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New genetic engineering: EU Commission proposal for new regulation endangers nature, the environment and our future livelihoods

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Table of Contents

Summary

In July 2023, the EU Commission presented a proposal for the future regulation of plants whose genome has been altered with new genomic techniques (NGTs), e. g. with CRISPR/Cas gene scissors. The Commission appears intent on abandoning the basic principle of current EU legislation, i. e. that all organisms obtained through genetic engineering processes must undergo risk assessment. The EU commission proposal suggests creating a new ‘Category 1’ for the majority of NGT plants – these would then only need to be registered but not undergo in-depth risk assessment. In legal terms, the NGT plants of Category 1 would then be equal to conventionally-bred plants, i. e. deregulated, even if they are biologically different. Under the new regulatory framework, neither the intended traits of the NGT plants nor the unintended genetic changes brought about by NGT processes would need to undergo risk assessment. The Commission also proposes abandoning its previous requirements in regard to methods of detection and labelling.

It appears that the EU Commission may be seeking to accommodate the interests of companies producing NGT plants, whose main aim is to market the seeds as quickly as possible, i. e. within the term of the patents (20 years). At present, current risk assessment practices can, in fact, cause some delays. Nevertheless, from a scientific perspective, a detailed analysis and risk assessment of all

plants produced using NGTs are essential before there can be any certainty about their safety. This requirement must therefore not be sacrificed to economic interests.

The new regulations would not only apply to annual crops, but also to perennial arable plants which can survive in the environment for several years, both in- and outside of agricultural areas where they may multiply and spread uncontrollably. Even more seriously: wild, non-domesticated species, such as trees, wild herbs, grasses, mosses or algae, which can also spread in particularly sensitive ecosystems, are likely to be released into the environment with no further controls. There would be no monitoring of short- or long-term consequences either for nature or the environment. Offspring, crossings and resulting new traits would also no longer need to undergo any specific testing or surveillance. Moreover, no provisions would be made for concepts and measures to remove such plants from the environment if this became necessary.

CRISPR/Cas gene scissors, in particular, have the potential to alter gene functions and properties of plants in ways that would not be expected through conventional breeding. The risks to humans and the environment cannot be regarded as lower in comparison to transgenic plants.

Many mutations in the genome of plants also occur naturally or arise from non-targeted mutagenesis processes. However, most of these mutations have no direct effect on the phenotype of the plants. If they do affect plant traits, it is usually not beyond the natural range of traits of the individual species. However, these species-specific biological limits do not apply to gene scissors - or only to a very limited extent. Even without inserting additional genes, the use of new genetic engineering (New GE) can result in intended and unintended changes that go beyond the known characteristics of the individual species.

The technical potential and also the technical shortcomings of tools like CRISPR/Cas, make it essential that all genetically engineered organisms continue to be subject to in-depth risk assessment in the future. This includes using appropriate analytical procedures to assess the intended and unintended genetic changes caused by New GE processes for direct and indirect, immediate or delayed, and cumulative long-term effects.

According to Directive 2001/18 EC, the precautionary principle is the basis of EU regulation for genetic engineering, and the EU Commission has said its proposal for new regulation will not change the legal framework. The precautionary principle requires that in order to prevent future damage to humans and the environment, market approval can only be given if both the known and currently unknown hazards and risks have been fully investigated. In addition, effective measures must be in place to enable intervention if damage to humans or the environment occurs. These cornerstones of the precautionary principle would be called into question by the new regulation for the deregulation of NGT plants, despite the Commission announcement.

From the perspective of the precautionary principle, all NGT plants must be thoroughly assessed on a case-by-case basis if their genotypes and biological characteristics (phenotypes) are likely to be achievable with conventional breeding methods. If they are different, the risks would need further assessment. However, under the terms of the new regulation, any differences and risks would in most cases simply not be examined, and would be set aside without further notification. Once the plants were released into the environment, they would no longer be subject to any special monitoring and, in many instances, there would be no way of detecting or removing them from the environment.

Testbiotech is, therefore, calling for the continuation of mandatory risk assessment for all genetically engineered organisms. Traceability and retrievability must also be maintained. To this end, the new Category 1 must be removed from the proposed regulations, and certain steps in risk assessment must be required for all NGT plants in order to assess their safety. These requirements should include a specific molecular assessment, such as genome sequencing, gene expression studies and so-called 'omics' (such as transcriptomics, proteomics and metabolomics). The methods used must be suitable for detecting and assessing unintended and intended genetic changes as well as all their expected and unexpected, direct and indirect, immediate and delayed effects that may constitute a risk to people, the environment and nature.

New GE plants that have the potential to persist in the environment where they can reproduce and spread for several years, must be particularly closely examined in this context. If there is a lack of certainty, they must not be released. In general, the introduction of genetically engineered organisms into the environment should be limited as far as possible. As is the rule elsewhere in sensitive areas of nature conservation, any interventions into the environment must be avoided as far as possible.

Testbiotech is not generally opposed to adapting the current approval procedures to the special technical properties of NGTs if this is done within the existing legal framework. However, we are warning that the EU Commission proposals seriously overshoot the mark.

Testbiotech is also warning against far-reaching patent monopolies that would jeopardise the future of conventional breeding. Additionally, to the opinion of Testbiotech, there is a risk that the concept of sustainability to become misused as a justification for introducing NGT plants. However, the introduction of NGT plants into agriculture cannot be called sustainable if it can lead to ecosystems collapsing, health risks accumulating unnoticed in food, breeding being blocked by patents or consumers no longer having any freedom of choice.

