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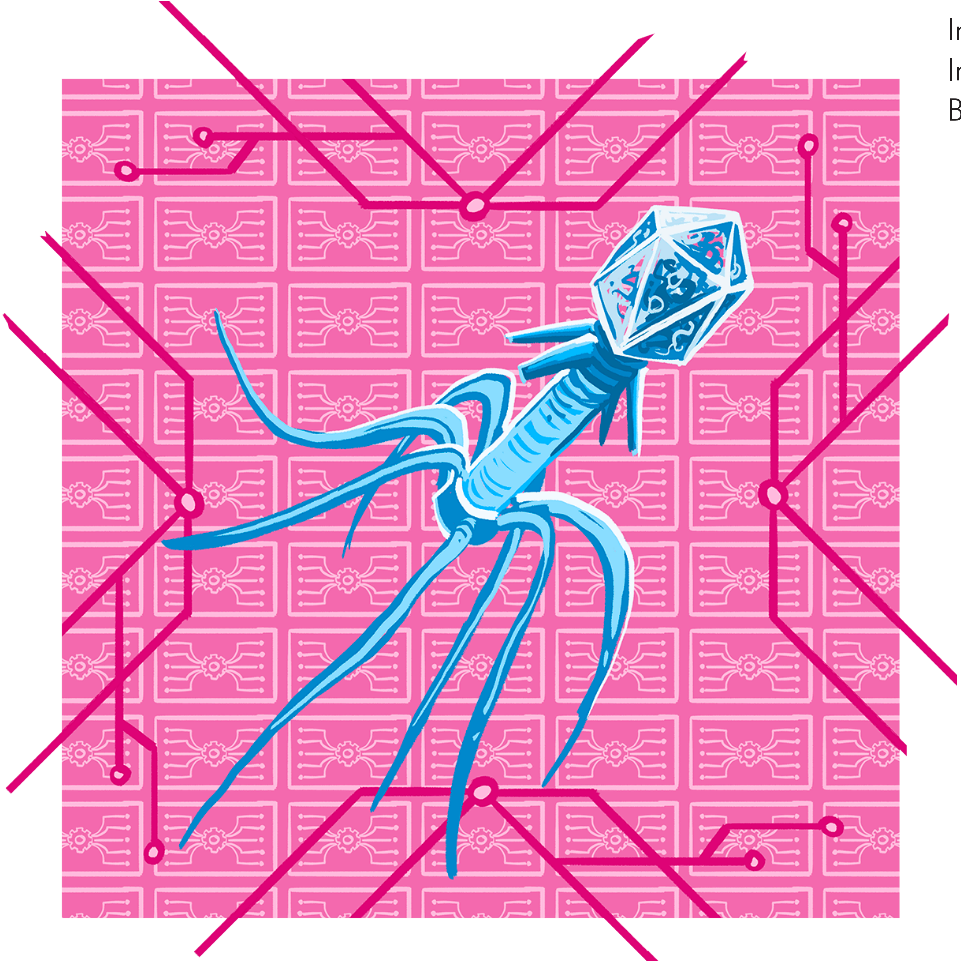

„… far beyond any control or prediction”

The convergence of genetic engineering and AI: risks to biodiversity

www.testbiotech.org | January 2026

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The convergence of genetic engineering and AI: risks to biodiversity

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Testbiotech is an independent institute for impact assessment in the field of genetic engineering. Our work is strictly based on scientific principles and evaluates the available information from the perspective of protecting health, the environment and nature. Testbiotech is free of any interests in the development, application and marketing of genetically engineered products. We are funded by private donations, public project and foundation funds.

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Summary

The convergence of artificial intelligence (AI) and genetic engineering/synthetic biology is currently attracting a lot of attention amongst experts. The new technologies are promising huge benefits, but also involve a great deal of risk. High on the list of concerns are questions related to biosecurity, including deliberate (malicious) threats to human health. In contrast, biosafety issues such as risks to the environment and biodiversity have so far been largely ignored.

Essentially, the convergence of AI and genetic engineering was made possible by two technological developments: first, large amounts of genomic data have been digitised and made available in databases. Researchers can now use AI to search through the huge amounts of molecular genetic information in very short periods of time, and subsequently use their findings to design new gene variants and gene combinations. Second, new genetic engineering (or new genomic technicques, NGTs) makes it possible to change almost any gene in any life form. Particularly noteworthy in this respect are the CRISPR/Cas 'gene scissors', which allow the experimental testing of new AI-designed gene variants and gene combinations.

It is the rapid and parallel development of these two high technologies that makes their convergence so explosive. The speed of technological development is by no means driven solely by conscious decisions. Rather, it results largely from synergies between different technological developments, which are often neither intentional nor predictable. Outcomes therefore tend to result from a wide range of convergences and synergies between the genetic engineering applications and AI. Despite the fact that these can only be partially predicted or planned, they may nevertheless result in major leaps in technical development. At the same time, this enormous self-amplifying dynamic is dramatically diminishing any possibility of control.

Political strategies and rivalries between the US, China and the EU are further fuelling this dynamic. The USA and China, in particular, perceive themselves to be in both political and economic competition when it comes to the convergence of AI and genetic engineering, as this is expected to be decisive for technological superiority, prosperity, security and military supremacy. The EU also wants to join this race with its new biotechnological initiatives, including the planned deregulation of NGT plants. Due to the rivalry between the geopolitical power blocs, there is a danger that the risks of releasing genetically engineered organisms will be accepted for strategic reasons in order to 'win' the competition for AI and genetic engineering. It is to be feared that legislators will largely withdraw from their responsibility to protect health and the environment and leave this to the free market forces. In the EU, libertarian ideas are also threatening to prevail, declaring supposed technological progress to be the measure of all things and rejecting any regulation, particularly in the field of AI and biotechnology.

This report focuses on the inherent risks to the environment and biodiversity. Especially in disruptive times, when the world is increasingly characterised by polarisation between major power blocs, the environmental consequences of technological developments and their impact on future generations must not be ignored. The examples presented here range from insecticidal AI maize and attempts to revive woolly mammoths to insects, microorganisms and viruses.

Genetically engineered plants, animals and microorganisms developed with the help of AI and released into the environment will inevitably pose risks to humans, the environment and food security if they are not adequately risk assessed. This is true not only for individual organisms, but also for the scale and speed of developments as a whole, including the diversity of new traits, the number of organisms released and the range of species affected in their entirety.

It is correct that some of these changes could also occur in the course of evolution. However, that does not

make them ‘safe’: the convergence of AI and genetic engineering enables many of these genetic changes to be made in extremely short periods of time. In addition, new genetic engineering techniques not only allow the imitation of naturally occurring gene variants, but can go far beyond that. Just a few changes in regulatory units are enough to achieve unique combinations of genetic changes that never previously existed, and which cannot be achieved through conventional breeding. AI is often used just for this purpose. In addition, the range of species to become genetically engineered is being hugely expanded, also including non-domesticated species.

Taken as a whole, new genetic engineering techniques allow a far deeper intervention into the characteristics of a species and their ecosystems than could ever be expected from conventional breeding and evolutionary processes. To put it bluntly, genetic engineering can make everything happen simultaneously in all species, whereas only a certain selection of characteristics emerge from evolutionary processes and usually only manifest after very long periods of time. For this to happen they also enable mutual adaptation through co-evolution.

As a result, the release of organisms emerging from new genetic engineering techniques has the potential to endanger ecosystems and be a new cause of species extinction. It is therefore important that risk research is extended and approval processes are amended accordingly. However, legislators are currently threatening to take a completely different direction, particularly in regard to NGT plants.

The planned deregulation of so-called NGT-1 plants would lead to their accelerated approval and release into the environment – without risk assessment, traceability or monitoring. More than 90 percent of all NGT plants would fall into this category. It would already include many genetically engineered plants whose characteristics differ significantly to those known from conventional breeding. Relevant characteristics include, for example, changes in the composition of plant constituents, premature flowering, increased fitness, as well as changes in the interactions between plants and microorganisms. This also applies to NGT plants discussed in this report that are toxic to insects or where flower shape has been adapted to enable robotic pollination.

Also plant species that can survive, reproduce and spread in the environment are concerned, including native wild plants. Examples found in the relevant databases include alpine cress, bellflowers, bristlegrass, camelina, false brome, foxtail, gentian, mustard, oilseed rape, pennycress, poplars, ryegrass, switchgrass, thale cress and wild strawberries. Furthermore, fast-track releases (including experimental releases) would lead to an increased risk of seed contamination in crops such as corn, rice, soybeans and wheat. Species of vegetables found in the relevant databases with NGT applications that could be affected by seed contamination are broccoli, cauliflower, chili peppers, cucumbers, eggplants, lettuce and tomatoes.

The following environmental risks associated with NGT plants have already been described in scientific literature: effects of altered plant composition on pollinators, plant pests and food webs; increased invasive potential; weakening of natural plant populations; spread of pathogens; yield depression; insect toxicity; changes in the composition of soil organisms with undesirable consequences and endangerment of protected species.

