undesirable genetic changes may spread rapidly and also accumulate in breeding populations, with possibly serious consequences for further breeding and food security. →

NGT plants face similar problems in regard to unintended insertions and off-target alterations (Braatz et al., 2017). In the above case, there are some interesting parallels to the planned deregulation of NGT plants: the number and types of genetic changes that are necessary to produce genetically engineered ‘hornless cattle’ would be within the proposed EU threshold for fast-track release and market approval of NGT plants. In addition, the proposed deregulation of NGT plants does not require a comprehensive assessment of unintended effects. The plants would only be subject to risk assessment if it were already known that transgenic elements (i.e. genes from other species) were present in the plant genome. However, the transgenes can also remain undetected as it was in the case of the ‘hornless cattle’. Furthermore, other unintended genetic changes that do not consist of transgenes, but which nevertheless pose a risk to breeding and the environment (Koller & Cieslak, 2023).

As there is currently no proposal for a deregulation regrading NGT animals in the EU, it is not clear if the NGT cattle described in this example would require mandatory risk assessment.

INSECTICIDAL AI MAIZE:

Endangering non-target species



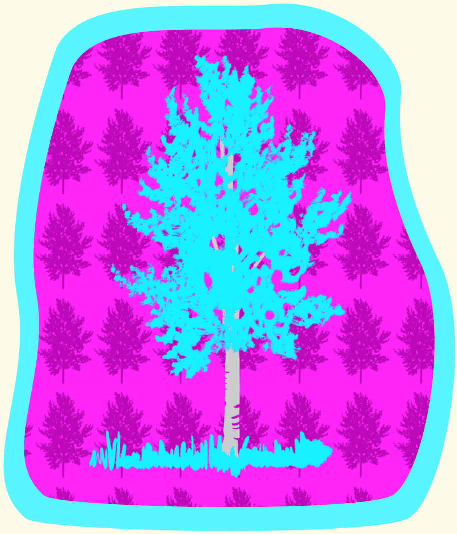
In 2025, it was demonstrated for the first time that it is possible to use a publicly available AI tool (ChatGPT 4o) to design a genetic blueprint for an insecticidal maize plant that could subsequently be produced with NGTs (Juhas et al., 2025). Although the number of genetic changes required is low (less than 20), it is very unlikely that the resulting specific combination of genetic changes could be achieved through conventional breeding methods.

Insecticidal plants may not only be toxic to the targeted pest species, they can also put non-target organisms, food webs, ecosystem functions and biodiversity at risk (Juhas et al., 2025).

According to the recent EU proposal for future regulation, NGT plants that produce known insecticides (or are made resistant to herbicides) must undergo environmental risk assessment. This is a sensible provision, but on its own is clearly insufficient with respect to the numerous environmental risks associated with many other NGT plants.

NGT POPLARS WITH REDUCED LIGNIN CONTENT:

Outbreeding depression



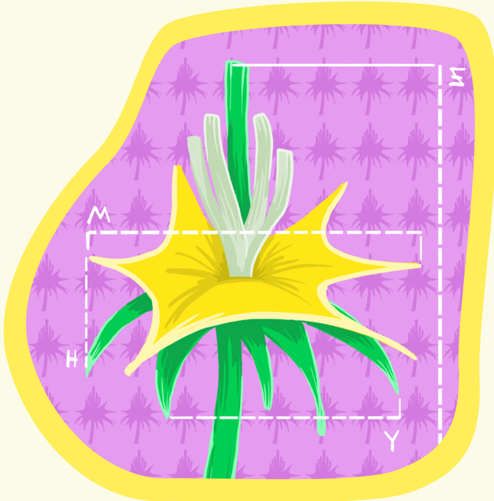
NGT poplar trees with reduced lignin content were developed with the help of AI (Sulis et al., 2023). The NGT poplars are expected to be more suitable for wood processing and paper production. They exhibit a previously unknown combination of genetic alterations and are new to the environment. The number and type of genetic changes necessary to generate this trait are within the proposed threshold for fast-track release and market approval.[3]