Overview of the EU Commission proposal

The EU Commission proposal consists of a regulation ("on plants produced using certain new genomic techniques and the food and feed products derived from them") with explanatory notes and three annexes.[1] In this regard, the EU Commission states that NGT plants fall within the regulatory scope of existing genetic engineering legislation, but intends to create a new 'lex specialis' for these plants.

This special right is intended to apply to all NGT plants, i. e. all plants in which the function of the plant's own genes has been disrupted or altered with genetic scissors, so that they fall within the scope of the new regulation. It would, in addition, also apply to plants in which genetic engineering techniques have been used to transfer genes from the same species or closely related species (‘cis-genetic engineering’, cis GE, or ‘cisgenesis’).

Only plants inheriting transgenes, i. e. gene segments originating from species in which cross-breeding can be ruled out, will be subject to the current GMO regulation (at least if the transgenes exceed the size of 20 nucleotides).

[1] COM(2023) 411 final 2023/0226 (COD) 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, https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX%3A52023PC0411

Category 1: Abandoning mandatory risk assessment

Under the new regulation, there will no longer be any requirements for all organisms obtained from genetic engineering processes to undergo an approval process and risk assessment, as is currently the case. Instead, many of the NGT plants would be given equal legal status to plants obtained from conventional breeding. Risk assessment would no longer be required for the NGT plants; they would only need to be registered. Neither the intended properties nor the unintended genetic alterations in the plants would undergo an in-depth risk assessment under this special new law. Previous requirements for methods of detection and labelling would also no longer apply. Only the packaging of the seed would indicate whether or not new genetic engineering has been used, but no label would be required for food and feed. However, NGT plants would still be banned in organic farming.

Around 90 percent of all currently developed NGT plants are likely to fall into the new Category 1, even though the relevant criteria are arbitrary and lack a sufficient scientific basis. They can also be easily circumvented.

According to the criteria, NGT plants could be legally equated to conventionally-bred plants even if they have very different characteristics. Therefore, the proposed new regulation is violating one of the basic principles as set out in recital 14 of the proposed regulation, which requires the criteria in Category 1 to be based on science.

Arbitrary criteria

Annex 1 lists the criteria that an NGT plant must meet in order to be equated with a plant obtained from conventional breeding (Category 1). These criteria specify that a plant may be genetically engineered at up to 20 predictable (target) genomic regions. However, the number 20 is purely arbitrary and without any concrete reference to the occurrence of risks. There are many plants obtained from new genetic engineering, such as the ‘GABA tomato’ (Nonaka et al., 2017)[2] or the ‘agrofuel camelina’ (Morineau et al., 2017)[3], whose properties go beyond can be achieved with conventional breeding, and which, at the same time, have been genetically engineered at fewer than 20 sites ('gene loci').

This EU Commission criterion is therefore is not suitable to determine whether NGT plants and their properties can be equated to conventional breeding. This will inevitably result in plants whose biology is significantly different to those obtained from conventional breeding, but which will, nevertheless, be equated to the latter.

The EU Commission proposal further describes the changes in the 20 genomic regions, stating that up to 20 nucleotides can be exchanged or inserted at each of the 20 gene loci in the genome. This criterion is based on the unfounded assumption that a change of more than 20 nucleotides is necessary to anchor new properties in the genome.[4] This assumption is in fact not tenable. For example, the ‘GABA tomato’ and the ‘agrofuel camelina’ show that considerably fewer than 20 changed nucleotides (per gene locus) can be sufficient to obtain plants with properties that could not be expected from conventional breeding.

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2 https://www.testbiotech.org/en/limits-to-biotech/crispr-tomatoes/basic_paper
3 https://www.testbiotech.org/en/limits-to-biotech/genetically-engineered-camelina
4 https://publications.jrc.ec.europa.eu/repository/bitstream/JRC63971/jrc63971.pdf

An interesting example also comes from the animal kingdom: it has been shown that fruit flies with fewer than 10 genetically engineered nucleotides exhibit monarch butterfly characteristics, and can tolerate toxins from plants that would otherwise kill them. If such flies (or their larvae) ingest these toxins, they could become toxic to their predators themselves. This shows that the alteration of a just a few nucleotides in a certain combination can have far-reaching consequences for natural food webs (Karageorgi et al., 2019)[5].

Similar risks can emerge from releases of NGT plants, whereby the risks are not generally lower compared to transgenic plants[6], as the 'agrofuel camelina' shows (Kawall, 2021a). In this case, 18 gene loci were simultaneously genetically engineered. The oil content and the composition of the oil in the plants were altered to a greater extent than could have been achieved with conventional breeding. The oil was modified with the intention of supposedly making it particularly suitable for agrofuel production. However, the altered oil content may also affect plant resistance to environmental stress, interactions with pollinators and associated camelina food webs. Uncontrolled gene flow might also cause these genetic conditions to be passed on to relative species or wild populations of camelina. Investigations are also needed into whether the plants may have adverse effects on human health if inadvertently introduced into food production systems.

In addition, the criterion of accepting a threshold of 20 altered nucleotides as 'safe' is itself questionable, as this also allows short fragments of transgenes to be present in the genome without triggering a requirement for more detailed risk assessment.

Other criteria in Annex I are also scientifically extremely questionable: for example, gene losses (deletions) and gene segments whose building blocks are incorporated into the genome in reverse order (inversions) can be present with unlimited length without the plants having to undergo risk assessment. Furthermore, additional gene segments (with unlimited length) can also be transferred into the genome if these gene segments occur in the 'gene pool' of a species (or related species). This is known as 'cisgenesis' or cis-genetic engineering (cis GE), as these genes are not transferred across species boundaries (transgenes), but within related species. Finally, all these types of genetic modifications can also be combined such as by further crossings.