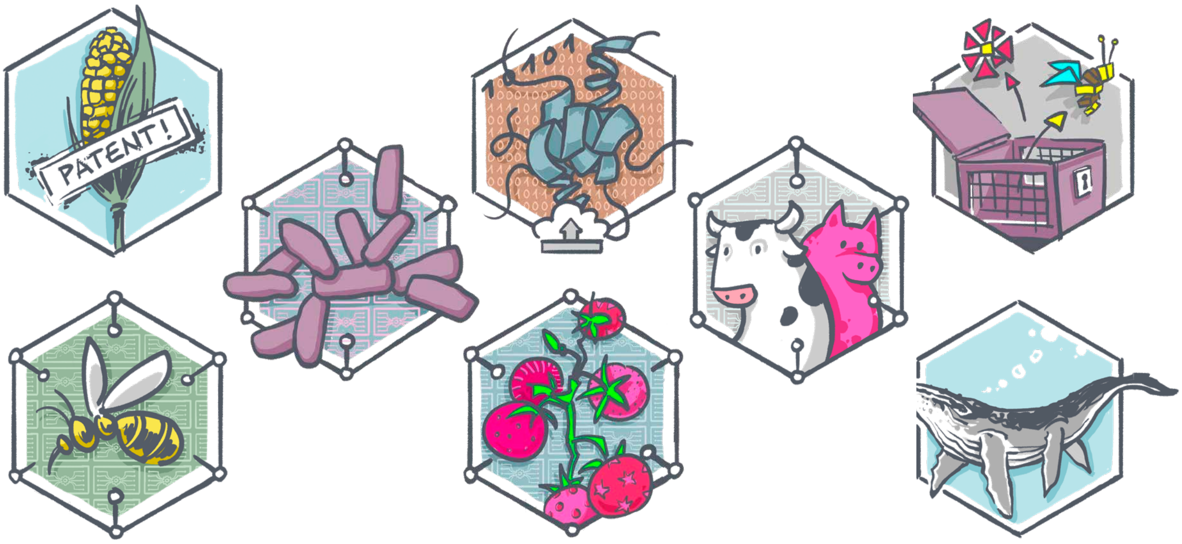
The uncontrolled spread of NGT plants can result in new gene variants persisting in the environment for years, centuries, or even ‘forever’, negatively impacting food production, ecosystems and biodiversity.

If NGT plants are deregulated, there are concerns that regulations for NGT animals and NGT microorganisms could follow suit.

A further aspect is that misuse cannot be ruled out. In many respects biosecurity and biosafety are closely connected and cannot be separated.

Based on publications and proposals made by other experts, Testbiotech drawn up a ten-point plan to mitigate the risks of current developments:

1. Promote risk research
2. Agree on international control mechanisms
3. Regulate access to particularly sensitive information and tools
4. Build expertise in civil society
5. Reduce the influence of industry
6. Expand state capacities to protect people and the environment
7. Strengthen international cooperation
8. Strengthen the precautionary principle
9. Reduce incentives for ethically problematic research
10. Expand technology assessment



1. Introduction

Applications of artificial intelligence (AI) are quickly becoming a part of everyday life, not only in the private sphere, but also in business and science. Genetic engineering and biotechnology are both fields of research that are particularly strongly impacted by the use of AI. We are currently witnessing a (super-)convergence of these advanced technologies, which will affect medicine, animal and plant breeding, agriculture and other sectors.

The convergence of AI, genetic engineering and biotechnology is attracting a great deal of attention in professional circles, as it not only promises great benefits, but also involves considerable risk potential. AI experts Suleyman and Bhaskar write in their book "The Coming Wave" (2023, page 7): *"The coming wave is defined by two core technologies: artificial intelligence (AI) and synthetic biology. Together, they will usher in a new dawn for humanity, creating wealth and surplus unlike anything ever seen. And yet their rapid proliferation also threatens to empower a diverse array of bad actors to unleash disruption, instability, and even catastrophe on an unimaginable scale."*[1]

Questions of biosecurity, i.e. the deliberate (malicious) endangerment of human health, are of particular concern. In a report published by the Nuclear Threat Initiative (NTI), experts warn: *"AI-enabled biological tools could make it possible to design pathogens that are more dangerous than what is found in nature or what humans can develop on their own with current scientific knowledge– for example, pathogens that are more virulent or more transmissible among humans. Although the timeline is uncertain, this misuse scenario could be feasible within the next few years if sufficient guardrails for Ai x Bio [Artificial Intelligence combined with Biotechnology] capabilities are not developed."*[2]

The convergence of AI and genetic engineering has given rise to a political and economic race for technological superiority, prosperity, security and military supremacy between geopolitical powers, in particular between the United States and China. A report published by the US National Security Commission on Emerging Biotechnology (NSCEB, 2025) puts it dramatically: *"Now for the first time in recent history, the United States finds itself competing with a rival over a new form of engineering that will create tremendous wealth, but, in the wrong hands, could be used to develop powerful weapons. Countries that win the innovation race tend to win actual wars, too. (…) China's recent success across core biotechnology capabilities, including AI-driven drug discovery platforms and biomanufacturing, signals that they may soon eclipse us. And if that happens, the United States may never be able to catch up. In previous generations, we might have had decades to maintain our lead, but now, the window to act is just years."*

This report focuses on the risks to the environment and biodiversity (= biosafety), which have received little attention in the discussion so far. It is generally accepted that technical innovations can have disruptive effects on existing technologies and economic systems, but in the field of genetic engineering this would imply to endanger natural biodiversity. Therefore, protecting the foundations of life, nature and biodiversity must be given high priority.

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[1] Synthetic biology is synonymous here with various applications of genetic engineering and biotechnology.

[2] https://www.nti.org/analysis/articles/statement-on-biosecurity-risks-at-the-convergence-of-ai-and-the-life-sciences/

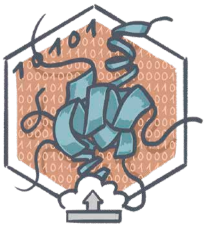
2. The convergence of genetic engineering and AI

An important prerequisite for synergies between genetic engineering/biotechnology and artificial intelligence is the extensive digitisation of genomic data. This data is now available in large databases, and includes the complete genomic sequencing of many species, in addition to extensive data on proteins and other biologically active molecules and metabolites. In this context, so-called pangenome databases are also being created. These contain all known gene variants within a species and, in some cases, related species. Some of these databases also contain information about the respective microbiomes (i.e. the microorganisms associated with plants and animals) that influence their health, responses to stress factors and yield (see, for example, Liu et al., 2025). Currently, the ongoing digitisation of nature is far from complete. For example, the US National Security Commission on Emerging Biotechnology suggests that future research projects should focus on the digital mapping of biological diversity in national parks – and this could even extend to private gardens (NSCEB, 2025).

AI makes it possible to search through huge amounts of molecular genetic information in very short periods of time, and subsequently use suitable data as a basis for designing new gene variants and gene combinations (generative AI).

New tools in generative AI and genetic engineering will allow almost any gene in any life form to be genetically engineered. Particularly noteworthy are the CRISPR/Cas 'gene scissors', as these can be used in the experimental testing of new AI-designed gene variants and gene combinations.

Li et al. (2025) published a detailed overview of the parallel development of AI and new genetic engineering (new genomic techniques, NGTs). Their findings show that the technologies first converged in 2013 when the gene scissors were developed. This was closely followed by a wealth of special AI algorithms and -platforms that can be used, amongst other things, to locate specific genes, identify regulatory elements, discover specific gene variants and predict the consequences of genetic engineering interventions or combinations of multiple genetic changes.



The program 'AlphaFold' developed by Google DeepMind is the best-known example of the convergence of biotechnology and AI. This program can predict the three-dimensional structure of proteins even if no experimental data is available, thus partially solving a decades-old problem in research: although genomic data can be used to obtain the sequence of amino acids that form the basis of protein synthesis, the complex folding of proteins, i.e. their actual three-dimensional structure, could not have previously been predicted from this data. With 'AlphaFold', this is now possible. The software can thus be used as a basis for many commercial applications, including the development of new enzymes for gene scissors (Fei et al., 2025).

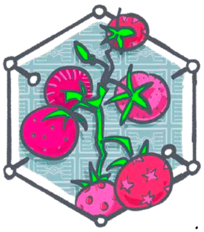
In 2025, scientists successfully used AI to redesign functional viruses for the first time (King et al., 2025). The experiments showed that AI can, in fact, be used to design virus forms which have never existed in nature, but which are nevertheless still functional. The AIs were trained with DNA from existing bacteriophages in a way that also took complex interactions between genes and their regulation into account. AI could therefore be used to re-synthesise entire biological systems and create novel properties.

It is the speed of developments in these two technological fields that makes their convergence so explosive. The speed and direction of these developments is by no means controlled or even subject to conscious decision making. Outcomes are largely the result of synergies in different technical developments, which are frequently neither intentional nor predictable. For example, when genomic data was first digitised on a large scale, it was not actually foreseeable that this data could one day be used with specialised generative AI programs to design new genetically engineered organisms. As described above: AI can be used not only to investigate the structure and function of existing proteins, but also to develop new enzymes for even more effective gene scissors (Fei et al., 2025).