Poplars readily spread via pollen and seeds, root suckers, cuttings or broken branches. They grow almost anywhere – in old quarries, gravel pits, in sand or clay, in wetlands, mountains, plains etc. When they grow on river banks, seeds and broken branches can be carried over long distances. If the NGT poplars are introduced into native populations, this may weaken the resistance of these populations to environmental stress conditions, as reduced lignin content usually is associated with lower stability and less resistance to tree pathogens. Therefore, the uncontrolled spread of NGT poplars could become a threat to protected species such as the black poplar (FGU, 2024).

[3] In this specific case, risk assessment would only be required if transgenic elements originating from the genetic engineering process (which are unnecessary for cultivation) remain in the genome.

MANIPULATED FLOWERING:

Disruption of eco-systems



More than 100 studies on NGT applications with a particular focus on altering the flowering time across a wide range of plant species have already been identified (Hodaei and Werbrouck, 2023). A further study shows that the architecture of flowers can even be adapted to robotic pollination (Xie et al., 2025). In many cases, the NGT plants exhibit a previously unknown combination of genetic alterations that are unlikely to occur through conventional breeding.

Colour, scent and the structure of the flowers are crucial for pollinator preferences. Experiments have shown that genetic enigineering to alter the colour of flowers can cause a switch in the preferences of pollinators, from hawkmoths (butterflies) to bees (Lüthi et al., 2022). Large-scale cultivation of NGT plants with manipulated flowering can cause a severe disconnect in plant-pollinator interactions, with cascading effects on entire ecosystems (Testbiotech, 2026a).

Applications such as extreme early first flowering in NGT poplars (Ortega et al., 2023), changes in ‘robotic flowering’ (Xie et al., 2025) and a change of colour to attract specific pollinators (Lüthi et al., 2022) can be achieved within the proposed threshold for fast-track releases and market approval.

PRODUCTION OF NITROGEN COMPOUNDS IN SOIL BACTERIA:

Disruption in soil ecology

Soil bacteria were genetically engineered to continuously produce nitrogen compounds (Wen et al., 2021). After release into the fields, the genetically engineered bacteria are meant colonise the roots of plants and ideally stimulate root and plant growth. These bacteria are completely new-to-nature. Although they have been approved in the US, it is unclear to which extent environmental risks have been tested.

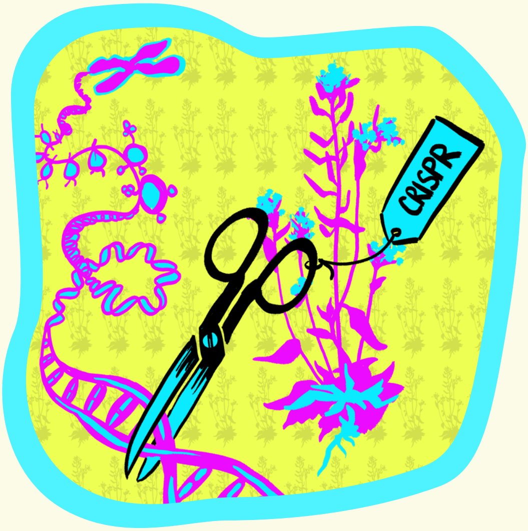
Frequent cell division is constantly changing the genetic material in bacteria. They can also exchange genes within and across species, possibly resulting in uncontrolled spread and instability in the genetic changes (Miklau et al., 2024; Eckerstorfer et al., 2025). Potentially, the genetically engineered bacteria may also spread beyond the fields and colonise other plant species, including weeds.

The European Commission presented a draft for the fast-track approval of genetically engineered bacteria, but it is very vague.[4] It is not clear whether the above described NGT bacteria would require mandatory risk assessment also in future.