Furthermore, the criteria completely disregard basic biological knowledge: the characteristics of NGT plants are often very different compared to plants obtained from conventional breeding. It is not so much the number of genetic changes that is important, but rather the respective functions of the genes affected by the changes, the resulting gene combinations (pattern of genetic changes) and the context in the genome. If, for example, deletions (or inversions), occur at sites in the genome with important regulatory functions, the plant response to the environment and/or the composition of the plant components can be drastically altered. Consequently, their safety in regard to health and the environment may be impaired. In this context, consideration needs to be given to whether multiple copies of a gene were altered and what interactions exist with other genes. Many genes fulfill multiple functions, and if one gene is knocked out, several characteristics are often affected simultaneously.

The effects of the altered genes can also depend to a great extent on the genetic background. For example, in the 'de-novo domesticated tomato' (Zsögön et al., 2018), several gene variants found in the original wild forms of tomatoes were altered with NGTs in a similar same way to that known from cultivated tomatoes. However, the composition of the genetically engineered tomatoes was

[5] https://www.testbiotech.org/en/limits-to-biotech/monarch-flies

[6] See also https://www.bfn.de/sites/default/files/2021-10/Viewpoint-plant-genetic-engeneering_1.pdf#page=5

very different compared either to the wild forms or cultivated tomatoes (Zsögön et al., 2018)[7]. Under the new regulation, these and similar NGT tomatoes could nevertheless still be included in Category 1. A similar situation applies to cis GE: here, too, the resulting phenotye can very much depend on the genetic background into which the additional genes are inserted.

There is no doubt that new genetic engineering (with and without cis GE) can produce genetic changes and plant characteristics that go far beyond what is known from conventional breeding, but the respective NGT plants would still be included in Category 1. In these cases (such as Nonaka et al., 2017 and Morineau et al., 2017) it is known that NGT was used because the desired characteristics could not be obtained from conventional breeding. These NGT plants cannot, therefore, be equated to conventional breeding outcomes, and associated risks can also not generally be considered lower than those of transgenic plants.

However, the criteria in Category 1 do not take any of the effects and risks connected to the respective genetic alterations into account. Which phenotypes in interaction with the receiving environment will occur, is not considered at all. It only requires the formal criteria, such as the number of intended genetic changes, for these to be adequately met.

Basic biological and technical knowledge disregarded

There are some fundamental differences between NGT and non-targeted mutagenesis used in conventional plant breeding. These differences are important for the risk assessment and identification of the genetically engineered plants. We have, therefore, summarised some of the differences between New GE and non-targeted mutagenesis in the following figure 1[8].

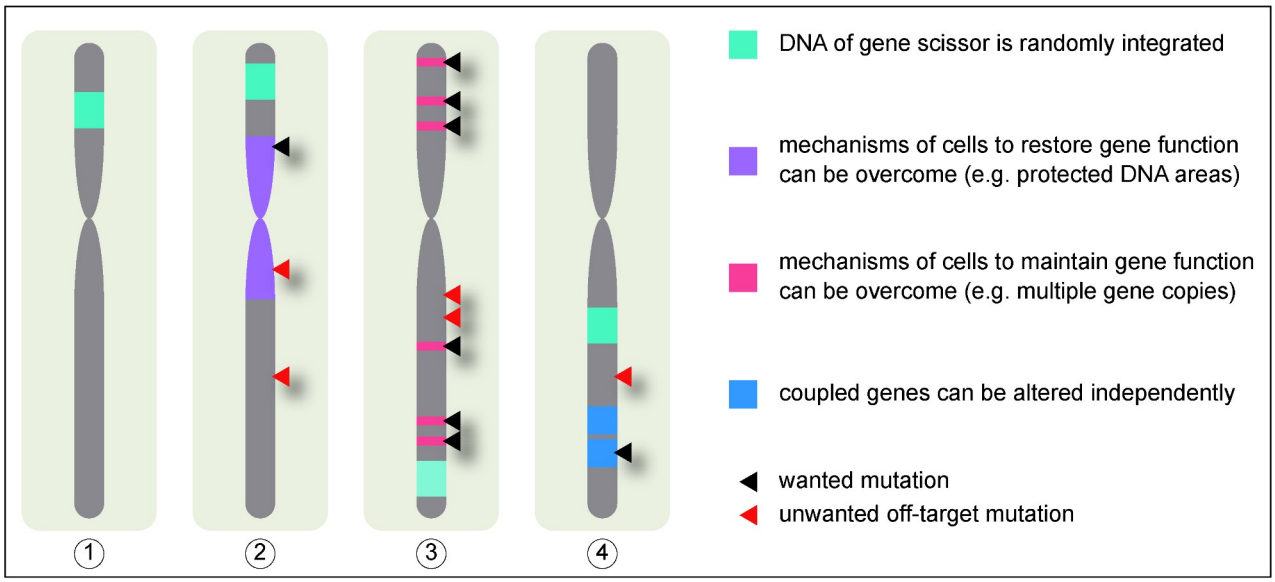

Figure 1: New genetic engineering applications in plants can result in genetic changes which are unlikely to occur with conventional breeding. One reason: unlike conventional breeding (including non-targeted mutagenesis), new genetic engineering can overcome the limitations of naturally evolved genome organisation. The diagram shows NGT applications using CRISPR/Cas on 4 DNA samples (simplified). Example 1 shows the transgenic DNA needed to produce the CRISPR/Cas nuclease being randomly integrated in the plant genome. Example 2 shows an intended mutation and an unintended mutation, both induced in a protected region of the DNA near the centromeres, with a further unintended mutation occurring in another region. Example 3 shows how the gene

[7] https://www.testbiotech.org/gentechnik-grenzen/neu-domestizierte-tomate

[8] see also https://www.testbiotech.org/en/content/differences-between-new-genetic-engineering-and-conventional-breeding

scissors can alter several (in this case six) copies of the same gene simultaneously, which would be unlikely to happen with conventional breeding; other unintended mutations also occurred in this case. Example 4 shows genetic linkage; the gene scissors can alter linked genes independently of each other even though they are typically inherited only as a pair.