CRISPR-GPT, which was developed by several US universities and Google DeepMind, demonstrates the enormous potential of generative AI to automate large parts of the workflow involved in applications of new genetic engineering techniques (Qu et al., 2025). This large language model agent is designed to assist in the selection of target genes and suitable CRISPR/Cas variants, and thus improve targeting accuracy. Besides making predictions about possible side effects, it can also produce corresponding laboratory protocols.

The result is a wide range of convergences and synergies between applications of genetic engineering and AI, which can only be partially predicted or planned, but which may result in major technical advances. However, whilst more and more is becoming technically possible, the chances of controlling these rapidly expanding technological developments are currently falling dramatically behind.

3. AI and NGT plants

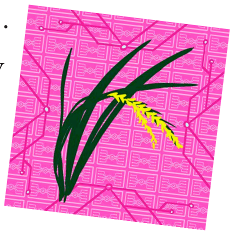


Rapid technological developments are also fuelling overly bold announcements and a great deal of expectation in the plant breeding sector. Some researchers are, for example, invoking an 'AI-Driven Revolution in Designed Plant Breeding', for example: *"The future of plant breeding is advancing towards greater precision, efficiency, and sustainability. Breeding 5.0 represents the forefront of future plant breeding, revolutionizing the field through innovative technologies and methods such as genome editing, artificial intelligence, and big data analysis, enabling integration and editing of genetic information. This will bring revolutionary changes to global agriculture, enhancing food productivity, improving food quality, and fostering resilience to climate change."* (Fang, 2024).

This often involves optimising genetic engineering applications, selecting target genes and improving predictions of changing traits based on genomic data – including in the context of conventional breeding (Feng et al., 2024; Farooq et al., 2024; Chen et al., 2025).

AI is now often used routinely at the planning stage of genetic engineering experiments in plants. Nevertheless, there are still only a few examples of AI playing a decisive role in the development of NGT plants. Poplar trees are one example where an AI algorithm was used to evaluate different gene combinations in regard to the lignin content of the wood. From around 70 000 possible strategies for the multiple alteration of 21 genes involved in lignin metabolism, seven strategies were selected, which resulted in genetic changes in up to six genes. CRISPR/Cas and AI were thus used together to produce 163 (different) NGT poplars with a very low lignin content, which is considered more suitable for wood processing (Sulis et al., 2023).

Herbicide-resistant rice is a further example, where AI was used to facilitate the transfer of particularly long gene segments. The role of AI in this case was to help make insertions more effective and reduce unwanted side effects (Sun et al., 2025).



In addition to programs targeting the genome of plants, there are also algorithms designed to make interactions between plants and their environment more predictable. Certain versions of 'AlphaFold', for example, may be used to predict interactions between plants and pathogens on the basis of molecular structures (Homma et al., 2023; Homma et al., 2024; Veeraganti Naveen Prakash et al., 2024). 'AlphaFold' can also be used to modify the functions of proteins in plants, e.g. to influence the oil content in soybeans (Wang et al., 2025a).

Furthermore, a Chinese study (Xie et al., 2025) shows that NGTs can be used to change the architecture of flowers in tomatoes and soybeans to facilitate robotic pollination. Tomato and soybean flowers have a very low rate of cross-pollination, so self-pollination is the norm. The aim of the NGT research was to alter the structure of the flowers in such a way that cross-pollination for breeding purposes became possible. The flowers were manipulated to exsert the female pistil and make the male stamens (which produce pollen) sterile. This change in the morphology of the flowers is intended to make them accessible for rapid robotic pollination, for which the robots were first trained with artificial intelligence.

The researchers achieved this aim by engineering DNA sequences that control flower development. Special data programs were used to select the target sequences, after which several deletions and inversions were introduced using CRISPR enzymes. The total number of genetic changes was kept at a low level (below the threshold of 20 permitted in Annex I of the deregulation proposal, see below). The resulting genotype and phenotype were previously unknown in these plant species. Protruding pistils or stigmata also occur in wild relatives of the tomato, but these traits are caused by other gene variants and also look different. Therefore, these plants must be considered 'new to the environment'. The NGT plants would primarily be used in plant breeding in greenhouses, but they have nevertheless also already been tested in the fields.

China and several other countries are extensively promoting the use of AI and genetic engineering in plant breeding. Several 'multiomics' databases, i.e. data on DNA (genome), RNA (transcriptome), proteins (proteome) and metabolites (metabolome), have been developed for various plants, including maize, lettuce, soybean and pumpkin, and are currently being systematically expanded (Zhang, 2025). This data enables the identification of gene functions and networks involved in important plant traits. At the same time, scientists are conducting field trials to collect data relevant to environmental interactions.

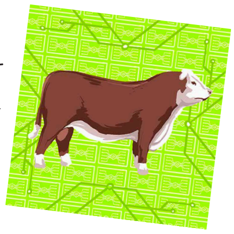
An article on the future of maize breeding authored by Chinese, European and American scientists (Liu et al., 2025) envisions the future of 'smart maize'. In this instance, generative AI and genetic engineering will be combined to evaluate and utilise databases containing information on related species (pangenome) and associated microbiomes (hologenome). The researchers claim that: *"Integrating these two, precise predictions of traits directly from genomic data and precise molecular design with guided targets will further make rational breeding more practical, leading to a holistic, data-driven, and predictive approach. While systems-based approaches laid the groundwork for understanding biological complexity, the intelligent-design era integrates AI and molecular-design technologies to accelerate and enhance breeding precision. We anticipate that, in the coming decades, intelligent maize breeding integrating these advances will move into a rapid, precise, and programmable framework."*

From this perspective, developments in plant breeding are no longer defined solely by access to genetic resources, breeding and biotechnology, but by their combination with specific AI programs. One danger here is that traditional methods of classical breeding will continue to fall behind. Not because they are less effective in breeding new varieties, but because the breeding environment is changing under the influence of financial interests associated with big data, high tech, big capital and also government interests. This can significantly distort competition in the plant breeding sector, and potentially narrow it down to certain technological paths that are not necessarily the most suitable.

It should not be overlooked that even though the combined use of AI and genetic engineering has so far been primarily of interest to companies, investor groups, technology experts and patent law firms, we still all owe our 'daily bread' to traditional breeding. Therefore, anything that could make traditional breeding more difficult, or even block it in future, should set alarm bells ringing.

4. AI and NGT vertebrates

Compared to plants, there are currently very few publications on AI and genetic engineering in animal breeding. The current focus here is on programs to evaluate data taken from conventional breeding (Adebayo et al., 2024). In particular, the aim is to improve the prediction of certain traits based on genomic data. Here, too, large databases containing the genetic information of various animal species have been established (Gao et al., 2023).[3] These are used, amongst other things, for breeding cattle (Xu et al., 2025; Liu et al., 2022), pigs (García-Vázquez, 2024) and poultry (Bani Saadata et al., 2024; Li et al., 2024), or in aquaculture for fish (Li et al., 2025) and shrimps (Nguyen et al., 2022). Similarly to plants, the databases also include associated microbiomes (Nguyen, 2024).



There are also numerous NGT applications in livestock (see Testbiotech, 2025a), thus raising expectations that the convergence of AI and genetic engineering will become even more pronounced in this sector. For example, researchers are investigating the combination of certain gene segments in the breeding of cattle, which they hope will result in 'ultimate genotypes' (Hayes et al., 2023). They are, in particular, interested in data for a possible change in gene regulation in pigs and cattle (Liu et al., 2022; Teng et al., 2024). The University of Edinburgh (Roslin Institute) is currently involved in cattle breeding projects funded by the Gates Foundation, amongst others[4], in which AI is being used to identify regulatory gene variants that could also be suitable for NGT applications (Zhao et al., 2024). In order to achieve this goal, they have developed AI strategies that can be used both in cattle and other species. The authors write: *"With the increased availability of high-quality training data [it is] expected to further improve the performance of livestock models in prioritising novel functional variants, and ultimately improving advanced breeding approaches."*

Publications and patent applications held by the US company Colossal Biosciences, which is seeking to 'bring back to life' extinct vertebrates, such as woolly mammoths, dire wolves, dodos and Tasmanian tigers, show where this journey could lead. However, what the company is actually creating (or wants to create) with the help of genetic engineering and AI are genetically engineered versions of existing species, e.g. Asian elephants, grey wolves, South American running birds and marsupial mice. Currently, patents are pending for at least some of these applications. This kind of undertaking requires genomic data and the analysis of complex genome networks. According to Colossal, it also uses AI programs for this purpose.[5] Chinese scientists also emphasise the role that AI can play in restoring or redesigning the genetic material of extinct species (Wang et al., 2025b). According to their assessment, this will primarily involve the discovery and modification of regulatory elements and the de novo construction of synthetic DNA sequences – up to entire chromosomes – based on fossil genetic material.

It is unclear what exactly these experiments will achieve (besides media hype). Ultimately, none of them will result in the revival of extinct species. Instead, they involve deep interventions into the genome of currently existing species. Quite often, the expression (activity) of species-specific genes is altered in order to obtain, for example, mice with extremely long fur that should resemble that of woolly mammoths (Chen et al., 2025).