[4] https://health.ec.europa.eu/publications/directive-regarding-placing-market-genetically-modified-micro-organisms-and-processing-organs_en

CHANGES IN KEYSTONE GENES:

Cascading risks to biodiversity

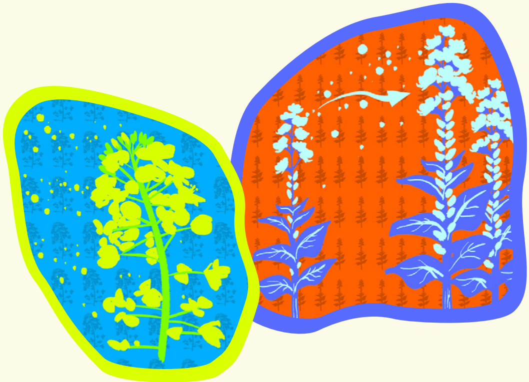


Scientists inserted different genetic variants into the genome of Arabidopsis thaliana to change the content of glucosinulates (bitter-tasting compound). The research focused on the impact different gene variants have on the occurrence of aphids and beneficial insects (parasitoid wasps) which parasitise the aphids (Barbour et al., 2022).

Results from the experimental field trials found a reduction in genetic diversity due to NGTs which led to a destabilisation of food webs. Frequently, the number of insects was reduced or the species being investigated became extinct. One of the genetic variants caused a strong increase in the number of the aphids and wasps, which can also cause disturbances in ecosystems (Barbour et al., 2022). The indications are that large-scale releases of NGT plants with specific changes in 'keystone' genes can result in a decrease of biodiversity, with cascading effects on several ecosystem levels.

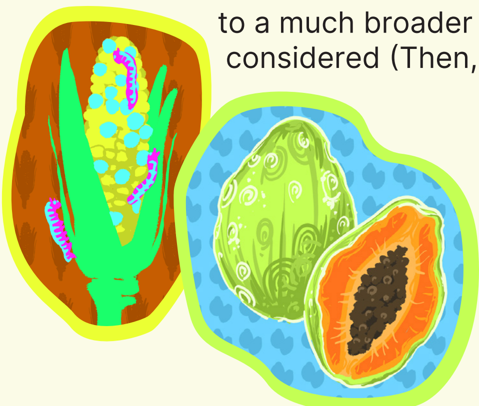
Again, the number and type of genetic changes applied in these experiments are within the proposed EU threshold for fast-track release and market approval.

THE NEED FOR RISK ASSESSMENT OF CUMULATIVE AND COMBINATORIAL EFFECTS



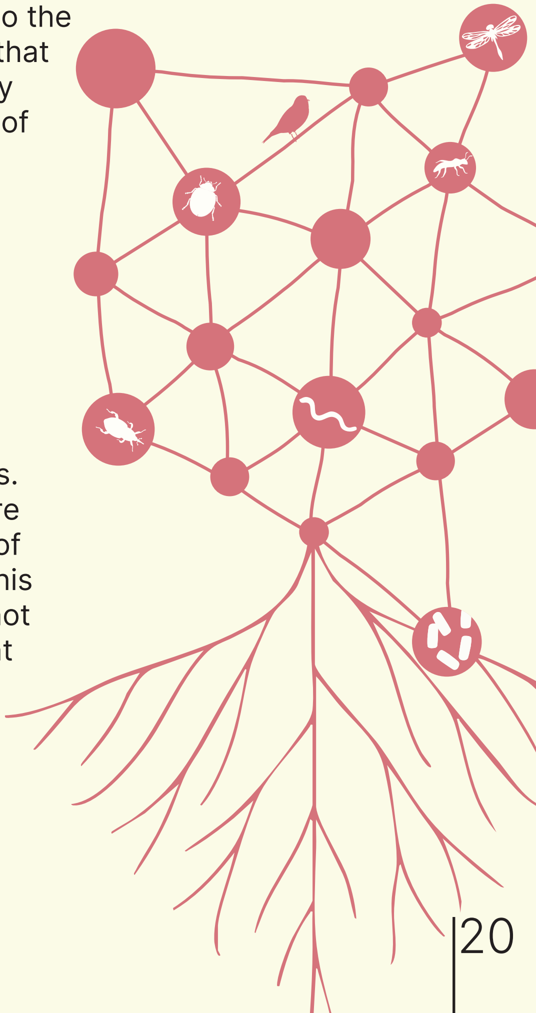
The experience from large-scale and long-term cultivation of transgenic plants shows that the results from small field trials are not sufficient to predict the factual environmental risks. For example, it was shown that under large scale cultivation, insecticidal Bt plants can cause a change in the wing shape of the pest insects enabling them to fly faster and cover longer distances (Mikac et al., 2025). Virus resistant papaya lost its resistance, it then spread in the environment and became a reservoir for several viruses (Yang et al, 2024); herbicide resistant plants caused the rapid adaptation of noxious weeds (Heap, 2014); diversisty of bird populations can also be impacted by the large-scale cultivation of transgenic plants (Engist et al., 2024).