Mutations in the genome of plants also occur spontaneously, or after contact with physical or chemical mutagens (non-targeted mutagenesis). However, most of the mutations do not have an effect on the phenotype of the plants. If they do change the plant characteristics, the effects typically do not go beyond the natural range of characteristics found in the individual species.

New GE in plants is typically used to achieve genetic changes that go beyond what can be obtained from conventional breeding. It does not require the insertion of additional genes. Unlike conventional breeding (including non-targeted mutagenesis), NGTs can overcome the constraints of natural genome organisation brought about by evolution, including maintenance mechanisms and/or restoration of gene functions, e. g. repair processes, gene copies and genetic linkage. CRISPR/Cas 'gene scissors' in particular are able to make more extensive changes to the genome in comparison to conventional plant breeding (Kawall, 2019).

In addition, New GE processes can also result in unintended DNA changes, which may differ in their patterns, sites and biological effects from those seen in conventional breeding. There are several reasons for this: in most cases, the transgenic DNA for the production of the gene scissors (CRISPR/Cas) is introduced into the genome using non-targeted methods. 'Old' genetic engineering methods are used for this purpose. These often cause unintended changes in the genome and the multiple insertion of DNA fragments, which often remain undetected. At the end of the process, so-called segregation breeding is applied to remove the transgenes from the plant genome, but nevertheless, unintended genetic changes will remain in many cases (see for example Braatz et al., 2017).

After the gene scissors are synthesized in the cells, they are meant to actively target specific genomic regions. As a result, in most cases, both strands of the DNA are cut. This step in the process may cause other unintended genetic changes, e. g. the confusion of target sequences (see Kawall, 2021b). Another example are so-called 'catastrophic events' in the genome (chromothripsis), caused by the double strand breaks in the target regions. Therefore, while it is possible to use gene scissors to target particular sites in the genome, it is not possible to sufficiently predict and control the consequences of these interventions in regard to the genome, the plants or the environment.

If the plants are not examined in detail, the unintended genetic changes can persist in their offspring and accumulate in populations through subsequent crossing. Long-term risks to humans and the environment can also not be ruled out. Consequently, a detailed analysis and risk assessment is necessary before the safety of the plants can be evaluated.

In regard to risk assessment, the EU Commission proposal anticipates that NGT plants (or their harvest) might fall under provisions included in EU Novel Food Regulation[9] if, for example, they exhibit previously unknown properties in food. However, there may be some cases where it is unclear what can be considered a 'novel trait', which would then require an assessment of the plants concerned (see 'de-novo domesticated tomato'). The Novel Food regulation also does not require investigation of unintended genetic changes.[10] Finally, there would be no investigation into

[9] Regulation (EU) 2015/2283 of the European Parliament and of the Council of 25 November 2015 on novel foods

[10] https://www.bfn.de/sites/default/files/2021-10/NT_Auffangrechte_RGutachten_Spranger_en.pdf

environmental risks and no health risk assessment for NGT plants not meant for food production (see agrofuel camelina).

Fast track decisions with long-term consequences

According to the proposal, just a single member state could decide whether a plant should be included in Category 1. If no other member states object within a short objection period, the EU Commission would make the decision. There is no provision for public participation in this process.

Once the plant is entered in the register, it could be grown and further crossed with no further restrictions, as is the case for conventionally-bred plants. The offspring of the plants would no longer be subject to any special monitoring or review. This would still apply if the progeny were crossed with each other, thus combining more than 20 genetic changes in the plant genome. This would make it very easy to circumvent the criteria set out in Category 1: plants with fewer than 20 genetic changes could be registered, but the NGT plants that would actually be marketed might have considerably more genetic changes combined through subsequent further crossing.

The regulations would not only cover annual crops, but also arable plants that can survive in the environment for several years, possibly multiplying and spreading uncontrollably. Even more seriously: wild, non-domesticated species, such as trees, wild herbs, grasses, mosses or algae, could also be released into ecosystems after only one registration. Consequences for the ecosystems would neither require previous risk assessment nor post-release monitoring.

In this context, the EU Commission is trying to introduce double standards: it quite rightly points out in recital 9 that current knowledge regarding releases of microorganisms, fungi and animals is too limited to exclude them from the current legislation. Nevertheless, even wild forms of plants and plants growing outside the field will fall within the scope of the new regulation. There is, however, currently insufficient experience worldwide (and certainly not in the EU) regarding the long-term consequences of an uncontrolled spread of genetically engineered plants.

Furthermore, the regulation does not include any measures or concepts to remove NGT plants from the environment if needed. This could become a massive problem for nature conservation if, for example, the plants spread into Natura 2000 sites.

Unexpected new traits may also emerge naturally or with conventional breeding. Typically, these are rare events and thus allow enough time for the adaptation to the surrounding ecosystems. New GE enables the release of many organisms that are not adapted to the environment within short periods of time, comprising many species. Similar to climate change, it is the speed of developments that can overstretch the resilience of natural systems.