From the perspective of biology, laboratory techniques and AI programs, the boundaries between humans and other vertebrates are often only gradual. Methods and AI programs that work on mice or grey wolves

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[3] See also: https://www.animalgenome.org/tools/SNPnmids/; https://azifi.tz.agrar.uni-goettingen.de/agreg-snpdb/

[4] https://www.research.ed.ac.uk/en/projects/artificial-intelligence-accelerated-genomic-improvement-in-lmic-l

[5] https://colossal.com/colossals-dire-wolf-and-woolly-mammoth-project-leverages-ai-to-advance-species-revival/

could also be tested on humans. More than ten years ago, George Church, co-founder of Colossal Biosciences, was already thinking about the 'resurrection' of Neanderthals: *"A later technique under development in my Harvard lab will allow us to resurrect practically any extinct animal whose genome is known or can be reconstructed from fossil remains, up to and including the woolly mammoth, the passenger pigeon, and even Neanderthal man. (…) the genome sequence of both the wooly mammoth and Neanderthal man have been substantially reconstructed; the genetic information that defines those animals exist, is known, and is stored in computer databases. The problem is to convert that information - those abstract sequence of letters - into actual strings of nucleotides that constitute the genes and the genomes of the animals in question."* (Church & Regis, 2012)

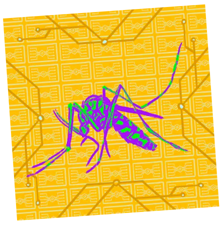
The reverse is also true: AI programs developed for medical use, e.g. the evaluation of regulatory DNA sequences, can also be used to genetically engineer other vertebrates (Gosai et al., 2023; Teng et al., 2024).

5. AI, NGT insects and gene drives

Various databases can nowadays be used to search for the genetic material of numerous insect species, including fruit flies (*Drosophila melanogaster)*, certain insect pests (e.g. the red flour beetle, *Tribolium castaneum*) or mosquito species (e,g. the Egyptian tiger mosquito *Aedes aegypti*). AI can be used to search for and process genomic data to:

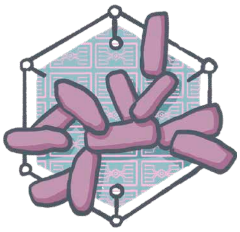
- Find target genes that are suitable for applications of insecticidal RNA in pests (Chen et al., 2024, Xu et al., 2024),
- Identify regulatory sequences that can be used to interfere with gene regulation (Asma & Halfon 2021), or specifically enhance the expression of certain genes (de Almeida et al., 2024, Tashkiran et al., 2022),
- Predict CRISPR/Cas outcomes in advance (Zhang et al., 2024).

AI is also involved in attempts to further develop genetic engineering processes via automated microinjection of insect or fish eggs using robotics (Alegria et al., 2024).



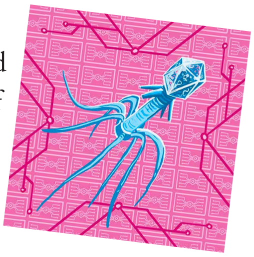
New genetic engineering techniques are also being used to develop so-called 'gene drives' for use in a number of insect species. NGT organisms with gene drives could be released in order to genetically engineer natural populations directly in the environment ('outdoor genetic engineering', see Testbiotech, 2024; Heinemann et al., 2025). The genetically engineered organisms with gene drives are able to rapidly spread artificial gene constructs throughout subsequent generations, and thus substantially outpace natural inheritance. The aims include, for example, combating mosquitoes that transmit the malaria pathogen, or are considered pests in agriculture. Gene drives have also been developed for applications in rodents and plants. In this context, AI can be used, amongst other things, to assess the impact on target populations (Allegretti et al., 2025), or to identify suitable target genes which could be genetically engineered via gene drives (D'Amato et al., 2023; Anderson et al., 2024, Champer et al., 2021; Collier et al., 2024, Gonzales et al., 2025; Verkuijl et al., 2024).

6. AI, genetically engineered microorganisms and viruses



Even though only a small proportion of the microorganisms colonising soils, for example, are known, large amounts of genomic data are nevertheless available in special databases.[6] The possible applications of AI programs, which can also be used to analyse the interactions between different species or design new combinations, are correspondingly diverse.

Yeasts, cyanobacteria, *Pseudomonas* and *E. coli* are among the most commonly used single-cell organisms when it comes to the use of AI for genetic engineering with NGTs (Feng et al., 2021; Dallo et al., 2025). Applications include research into metabolic networks (Miao et al., 2023), interventions in gene regulation (Seo et al., 2023; Lei et al., 2025), the increase of certain metabolites (Su et al., 2025; Zhang et al., 2020; Fontana et al., 2023), switching off gene functions (Yu et al., 2024), killing specific bacterial populations (Rottinghaus et al., 2022), and interactions of microbiomes in the gut (Westfall et al., 2021) or in the root zone (García-Tomsig et al., 2021; Roghair Stroud 2024). In US agriculture, NGT bacteria have been commercially marketed for several years as fertilisers to improve nutrient uptake in crops (Wen et al., 2021; Miklau et al., 2024). Through the combined use of AI and NGTs, amongst others, Bayer is also aiming to establish itself in the 'biologicals' industry by setting up a collaboration with Ginkgo Bioworks (under the name 'Joyn Bio'). They state that they can access more than 300,000 agronomically relevant bacterial strains with more than 2.7 billion metagenome data sets in their databases.[7]



AI was successfully used to redesign functional viruses for the very first time in 2025. This has resulted in previously unknown virus variants that specialise in bacteria, known as bacteriophages. Some of the properties of these AI viruses are superior to those of the original strain of bacteriophages ΦX174. In an experiment, the scientists were not only able to alter individual DNA segments, they were able to rewrite and redesign the entire genetic material of the virus.

Bacteriophages are known for using bacteria to reproduce. The infected bacteria die, thus giving rise to the next generation of viruses, which can then re-infect bacteria. Some bacteriophages are therefore thought to be a possible replacement for antibiotics in combating particularly resistant germs. In theory, this could be one of the benefits of the current experiments.

Ultimately, however, the experiments have shown for the first time that AI can be used to design forms of viruses that do not yet exist in nature, but are nevertheless functional. The AI models 'Evo 1' and 'Evo 2' were trained with almost three million genomes from existing bacteriophages in a way that also took complex interactions between genes and their regulation into account. AI could therefore be used to synthesise entire biological systems and create novel properties.

The genome of phages is relatively small, which is the reason they have been used for several years in experiments to synthesise entire genomes. However, these experiments have so far been largely unsuccessful in terms of newly designed viruses. Guided by experts, the AI models 'Evo 1' and 'Evo 2' have succeeded in creating bacteriophages with biological properties that differ from those of the original forms, but which continue to function. Some of the newly designed virus variants cannot only reproduce successfully with the help of bacteria, they can also overcome resistance and spread with greater effectiveness.

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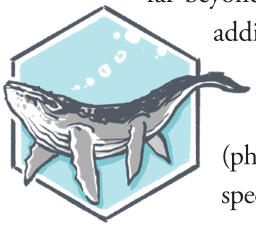
[6] See, for example: https://allthebacteria.org/; https://wdcm.org/; https://bacteria.ensembl.org/index.html

[7] https://ag.ginkgo.bio/tech-ag-biologicals
https://www.cropscience.bayer.us/news-press/crop-protection/bayer-and-ginkgo-bioworks-unveil-joint-venture-joyn-bio-and-establish-operations-in-boston-and-west-sacramento

7. Spotlight: Interventions in gene regulation

Interventions into gene regulation, sometimes euphemistically referred to as 'fine tuning', are currently booming in the NGT plant and animal sector. They allow drastic changes in the characteristics of species that go far beyond what would otherwise be possible with conventional breeding methods – all without inserting additional genes.



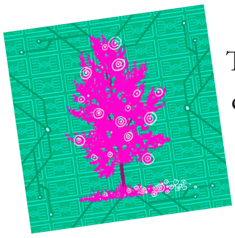
The approach of interfering with gene regulation is based on findings in developmental biology (ontogenesis – the development of an organism from a single cell) and the fundamentals of evolution (phylogenesis – the development of species). It is important to note that the appearance of organisms and species does not depend solely on the genes they carry in their genetic material, but also on how these genes are regulated. The development of the human body is a good example: human organs, with all their complex differences, are based on the same genetic foundations – it is gene regulation which enables the different manifestations. Another example is the evolutionary development of whales, whose skeletons still show the rudimentary structures for hind limbs. These internal remnants are an example from evolution of how strongly the characteristics of species can be influenced by the regulation of genetic structures.

Gene regulation reflects the influence of cells, as they determine how genes are read. We now have a significant body of knowledge in regard to the active role of cells as the organising level of genetic information (see, for example, Ball, 2023). Diverse genetic predispositions for the production of biologically active molecules (such as RNA or transcription factors) play a decisive role in this process, as they intervene in a controlling manner in gene networks. Other mechanisms of gene regulation are not genetically anchored, but epigenetic: cells can also change gene activity in the short to medium term via biochemical mechanisms in response to environmental influences. The ability of organisms to live and develop depends solely on the interaction of these complex organisational levels.