Insecticidal and herbicide resistant traits are often combined in the fields, from where they may facilitate interactions promoting the spread of pest insects (Almeida et al., 2021; Páez Jerez et al., 2022). In addition, the insecticides produced in the transgenic plants and complementary herbicide residues can each act as environmental stressors. The combination of these stressors can result in the cultivation of the plants becoming detrimental to a much broader range of species than originally considered (Then, 2010). ⟶



It is already known that many transgenic plants have spread beyond the fields into the environment (Bauer-Panskus et al., 2013); much of the data points to the higher fitness of the weedy hybrids (Bauer-Panskus et al., 2020).

These findings are highly relevant to the potential cultivation of NGT plants that are new to the environment, as they may involve a much broader range of species and traits than transgenic plants. Whatever the case, results from smaller experiments are insufficient to conclude on the factual risks of their large-scale and long-term cultivation.



In regard to monitoring, plants must to be traceable, including their offspring and potential hybrids. However, under the proposed future EU regulation of NGT plants, none of these requirements would apply. This means that the NGT plants would not be retrievable from the environment if damage occurs.

EFSA OPINIONS - A 'CRACK' IN SCIENCE

The European Food Safety Authority (EFSA) recently published further opinions on the risks associated with organisms obtained from NGTs (EFSA 2025; 2026). Once again, the opinions state that NGT plants do not present any 'new' risks. None of the above studies were mentioned in these opinions. EFSA has in the past already issued opinions which simply 'overlooked' many relevant studies on NGT plants (Testbiotech, 2022).

Gaps in EFSA opinions are by no means arbitrary, but result from a basic misconception: unlike other authorities and institutions, EFSA has never presented a systematic analysis of the differences between NGTs and conventional breeding (Kawall, 2019; ANSES, 2024; Koller, 2025; Mundorf et al., 2025). Furthermore, EFSA has also never looked into the convergence of artificial intelligence and NGTs (Testbiotech, 2026b; Mundorf et al., 2025; Juhas et al., 2025). However, these issues are essential for the future regulation of NGT plants.

In addition, EFSA only feels obliged to look for so-called 'new' risks that it could not identify. It simply 'overlooks' that specific risks associated with NGT plants have already been described in several publications (see above). These risks need to be assessed before potential releases or approvals are granted, regardless of whether the risks are considered 'new'.

Following the EFSA procedure would make it impossible to identify risks associated with a genetically engineered 'dire wolf' or NGT plants with manipulated flowers. In fact, the EFSA approach is limited to taking the number and types of mutations into account. As such, neither the 'dire wolf' nor 'NGT flowers' would exhibit any particular abnormalities. Nevertheless, this does not mean that associated risks can be equated to those associated with plants or animals obtained from conventional breeding or natural populations.