NGT organisms have the capacity to trigger another man-made crisis, contribute to further destabilisation of ecosystems and threaten our livelihoods: similarly to environmental pollution with plastics and chemicals, it does not necessarily have to be a specific genetically engineered organism that causes the problems. Rather, it may be the totality of the effects of GE organisms and their interactions that are critical. In this context, many future generations may have to deal with the environmental problems or organisms able to persist in the environment for a very long time, in some cases for a potentially unlimited time.

Category 2: Fragmented approval processes for other NGT plants

NGT plants inheriting transgenes will in future still be subject to the current GMO regulation (at least if the transgenes exceed the size of 20 nucleotides). All other NGT plants that, e. g. inherit more than 20 genetically engineered gene loci, would still be subject to approval procedures, risk assessment and labelling requirements, even though this would be with substantial limitations. Wheat with a reduced gluten content is an example of a crop that could fall into this category. More than 20 gene loci would have to be genetically engineered for this to happen (Sanchez-Leon et al., 2018)[11]. Other plants within this category would be those in which additional gene segments are inserted in a non-targeted way using cis GE.

The current requirements for risk assessment and detection methods would be significantly weakened. For example, the proposal suggests categorising the requirements for risk assessment according to so-called 'risk profiles'. In most cases, these risk profiles would only be based on the intended characteristics of the plants. As a result, the new regulation would fragment any risk assessment in a way that would allow the unintended genetic modifications and associated risks to be set aside without assessment.

Current risk assessment would no longer be applied to plants in Category 2 (see figure 2): according to the requirements of Directive 2001/18/EC, as last amended by (EU) 2018/350, all genetically engineered organisms must be examined for intended and unintended genetic modifications and any potentially associated effects, no matter whether these are direct or indirect, immediate or delayed. Long-term effects and cumulative effects (such as interactions between the GE organisms) must also be taken into account.

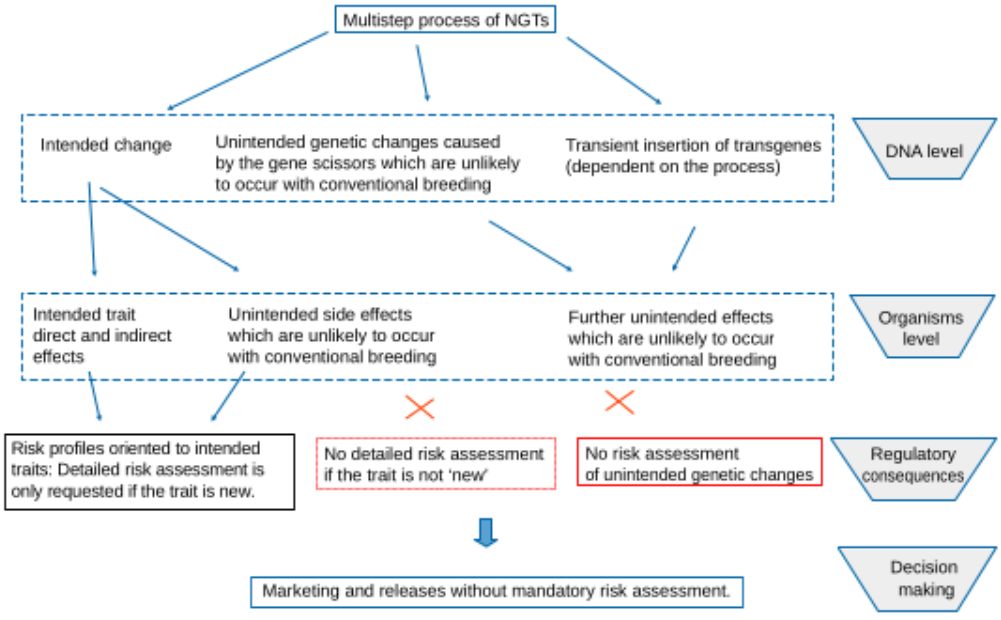

Figure 2: Consequences for the risk assessment of NGT plants (SDN-1 and SDN-2) resulting from the introduction of 'risk profiles' proposed by EFSA (2022). Red highlight: these steps are currently requested in risk assessment, but could be abandoned in future (source: Testbiotech, 2022).

[11] https://www.testbiotech.org/en/limits-to-biotech/genetically-engineered-wheat

No comprehensive assessment of unintended effects

The European Food Safety Authority (EFSA) has already proposed some criteria for defining risk profiles (EFSA 2022). According to these criteria, the site of insertion into the genome would only be examined if additional gene segments (cis GE) with the potential to disrupt the 'endogenous' genes of the recipient plants were inserted. Otherwise, the risk profiles will be based primarily on the intended characteristics of the plant.

The EFSA risk profiles and the Commission proposal ignore the fact that NGTs can trigger unintended DNA changes that differ in their patterns and biological effects from those found in conventional breeding. Again, the particular risk depends on which gene functions are affected. The technical potential of NGTs and CRISPR/Cas in particular can affect gene functions that would hardly be altered at all with conventional breeding. The unintended changes may affect large parts of the genome: gene scissors in particular can also cause chaotic conditions in the genome (chromothripsis), thus affecting the structure of whole chromosomes (see Figure 3).