Stabilising factors are necessary to maintain this complexity in a functional state. The development of a species is subject to certain restrictions and is influenced by mechanisms that enable further adaptation and protect the preservation of species characteristics. These 'flexible guard rails', which were 'invented' by evolution, can be described at the level of cells, organisms and species (see, for example, Lala et al., 2024). They are the important outcomes of evolution and co-evolution that have been taking place for over four billion years. New genetic engineering, however, can overcome many of these 'flexible guard rails' at the molecular level – giving it huge technical potential for genetically engineering organisms.

This technical potential is also evident in medical research, amongst others. Currently, attempts are being made to grow entire organs from individual embryonic stem cells, which can then be used for transplants. The key here is the manipulation of gene regulation. AI is designed to help identify which regulatory elements are crucial and how they can be genetically engineered to grow organs in the laboratory. Special AI programs developed for this purpose are, for example, CellCartographer (Appleton et al., 2025) and Malinois (Ventimiglia and Zelezniak, 2024; Gosai et al., 2024).

Such programs could also be used for other purposes. One example is the aforementioned 'resurrection' projects involving 'mammoths' or 'dire wolves', in which many new characteristics can be achieved without inserting additional genes (see also Wang et al., 2025b). The overlaps between medical applications in humans and interventions into the genetic material of dire wolves and the like are also reflected at the level of the scientists involved in the projects. For example, the geneticist George Church is involved in the development of AI programs for medical research (Appleton et al., 2025; Jung et al., 2021) and is at the same time also a founding member of Colossal Biosciences. Interestingly, he is also one of the signatories of the aforementioned Nuclear Threat Initiative appeal on biosecurity risks.



The situation with plants is similar: an evaluation of pangenomic data for maize showed that the differences between maize varieties are largely due to gene regulation (Engelhorn et al., 2025). Changes in regulatory elements also play a prominent role in NGT plants. One example is the 'GABA tomato': Japanese authorities granted the world's first approval for a CRISPR plant in 2021. The extremely high levels of gamma-aminobutyric acid (GABA) in the tomato fruits were achieved through minor interventions in regulatory elements, which, according to the authors, were not possible with random mutagenesis (Nonaka et al., 2017). GABA is said to promote sleep and lower blood pressure. Another example is NGT poplar trees in which flowering was induced after only four months rather than the usual seven to ten years. Here, too, minor interventions in the gene regulation of the plants were sufficient (Ortega et al., 2023). A further example is NGT lettuce, in which the vitamin C (ascorbic acid) content was increased to such an extent that it even became tolerant to herbicides, such as paraquat (Zhang, et al., 2018; Testbiotech 2025b). Among the examples are the aforementioned insecticidal AI maize and NGT plants, in which flower shape has been adapted for robotic pollination.

In many cases, it is problematic that interventions into gene regulation simultaneously affect several functions, which then often influence each other in their effects. One example is small RNA sequences (micro-RNA or miRNA), as these can interfere in the regulation of several gene functions at the same time by inhibiting gene activity. Gene regulation in cells is finely tuned, and therefore the inhibition of certain genes can often result in the over-expression of other genes.

The microRNA MiR529a in rice, for example, is involved in the regulation of five transcription factors (proteins that in turn influence gene activity) affecting plant height, architecture, grain number and size (Yan, et al., 2021). Genetically engineering this miRNA appears to be a promising approach, as it is almost impossible to alter its functions with current breeding methods. However, as these small molecules are involved in so many vital plant processes, serious side effects are often observed when genetic engineering is used (see also Yadav et al., 2023).

Due to the complexity of the mutually influencing networks, scientists are turning to AI for help: there are already a wealth of AI programs to identify regulatory units and design targeted alterations. In addition to the aforementioned AI programs used in medical research ('Malinois', Gosai et al., 2023 and 2024; 'CellCartographer', Appleton et al., 2025), there are also equivalents for plants (e.g. 'FloraBert', Levy et al., 2022), insects (e.g. 'REDfly/SCRMshaw', Asma & Halfon, 2021) and microorganisms (e.g. 'PromoGen', Xia et al, 2024). The respective algorithms can also be used across species, as is explicitly emphasised in the respective publications:

- *"In this paper, we propose and implement a model, FloraBERT, that implicitly learns regulatory motifs from promoters in nearly every publicly available sequenced plant genome." (Levy et al., 2022)*
- *"Together, we provide a generalizable framework to prospectively engineer CREs8 and demonstrate the required literacy to write regulatory code that is fit-for-purpose in vivo across vertebrates." (Gosai et al., 2023)*
- *„We (…) focus on two tools that we have developed, REDfly and SCRMshaw. These resources can be paired together in a powerful combination to facilitate insect regulatory annotation over a broad range of species, with an accuracy equal to or better than that of other state-of-the-art methods." (Asma & Halfon, 2021)*
- *"Here, we developed PromoGen, a collection of nucleotide language models to generate species-specific functional promoters, across dozens of species in a data and parameter efficient way." (Xi et al., 2024)*

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[8] Cis-regulatory elements (CRE) are regions of non-coding DNA that regulate the transcription or expression of neighboring genes.

When assessing the risks of organisms whose gene regulation has been altered with genetic engineering, it is important to understand that some of these changes could also occur in the course of evolution. However, this does not make them in any way 'safe', as the convergence of AI and genetic engineering means that many of these genetic changes can occur in extremely short periods of time. Altogether, this represents a far greater intervention into the characteristics of species and their ecosystems than could ever be expected from conventional breeding and evolutionary processes. Put simply, genetic engineering makes it possible for everything to happen all at once in all species, whereas evolutionary processes only allow the realisation of a certain selection of characteristics, usually manifesting only after very long periods of time, and which require mutual adaptation through co-evolution. New genetic engineering can thus create organisms that have the potential to disrupt entire ecosystems and be a new cause of species extinction.

8. Risks to the environment

Against the backdrop of the convergence of AI and NGTs in plants, animals and microorganisms, we need to elevate the importance of the precautionary principle. It is difficult to specify long-term risks in advance if NGT organisms can persist in the environment and inherit characteristics that the species did not have in the first place. There are simply too many factors impacting their interactions with the environment.

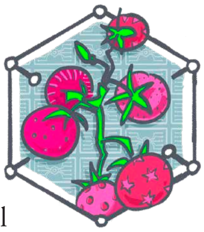
Concerns about the long-term consequences for biodiversity are also addressed by AI experts Suleyman and Bhashkar (2023, page 114): *"New forms of autonomy have the potential to produce a set of novel, hard-to-predict effects. Forecasting how bespoke genomes will behave is incredibly difficult. Moreover, once researchers make germline gene changes of a species, those changes could be out in live beings potentially for millennia, far beyond any control or prediction. They might reverberate down countless generations. How they go on to evolve or interact with other changes at these distances is inevitably unclear – and beyond control. Synthetic organisms are literally taking on a life of their own."*

The pace of developments also plays a major role in terms of risk. Depending on the speed of developments, the depth of the intervention and the extent of the release of NGT organisms, tipping points could be reached that significantly disrupt food webs and ecosystems. Once organisms that have not had a chance to adapt through co-evolution are released on a certain scale, interactions in ecosystems could change so significantly that the system as a whole would be severely impaired. Further negative synergistic interactions could possibly result in widespread collapse. Therefore, in addition to the risk assessment of individual NGT organisms, a technology assessment is also needed in order to assess systemic and long-term risks that go beyond those of the individual organisms.

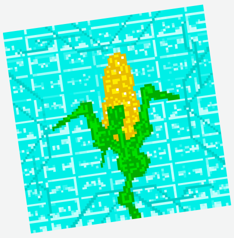
8.1 Extinct species

Not all environmental risks that may arise from the convergence of AI and genetic engineering/NGTs are obvious or even foreseeable (so-called 'unknown unknowns'). However, in some cases, they are obvious, e.g. if the 'dire wolf' escaped into the natural populations of grey wolves, it could also reproduce. Since it is larger and stronger than its natural counterparts, these wolves and their offspring would have a fitness advantage and therefore displace the natural populations. This would have significant consequences – not only for the protected wolf species themselves, but also for ecosystems and possibly humans if the genetic changes also result in changes to hunting behaviour. One could see unexpected consequences in the medium term. If, for example, the genetically engineered animals were more susceptible to disease, this trait could also spread among other wolves, posing an additional risk to the species' survival. Colossal Biosciences projects could thus achieve the exact opposite of their claimed objective. Instead of reviving extinct species, they would only endanger the survival of existing species.