CONCLUSION

The proposed future regulation of NGT plants in the EU is inadequate to allow safe applications. Therefore, we recommend:

- If NGT plants exhibit genotypes that were previously un known and practically cannot be achieved through previous breeding methods, this has to be defined as a trigger for mandatory environmental risk assessment.

- In general, approval for commercial cultivation – and also for experimental releases – should only be approved after case-by-case risk assessment, starting from molecular characterisation (ANSES, 2024).

These requests are especially relevant to plants that can persist in the environment and exhibit gene flow to other plants, including wild plant species.

Future regulation must also enable to trace, track and monitor the effects from long term and large scale releases, including (hybrid) offspring.

ANNEX - ANALYSIS OF ANNEX 1 OF THE PLANNED NEW NGT REGULATION[6]

Proposed text	Testbiotech comment
Annex I - Criteria of equivalence of NGT plants to conventional plants	
A NGT plant is considered equivalent to conventional plants if the genetic modifications introduced by the new genomic technique(s) meet the following conditions:	
(1) In the case of plants obtained by targeted mutagenesis, the number of the following genetic modifications, does not exceed 3 per each protein-coding sequence taking into account that genetic modifications in introns and regulatory sequences are excluded from this limit:	Introns and regulatory sequences can impact function and expression of proteins. Many NGT applications aim to alter these regulatory elements. To achieve new genotypes (and phenotypes) that are new to the environment, it is enough to introduce a combination of a small number of genetic changes in these regulatory elements. There is no scientific justification to exclude these sequences from risk assessment (examples listed in Koller, 2025).
(a) substitution or insertion of no more than 20 nucleotides;	There is no sufficient scientific justification for this threshold. There are many examples of NGT plants with a lower number of changed nucleotides (per genetic site) which are nevertheless very different to previously known plants (examples listed in Koller, 2025).
(b) deletion of any number of nucleotides;	The combination of several small deletions can cause huge changes in gene function and regulation. This can go far beyond what is possible using conventional breeding (examples listed in Koller, 2025).
(2) In the case of plants obtained by cisgenesis, the genetic modifications:	
(a) consist of any of the following types:	

[6] https://data.consilium.europa.eu/doc/document/ST-16661-2025-INIT/en/pdf

Proposed text	Testbiotech comment
(i) insertion of continuous DNA sequences existing in the gene pool for conventional breeding purposes;	There is some scientific reasoning that can be used to partially justify this passage.
(ii) substitution of endogenous DNA sequences with continuous DNA sequences existing in the gene pool for conventional breeding purposes;	There is some scientific reasoning that can be used to partially justify this passage.
(iii) inversion or translocation of continuous endogenous DNA sequences;	The restriction 'that occur in the gene pool for conventional breeding purposes' needs to be added. Otherwise, this passage allows fast-track approval of NGT plants that are new to the environment (examples listed in Koller, 2025).
(b) and fulfil <u>one or both</u> of the following conditions: they result in a combination of DNA sequences that occurs in the gene pool for conventional breeding purposes; or they do not lead to interruptions of endogenous genes, including those interruptions that create chimeric proteins.	The phrase 'one or both' (emphasis added) prevents this paragraph from delivering a meaningful regulatory function in regard to environmental risks; 'one or both' has to be deleted.
(3) The genetic modifications referred to in points 1 and 2 in any combination do not exceed the number of 20 per monoploid genome.	There is no scientific justification for this threshold. Unintended genetic changes and effects that go along with the applications of NGTs should not a priori be excluded from risk assessment. However, they are not mentioned in the proposed text.
<u>Annex Ia</u>	
(a) Traits referred to in Article 3(7) that exclude NGT plants from category 1 status (1) tolerance to herbicides (2) production of a known insecticidal substance.	These provisions can be regarded as an advantage. However, in respect to the environmental risks associated with many other NGT plants, these single provisions are not sufficient.

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IMPRESSUM

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