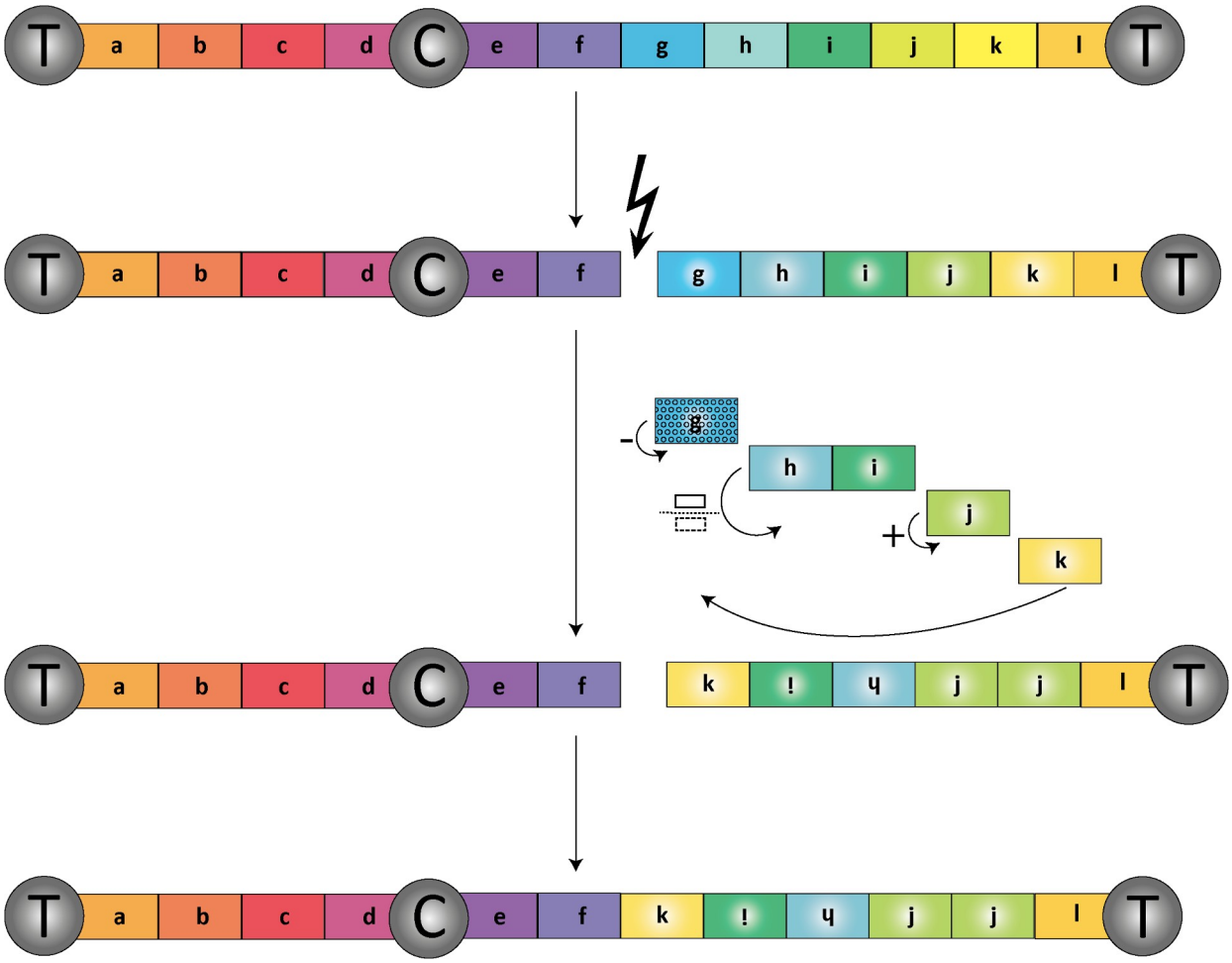

Figure 3: Examples of effects caused by chromothripsis: various processes can occur at the ends of the genome which are disconnected from the chromosome. Sections of the genetic material are incorporated in a twisted manner, duplicated, or may even be lost altogether (adapted from de Groot et al., 2023).

As already noted, it is possible to modify specific sites in the genome. However, it is not possible to predict or sufficiently control the consequences of this intervention for the genome, the plants or the environment.

In particular, NGT plants with a higher number of intended genetic changes in their genome (as in gluten-reduced wheat) mean there is also a higher probability of unintended changes. However, the risk assessment as required in Category 2, would not include an in-depth investigation into which unintended genetic changes are caused by the many 'cuts' in the genome (which are necessary to achieve low gluten levels, see Sanchez-Leon et al., 2018) or where they are located. The risks are highly relevant as the unintended genetic changes may influence the formation of new pro-inflammatory proteins. In addition, the cultivation of these NGT plants can affect the environment, as changes in the gluten metabolism of cereal plants can also can result in altered interactions with the environment.

Another cause of risks resulting from new genetic engineering is, in many cases, the initial integration of DNA into the genetic material of the plants for the production of the gene scissors (CRISPR/Cas). This enables the gene scissors to be formed in the cells. Older genetic engineering methods are typically used for this initial insertion (at least so far), which can often lead to unintended changes in the genetic material. Amongst other things, these older methods often result in insertions of multiple DNA sequences and fragments at different locations in the genome, which in many cases go undetected. The multi-step procedures, which are almost always used when NGT methods are applied to plants (including the ‘GABA tomato’[12], the ‘agrofuel camelina’[13] and the ‘gluten-reduced wheat’[14]), can also trigger other unintended genetic changes which may not have otherwise been expected.

Unintended genetic changes can also accumulate in the populations after subsequent crossing. Risks to humans and the environment cannot be ruled out. Therefore, more detailed analysis and risk assessment are necessary before the safety of a Category 2 plant can be evaluated.

From the perspective of the precautionary principle, all NGT plants need to be analysed if their genotypes and biological characteristics (phenotypes) are likely to be achievable in practice with conventional breeding methods and, if they are different, the risks have to be assessed. However, under the terms of the new regulation, these differences and their risks would in most cases be set aside.