8.2. NGT plants



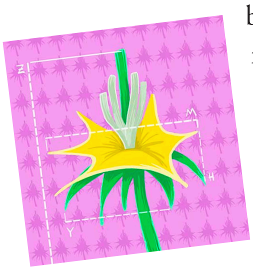
Insecticidal AI maize (see box) is another example of a self-evident degree of risk. The targeted regulatory elements in this case are part of the finely tuned network of interactions within the genome and cells that enables plants to defend themselves against pest insects. These networks have evolved through evolutionary processes and are also involved in plant responses to other environmental factors, e.g. pathogens, climate change and interactions with other species such as pollinators and soil organisms. All of these interactions have evolved over time, but they can be significantly disrupted if genetically engineered plants with an 'out-of-tune' gene expression are released into the environment. Their altered characteristics could permanently jeopardise the coordinated functions of ecosystems, food webs and biological diversity (Juhas et al., 2025).



In 2025, it was demonstrated for the first time that it is possible to use a publicly available AI tool (ChatGPT 4o) to design the genetic blueprint for an insecticidal maize plant that would be feasible using new genetic engineering techniques (Juhas et al., 2025). Not only can insecticidal plants be toxic to the targeted pest species, they can also put non-target organisms, food webs, ecosystem functions and biodiversity at serious risk. The number of genetic changes required is low (less than 20), but the resulting specific combination of genetic changes cannot be achieved using conventional breeding methods. According to the recent EU proposal for future regulation of NGT plants, any plants that produce known insecticides (or are made resistant to herbicides) must undergo environmental risk assessment. There is agreement here at least that some plants still require an environmental impact assessment (NGT-1 criteria, see below), even though they have only minor genetic changes. However, this overlooks the fact that many other NGT plants, which also have only a small number of genetic changes, can pose significant risks to pollinators and other beneficial or protected insects. These include NGT plants with changes in plant composition (Koller et al., 2024) or manipulated flowers (Testbiotech, 2026). However, if the current deregulation proposal is implemented, none of these NGT plants would be subject to environmental risk assessment.

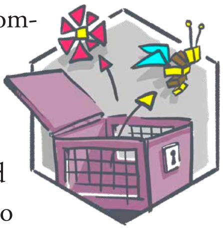
In addition, plant health and food security may be compromised if plants are no longer able to respond to or interact with the environment as they have done in the past. For example, when NGT plants are exposed to pathogens and/or more extreme climatic conditions, the 'out-of-tune' plants may perform significantly worse. The enhancement of certain metabolic cycles often comes at the expense of other biological functions, which can then lead to a weakening of the plants.

The environmental risks associated with NGT plants must therefore be investigated on several levels, including the consequences for plant health. Investigations should include the toxicity of the plants themselves as well as their degradation products (even after harvest) to beneficial insects, worms, pollinators and/or soil life. Animals such as birds that eat insects which feed on NGT plants must also be taken into account (see Testbiotech, 2025c).



Special care is required when assessing the risks of NGT plants whose flowers have been manipulated (Testbiotech, 2026). This also applies to plants with 'robot flowers' (Xie et al., 2025), as the structure of the flowers in these plants has been altered by NGTs to enable robotic pollination. Although some flowers showed exserted pistils, they also produced fertile pollen, meaning that they were not male sterile as intended. Such NGT plants could spread more quickly and cross more easily. Spontaneous 'stacking' can also lead to the simultaneous development of several NGT traits in an NGT plant. If similar research were to be conducted with species that can survive and reproduce in the environment, this could significantly alter the environmental interactions of NGT plants. For example, many NGT applications are first tested on the model plant *Arabidopsis thaliana* (thale cress) before being introduced into other plant species. *Arabidopsis thaliana*, like tomatoes, only has low cross pollination rate. A change in flowering characteristics could therefore turn NGT *Arabidopsis* into a harmful weed or an invasive species. *Arabidopsis* species occur worldwide in different ecosystems with regional genomic variations (see, for example, Bastias et al., 2024), so this could have far-reaching consequences for the environment.

Likewise, the above-mentioned poplars with reduced lignin content, which was achieved with a combination of AI and NGTs (Sulis et al., 2023), still need to be risk assessed: it is unclear what effects these genetic changes will have on the trees' interactions with other species, or on their responses to environmental stress throughout their lifetime. Currently available data is from trees that are only a few months old. Notably, some of the trees have a higher volume of wood and a reduced lignin concentration. This is a sign of unintended changes and that the targeted genes appear to influence several metabolic cycles.



Poplars naturally grow in sensitive ecosystems, including the protected black poplar (*Populus niger*). If the NGT trees were to successfully spread into these natural populations (through pollen, seeds, cuttings or broken branches), it would be very difficult or even impossible to retrieve them, as poplars produce millions of pollen grains and seeds (see also: FGU, 2024).

Similar to transgenic plants, the NGT poplars exhibit characteristics that go beyond the typical properties of the species. How these changes will affect natural populations and their interactions with other species over the entire lifetime of the trees cannot be reliably predicted. The long-term effects depend on too many factors such as interactions within the genome and with the environment.

In addition to poplars and *Arabidopsis thaliana*, current databases[9] show that scientists are applying NGTs in many other species that can survive, reproduce and spread in the environment. The list includes wild plants native to the EU, such as camelina, foxtail, mustard, oilseed rape, pennycress, ryegrass, switchgrass and wild strawberries. Other sources also mention alpine cress, apple trees, bristlegrass, bellflowers, gentian and false brome (Hodaei & Werbrouck, 2023; Raheena et al., 2025). The uncontrolled spread of NGT plants in these species can lead to new gene variants persisting in the environment for years, centuries, or even 'forever', negatively impact food production, ecosystems and native biodiversity.

Furthermore, fast-track releases (including experimental releases) would lead to an increased risk of seed contamination in crops such as corn, rice, soybeans and wheat. Species of vegetables found in the relevant databases with NGT applications that could be affected by seed contamination are broccoli, cauliflower, chili peppers, cucumbers, eggplants, lettuce and tomatoes.

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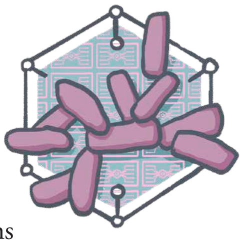
[9] z.B. https://www.eu-sage.eu/

The following environmental risks associated with NGT plants have already been described in scientific literature: effects of altered plant composition on pollinators, plant pests and food webs; increased invasive potential; weakening of natural plant populations; spread of pathogens; yield depression; insect toxicity; changes in the composition of soil organisms with undesirable consequences and endangerment of protected species (see ANSES, 2024; Bohle et al., 2023; Eckerstorfer & Heissenberger, 2023, Testbiotech, 2025 and 2026; Mundorf et al., 2025; Juhas et al., 2025; Kawall, 2021; Koller et al., 2024; Koller, 2025; FGU, 2024; FGU, 2025).

8.3 'Outdoor genetic engineering'

Particularly worrying in this context are plans to release genetically engineered organisms in order to genetically engineer / transform natural populations directly in the environment ('outdoor genetic engineering', see Testbiotech, 2024; Heinemann et al., 2025). Gene drives are one of the approaches in this context, as they enable artificial gene constructs to spread much faster in a species than would be the case with natural inheritance. The aim is to decimate, eradicate or genetically engineer certain species that are considered pests or which transmit diseases. Gene drives can trigger a mutagenic chain reaction in natural populations, amongst others, which can result in the extinction of the affected populations (Gantz & Bier, 2015). AI can also be used to better assess the impact on the respective populations. However, with or without AI, there remains a considerable residual risk when using these methods. If gene drive organisms are released, it is not unlikely that subsequent generations will exhibit undesirable traits that were not observed in the laboratory (Then et al., 2020). If unwanted developments occur, there may in many cases be insufficient options to control or retrieve the organisms.



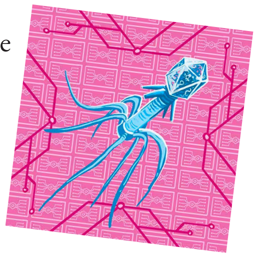
8.4 Interactions between bacteria and plants

The release of genetically engineered microorganisms is similarly problematic. Here, too, there is often a lack of reliable criteria for robust risk assessment (Miklau et al., 2024). One problem is that the reproduction and spread of microorganisms is almost impossible to control. Some studies have shown that the properties of transgenic plants can sometimes be transferred to other plants via microorganisms (Garcia-Pichel et al., 2025). The research is based on the premise that transgenic plants can be engineered to secrete a substance to attract more bacteria. The aim is to change the composition of the microbiome at the roots, and thus enhance plant growth. Surprisingly, non-genetically engineered plants growing nearby were also found to have improved growth. Analysis showed that the composition of the microbiome had also changed in the control plants. The researchers found that the altered microbiome not only influenced the nutrient supply to the plants, but also released signalling substances that interfered with their gene regulation, and thus resulted in changes to the plants' phenotype. The authors (Garcia-Pichel et al., 2025) also mention the risk to the environment: *"Notably, this finding suggests that the genotype of one plant can significantly modify the expression of another plant's genotype, which raises important considerations for the deployment of transgenic plants. Specifically, some of the vigor exhibited by transgenic plants may be redirected toward supporting the growth of neighboring plants, potentially including undesired species."*

Even AI would have been unable to predict this interaction between transgenic and control plants. In general, AI algorithms can only make reliable predictions on the basis of sufficient data. For example, when it comes to understanding interactions in constantly changing environmental conditions, AI programs face many (at least so far) insurmountable hurdles. This can have trivial causes: for example, even after more than 25 years of growing transgenic insecticidal maize in Spain, Bayer did not consider it necessary to provide reliable data on the threat to protected insects or the development of resistance in pests (EFSA, 2025).

AI-designed genetically engineered plants and microorganisms intended for agricultural use pose risks to humans, the environment and food security if they have not been adequately tested for risks prior to release. This is not only about the risks posed by individual organisms, but also about advancing technologies, the speed of developments, the diversity of the new traits, the number of organisms to be released and the range of species affected as a whole (Koller et al., 2023).

8.5 AI-Viruses



Misuse cannot be completely ruled out. Under these circumstances, biosecurity and biosafety are closely interlinked and cannot be considered separately.

The aforementioned AI viruses are evidence of these risks (King et al., 2025): on the one hand, bacteriophages can continuously evolve, acquire new properties and, for example, kill bacteria that are essential for human life, plants and animals. On the other hand, this approach could also be applied to viruses that spread dangerous diseases. As a precaution, the AI was not trained with data from human pathogenic viruses. However, technically speaking, the approach of these experiments may be transferable to viruses that are dangerous to humans. It is also conceivable that completely new viruses could be created. In this context, many experts are warning of the dangers of malicious applications, or even military use. Nevertheless, humanity now seems to be moving very much closer to these dangers.

9. Patents

Patents granted in the genetic engineering sector not only claim the respective processes, they also claim the resulting plants, animals and microorganisms.

The increasing use of AI in the design of genetically engineered organisms is currently opening up a new, additional dimension of exclusive property rights. Once more, attempts are being made to claim not only the AI programs, but also the resulting organisms, regardless of their specific characteristics. One extreme example is a patent application filed by the US company Inari, which is also involved in the development of the generative AI 'FloraBert'. The international patent application, WO2023250505, claims the use of DNA variants that can occur in all plant species and which regulate gene activity. The company is not claiming a specific trait or plant species, but rather the use of an unlimited number of DNA sequences that are crucial for gene regulation in plants. Consequently, Inari is attempting to claim as its own invention genetic information that is important for all breeders, including genetic information for conventional breeding. The patent claims all plants that have been developed with the help of AI and contain the corresponding gene sequences – even if they have not been genetically engineered, but bred using conventional methods.

Similarly, Pioneer (a Corteva subsidiary) has filed a patent application for an AI program that can be used to design the characteristics of plants, animals and microorganisms (WO 2024006802). The AI described in the patent is actually intended to optimise the function of gene scissors such as CRISPR/Cas. Researchers in this case were aiming to analyse the prospects of success in genetically engineering certain genes, and to adapt the gene scissors accordingly. However, some of the patent claims are worded in such a way that the use of the AI alone would be considered a breeding method. This means that all organisms 'processed' with these programs could also be considered patented 'inventions'.

These developments risk creating an impenetrable 'patent thicket'. In addition to patents claiming the respective genetic engineering processes, seeds and livestock, amongst others, would also be affected by patents on the digital processing of genetic data, thus further strengthening the dominance of large companies. Corteva (formerly DowDuPont) is already a leading player in filing patent applications for NGT plants. Ultimately, this kind of over-patenting also threatens biodiversity in agricultural systems.

10. The debate in the EU on the regulation of NGT plants

The release of NGT organisms has considerable potential to endanger ecosystems and become a new cause of species extinction. The convergence of AI and genetic engineering dramatically increases this potential. It is therefore important that risk research and GMO regulation are expanded and adapted accordingly. However, legislators are threatening to take a completely different direction, particularly in regard to NGT plants. Current technical developments show that the EU proposal for the future regulation of NGT plants is inadequate. It would already be outdated before it could even be implemented (see also Testbiotech, 2025c).

Annex 1 is at the heart of the proposed EU deregulation, as it defines which NGT plants will be treated as equivalent to conventional plants.[10] It introduces a threshold for the number of 'permitted' genetic changes, which would allow NGT plants to be approved without the need for environmental risk assessment. The plants would be classified as 'NGT 1' plants. According to current estimates, more than 90 percent of all NGT plants would fall into this category. The only exceptions would be transgenic plants and NGT plants that produce known insecticides or are herbicide-resistant.

In short, it is based on a 'magic threshold' of 20 mutations per chromosome set.[11] Each of these mutations can comprise up to 20 altered nucleotides as well as deletions and inversions without size restrictions.

This means that NGT plants with genetic changes below this "threshold" would not be subject to mandatory environmental risk assessment. There would also be no requirements for methods to either trace the plants or label food products. Furthermore, hybrid offspring produced by breeders, or resulting from spontaneous gene flow, would not be subject to any further assessment or approval procedures. All in all, this is a substantial watering down of existing genetic engineering legislation[12], which is why it must be called a proposal for deregulation.

As demonstrated by Vogel (2025), Mundorf et al. (2025) and Juhas et al. (2025), this legal framework could be used by AI as a kind of 'design room' to develop NGT plants that fall below the specified thresholds, but which at the same time exhibit new, risk-laden characteristics and are different from plants obtained from conventional breeding. This would be easily achievable, particularly through interventions in gene regulation, as has been demonstrated in the case of NGT maize with insecticidal properties (Juhas et al., 2025) or tomatoes and soybeans with 'robo flowers' (Xie et al., 2025).

Adopting the above criteria could thus result in the development of large groups of NGT plants with a wide range of unassessed risks being brought to market and/or released into the environment. AI applications could further exacerbate the speed of developments. It must be kept in mind that the risks include unintended effects caused by the use of NGT tools themselves.

Moreover, potential damage to human health and the environment would accumulate over time, and could increase dramatically if more and more NGT 1 plants were to be approved for cultivation and/or import into the EU without being risk-assessed. Neither would there be any means of verifying the genetic stability of the plants in certain environmental conditions, or in (hybrid) offspring.

There are already many examples of genetically engineered plants that would be classified as NGT 1, but whose characteristics differ greatly from those known in conventional breeding. As numerous scientific publications

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[10] https://www.keine-gentechnik.de/fileadmin/user_upload/20251210Draft_agreement-NGT-VO_2023_0226_COD_.pdf

[11] Plants often have multiple sets of chromosomes, for example wheat with six or even eight sets. Accordingly, a higher number of genetic changes is permitted.

[12] https://eur-lex.europa.eu/eli/dir/2001/18/oj

show, there is in fact no ‘magic threshold’ for the number of mutations above which NGT effects can be assumed to be risk-free: insecticidal NGT plants (Juhas et al., 2025) or tomatoes with ‘robo flowers’ (Xie et al., 2025) are by no means the only ones that could be marketed as NGT-1 and therefore pose environmental risks. Changes in the composition of plant constituents (Kawall, 2021; Koller et al., 2024), premature first flowering (Ortega et al., 2023), increased fitness (Koller et al., 2024) and changes in the interactions between plants and microorganisms (Yan et al., 2022) are further examples of NGT-1 applications for which thorough risk assessment should be mandatory (see also Mundorf et al., 2025; Koller, 2025).

Therefore, NGT plants require a regulatory approach which does not include thresholds. Instead, there should be a case-specific comparison of NGT plants and conventionally-bred varieties based on their molecular characterisation, which takes intended and unintended changes into account. Future regulation must be scientifically justifiable and include case-by-case risk assessment, traceability and monitoring methods to secure the future of food production and protect biodiversity (see, for example, ANSES, 2024; Koller, 2025).

Adopting the present proposal would lead to fast-track releases of genetically engineered plants, including native wild plants, such as alpine cress, bellflowers, bristlegrass, camelina, false brome, foxtail, gentian, mustard, oilseed rape, pennycress, poplars, ryegrass, switchgrass, thale cress and wild strawberries (see above). In addition, accelerated (including experimental) releases would make the contamination of crop and vegetable seeds likely.

Included are NGT plants which:

- pose risks to the food chain and pollinators,
- have the potential to become invasive,
- weaken natural populations after outcrossing and
- can alter the composition of soil organisms with undesirable consequences.

The potential for harm to humans and the environment could accumulate over time and possibly increase dramatically if more and more NGT 1 plants were to be approved for cultivation and/or import into the EU without ever having undergone risk assessment. There would also be no assessment of (hybrid) offspring characteristics.

There is also cause for concern that the deregulation of NGT plants would soon be followed by the weakening of protection regulations for NGT animals and NGT microorganisms.

11. Global competition

The convergence of AI and genetic engineering is perceived to be of central geopolitical importance, particularly when it comes to competition between the United States and China. The US National Security Commission on Emerging Biotechnology (NSCEB, 2025) has addressed issues of technological supremacy, military options and threats stating that:

"We are entering the age of biotechnology, a time when biology is the basis of innovation. From more productive seeds and targeted cancer therapies to the possibility of genetically enhanced soldiers, biotechnology's reach extends far beyond the laboratory. Every strategic sector—including defense, healthcare, agriculture, energy, and manufacturing—can be advanced by biotechnology, but also breached by it, too. These are not just matters of scientific achievement; they are questions of national security, economic power, and global influence.