Therefore, the EU Commission proposal does not meet the requirements that the EU Commission has declared to be its first objective, i. e. to "maintain a high level of protection of human and animal health and the environment in accordance with the precautionary principle."[15] To fulfill this requirement, the provisions of current EU regulation also have to be applied in future as summarized in figure 4.

[12] https://www.testbiotech.org/en/limits-to-biotech/crispr-tomatoes/basic_paper
[13] https://www.testbiotech.org/en/limits-to-biotech/genetically-engineered-camelina
[14] https://www.testbiotech.org/en/limits-to-biotech/genetically-engineered-wheat
[15] Page 12 of the Commission proposal

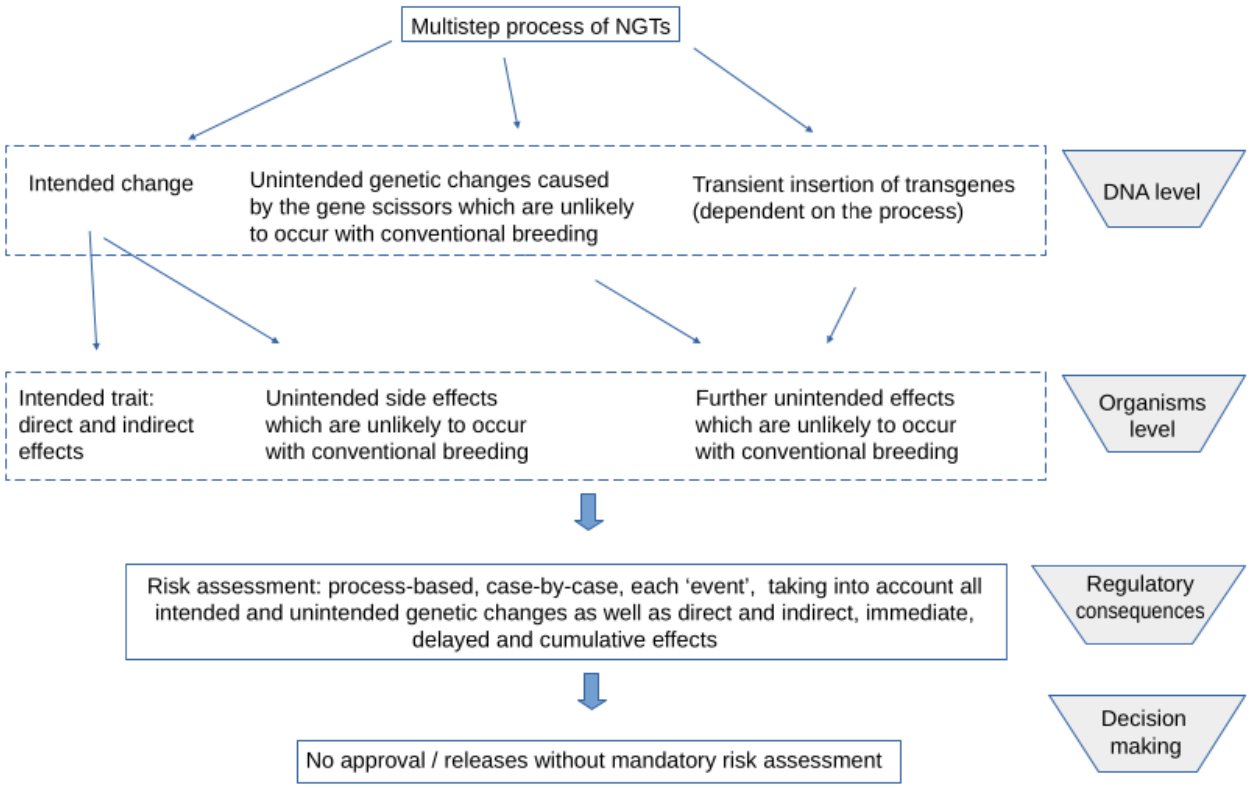

Figure 4: Current regulation of NGTs: Intended traits, unintended side effects and unintended genetic changes triggering the need for risk assessment.

Further Category 2 changes

- Currently approvals must be reviewed every 10 years. In future, NGT plants may have unlimited approval after only one review, i. e. after 10 years.
- The obligation to submit methods of identification may be restricted if the applicant considers them to be too difficult to implement.
- EU member states can no longer issue national bans on cultivation, but are still meant to ensure coexistence rules (i. e. protection of GMO-free agriculture) in their country.
- It is unclear whether an additional approval procedure is necessary for combination crosses of NGT plants in Category 2, as is currently the case ('stacked events').
- NGT plants in Category 2 can made exempt from the monitoring of possible environmental effects.

As with Category 1, all these specifications apply not only to annually grown crops, but also to perennial, non-domesticated species (e. g. trees, grasses, wild herbs, mosses and algae). These plants are particularly able to persist in the environment, reproduce and spread - even in sensitive nature reserves that need a high level of protection. In this context, the risks cannot be considered to be generally lower in comparison to transgenic plants.

The proposed categorisation of NGT plants is further intended to create new incentives for seed producers to make agriculture more sustainable. If the plants have the appropriate characteristics, their products would be allowed to have special labels, approval processes would be accelerated and costs reduced. The plan is to only evaluate the information on possible benefits provided by producers within the framework of the variety protection system.[16] However, the variety protection system cannot simply be regarded as a substitute for a comprehensive technology assessment to evaluate the producers claims in regard to real sustainability. Unless a comprehensive technology assessment is carried out, there is a real risk that short-term advantages in the cultivation of specific varieties will turn into disadvantages in the long term, as was the case, for example, with transgenic, glyphosate-resistant plants. The initial effects of reducing herbicides in the cultivation of these plants were reversed in the medium- and long-term. Similar developments were observed in the resistance of insect pests to the insecticides produced by transgenic plants (Testbiotech, 2023a).

In addition, there are no plans regarding less hazardous varieties or other cropping systems, thus risking more sustainable alternatives not being used or crowded out, as they receive less support or are less aggressively promoted.

More power for the EU Commission

Bringing in the new regulation means that the EU Commission would not only be given a central role in decision-making for individual NGT plants, but would also in future have the power to change essential components of the legislation. At the same time, this would restrict opportunities for public participation as well as the rights of the parliament and the member states.

The EU Commission could decide whether individual NGT plants should be treated as equivalent to conventionally-bred plants (Category 1) without involving the public or the EU institutions. Decisions on market approvals of GE plants currently involve member states and include public consultation. Category 2 also appears to have no provisions for public participation.

With regard to the further development of the legislation, the EU Commission seems to be wanting unlimited freedom of action: if there is no opposition from parliament or member states, the Commission could itself, amongst other things, take decisions to change the criteria and testing requirements for NGT plants in both Category 1 and 2.

Overview: The most important planned legal changes

- The principle that all genetically engineered plants must undergo risk assessment would be abandoned and the precautionary principle would be eroded in its very fundamental basis.
- Most NGT plants would only have to be registered, but not risk assessed (Category 1). In this context, even NGT plants that are clearly different in terms of their biological characteristics (genotype, phenotype) would be equated to conventional breeding.
- For some NGT plants, there would still be some risk assessment (Category 2). However, the requirements could be substantially reduced in this process: in most cases, only the intended characteristics of the plants would have to be considered, but not the unintended genetic changes caused by the NGT processes.

[16] https://food.ec.europa.eu/plants/plant-reproductive-material/legislation/future-eu-rules-plant-and-forest-reproductive-material_en

- In most cases, subsequent generations (combination crosses) would not have to undergo additional risk assessment.
- Wild, non-domesticated species, e. g. trees, wild herbs, grasses, mosses or algae, could also be released into ecosystems without undergoing risk assessment. There would be no monitoring of short- or long-term consequences for nature and the environment.
- There would be no monitoring of cumulative processes and interactions between the GE organisms if released into the environment or used in food production.
- In most cases, there would be no public participation in decisions to approve or register NGT plants; the rights of member states would also be restricted.
- In most cases, there would no longer be sufficient data and labelling to allow traceability or retrievability.
- In most cases, there would be no food or feed labelling, and the freedom of choice for consumers would be significantly reduced or eliminated.
- Producers who want to avoid genetically engineered plants would be left solely responsible for separating the production processes.
- Member states would no longer be able to enact national bans on cultivation.
- The EU Commission would be given new decision-making powers with regard to future changes in GMO legislation.
- Data relevant to underwriting could be kept secret.

Moreover, technology assessment is still insufficient to assess the consequences of deregulation on the sustainability of the agricultural and food systems as well as in terms of systemic risks to ecosystems.

Demands: Strengthen the precautionary principle!

Testbiotech demands that all genetically engineered organisms must in future still be required to undergo detailed risk assessment. Traceability and retrievability must also remain guaranteed. To this end, the new Category 1 must be removed from the regulatory framework and certain steps in risk assessment must be mandatory for all NGT plants before their safety is assessed. Plants should continue to be subject to mandatory labelling and traceability requirements.

The corresponding requirements for risk assessment should be based on EU Directives 2001/18/EC. A specific molecular assessment should be carried out in each case. This should include appropriate analytical procedures to assess all intentional and unintentional genetic alterations resulting from NGT processes in regard to direct and indirect, immediate or delayed as well as cumulative long-term effects. There should be in-depth examination of the genetic alterations and effects, e.g. on gene expression and cell metabolism ('omics'). The necessary data have to be made publicly available.

The results of the molecular assessment (which are associated with relatively low costs and are not really time consuming) can then be used as a basis for determining the subsequent necessary steps in risk assessment for each NGT plant (event).

NGT plants that have the potential to persist, reproduce or spread in the environment for several years should be particularly closely examined with regard to their impact on nature and the environment and, if in doubt, should not be released.

If releases of multiple NGT plants into a shared environment were to happen, clear criteria and methods must be established in advance to assess their potential interactions and avoid overloading ecosystems with novel NGT plants (Koller et al., 2023).

In addition, accompanying research programs should be launched and guidelines for technology assessment should be established to avoid overestimating the potential benefits of NGT plants, and thus misjudging the consequences for sustainable agriculture and food security. This should include better and less hazardous alternatives. The impact of patents on seeds, some of which extend to conventional breeding, also needs to be examined: many of these patents cover genetic resources and gene variants that are essential in conventional breeding. Such patents can block access to biodiversity and stop traditional breeding being carried out by small- and mediums-sized breeders (Testbiotech, 2023b). In addition, future research should focus on the protection of a GMO-free agriculture.

The concept of sustainability should not be misused as an overall justification for introducing NGT crops. Ultimately, as in other market segments, the market is driven by the possibility of making profits. The introduction of new genetic engineering in agriculture cannot be considered sustainable if it can lead to ecosystems collapsing, health risks accumulating unnoticed in food, breeding being blocked by patents or consumers no longer having a choice.

In general, the introduction of genetically engineered organisms into the environment should be kept to a minimum. As is the rule elsewhere in sensitive areas of nature conservation, any intervention in the environment should be avoided as far as possible.

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