Falling further behind would signal a global power shift toward China and create an array of new strategic challenges for the U.S. government:

- *What would it mean for world order if China developed biological means for dramatically extending human life or enhancing cognitive capabilities?*
- *Who will control the biological intellectual property (IP), from sustainable energy to advanced agriculture, that may prove as vital in the 21st century as fossil fuels were in the 20th?*
- *What would the implications be for global security if an adversary engineered pathogens and used them against us?"*

The urgency is underscored in reasoning that is sometimes questionable and presented as if there were no alternative: *"Our window to act is closing. We need a two-track strategy: make America innovate faster, and slow China down."*

A National Academies of Sciences, Engineering, and Medicine (NASEM, 2025) report, commissioned by the NSCEB, takes a similar line: *"The recommendations aim to ensure that the United States remains at the forefront of biotechnology innovation while safeguarding against the risks associated with its misuse. The creation of the BioCATALYST network is central to this vision, offering a blueprint for a national strategy that enhances defense capabilities, secures supply chains, and positions the United States as a global leader in the responsible development of AI-enabled biotechnologies."*

China also sees itself in strategic competition with the US in the biotechnology sector. Experts working at various Chinese national research institutions compare the state of development in plant breeding in China with that in the US (Zhang et al., 2025). They also emphasise fundamental strategic issues in the economic rivalry with the US. In this context, the US is currently still seen as having an advantage in terms of patents and concrete applications. A national action plan could change this status quo: *"Based on an in-depth analysis of the current status and challenges of China's seed industry technology development, we propose strategic goals and key tasks for China's new generation of AI and big data-driven intelligent design breeding. These suggestions aim to accelerate the development of an intelligent-driven crop breeding engineering system that features large-scale gene mining, efficient gene manipulation, engineered variety design, and systematized biobreeding. This study provides a theoretical basis and practical guidance for the development of China's seed industry technology."*

The rivalry between the US and China is also having an impact on EU policy. In July 2025, the European Commission presented its Life Sciences Strategy, with which it aims to become a leading global location for biotechnology (European Commission, 2025). Currently, they see Europe as lagging far behind: *"The EU faces fierce competition at global level from other economies such as the US and China, with a growing innovation gap and an alarming failure to translate innovation into products or services. Innovative companies struggle to scale up* *in Europe. The gap in venture capital investments is also widening. These negative trends signal structural barriers affecting Europe's life science value chains. Fragmented R&I ecosystems, limited and often delayed valorisation of technology breakthroughs and underuse of data and artificial intelligence (AI) are limiting our potential."* Authorisation procedures, such as those currently in place for genetically modified organisms (GMOs), were identified as a further bottleneck in global competitivity: *"Long authorisation procedures under regulatory frameworks that require pre-market authorisation to ensure safety for human health and the environment can delay market entry of innovative products."*

The EU proposal to deregulate NGT plants also reflects global competition issues. It states: *"The Union's seed sector is the world's largest exporter of seeds, and the ability to use innovative technologies is a prerequisite for maintaining competitiveness on the global market."*[13] In order to facilitate trade with partners, such as the USA and South American countries, most individual organisms would in future no longer be risk assessed. Instead, the Commission proposes to create categories for large groups of organisms, which could then be assessed on a 'blanket' basis or released into the environment very quickly without risk assessment. Similar ideas can also be found in the NSCEB proposal (2025), which also takes the view that case-by-case assessments should be avoided in future by grouping 'similar' products into categories.

However, the NSCEB report fails to provide sufficiently factual arguments. One example: gene drives intended for use in mosquitoes are classified on the same level as other methods (without genetic engineering) to control mosquito populations. This ignores the fact that the risks associated with gene drives depend heavily on how they spread in natural populations (see above). Therefore, a comparison – or attempts to equate – gene drives with other methods used to decimate insect populations is not possible, as this would completely obscure the different risks involved.

Due to the geopolitical rivalries, there is a danger that the risks of releasing genetically engineered organisms will be accepted for strategic reasons in order to 'win the AI+GE competition'. Priority is given to power politics, technological sovereignty, competitiveness and profit – rather than to the organisms' actual benefits or the protection of the environment. It is to be feared that legislators will largely withdraw from their responsibility to protect people and the environment and leave this to the free market forces. Libertarien ideas appear to be prevailing in the EU - declaring supposed technological progress to be the measure of all things and rejecting any regulation, particularly in the field of AI and biotechnology. Testbiotech believes that the EU in particular must continue to fulfil its responsibility towards people and the environment, even and especially in competition with other geopolitical power blocs. Without adequate protection for people and the environment, the convergence of AI and genetic engineering carries the risk of a global catastrophe.

In 2025, the Nobel Prize in Economics was awarded to Philippe Aghion and Peter Howitt, who conduct research on technical innovation and 'creative destruction'. In the field of technical innovation, it is generally accepted that this also has disruptive effects on existing technologies and economic systems. With the convergence of AI and genetic engineering, the deregulation of new genetic engineering as well as geopolitical competition between power blocs amounts to a risk that could also be extended to the environment. This would have fatal consequences – especially for future generations. It should not be overlooked that in the field of genetic engineering, high priority must be given to protecting the foundations of life and native biodiversity. If 'creative destruction' (a term coined by the Austrian economist Schumpeter) takes hold of the planet's foundations of life, we will also destroy our own future.

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[13] https://eur-lex.europa.eu/legal-content/DE/TXT/HTML/?uri=CELEX:52023PC0411

12. Containing the risks

Suleyman and Bhaskar (2023) are urging that strong action be taken in efforts to contain and control the risks associated with the convergence of AI and genetic engineering and/or synthetic biology. This is the only way that potentially catastrophic effects can be prevented. Viable solutions are required on an international level, and therefore competition between nations must be avoided as far as possible. An editorial published in the science magazine Nature (2026) identifies global cooperation as a priority: *„AI is potentially a transformative technology. However, we don't know how that will manifest, or what impact it will have. Many countries are rightly being cautious and assessing risks, but more coherence is needed in policymaking. Nations should work together to design policies that not only enable development, but also incorporate guardrails. Let 2026 be the year everyone agrees on that.“*

Like many other experts, Suleyman and Bhaskar focus primarily on the risks to human health and safety (biosecurity). In their book, they present ten proposals for mitigating the impending global threat. Based on this, Testbiotech proposes ten measures for discussion which take particular account of the risks to the environment and biodiversity (biosafety):

1. Promote risk research

A great deal of money flows into the development of new applications and products created with genetic engineering and biotechnology. In contrast, there is hardly any money available for independent risk research. Scientists therefore lack the necessary incentives to engage in research into the prevention of risks. Consequently, there is a complete imbalance in research: the user perspective and the expectation of potential gains has the upper hand, while the perspective of the protection goals is underrepresented. In order to remedy this shortcoming, a fixed percentage of technology funding should be invested in risk research and technology assessment that is free from any interest in applications and commercialisation.

2. Agree on international control mechanisms

It must be mandatory to integrate programs into devices and instruments used in the synthesising process of DNA or RNA to enable the monitoring of the synthesis of material that is of a pathogenic nature or of other high-risk life forms.

3. Regulate access to particularly sensitive information and tools

Access to particularly high-risk technologies, tools and genetic information that could be susceptible to misuse must be regulated and subject to stringent requirements.

4. Build expertise in civil society

Make programs ('capacity building') widely available to the general public in order to promote an informed and critical approach to the technology. Non-governmental organisations should be enabled to carry out their own appropriately funded projects.

5. Reduce the influence of industry

The purpose of research incentives should be to promote benefits for the general public and decouple the development of the technology from private-sector interests. Research programs of this nature should be developed with the involvement of civil society.

6. Expand state capacities to protect people and the environment

Authorities and their employees must be equipped with the qualified personnel as well as the technical and scientific resources to evaluate and monitor current developments. They also need the skills to consistently represent the perspective of protecting people and the environment.

7. Strengthen international cooperation

Measures to curb the uncontrolled proliferation of high-risk applications should be subject to international treaties and part of transnational cooperation between authorities.

8. Strengthen the precautionary principle

The risks associated with the use of high-risk applications should be openly communicated. Safety issues must be an integral part of research projects. All uncertainties and other uncertainties regarding the control or assessment of risks should lead to the prioritisation of lower-risk alternatives, including the avoidance of irreversible processes. Cut-off criteria must be defined for projects with an excessive degree of uncertainty.

9. Reduce incentives for ethically problematic research

In order to avoid ethically problematic incentives, patents should not be granted on inventions which endanger the protection of human embryos or involve experiments on animals capable of suffering. There should be no commercial incentives for the release of genetically engineered organisms that are associated with a high degree of environmental risk. In order to curb the exploitation pressure associated with the term of patents, any 'patents on life' must be subject to particularly high ethical and legal hurdles.

10. Expand technology assessment

The convergence of (generative) AI and (new) genetic engineering may result in a considerable acceleration of current developments. It may also trigger a new wave of technology developments with multiple associated disruptions, instabilities and even catastrophes. Therefore, special attention must be paid to any systemic and long-term risks that go beyond those of individual products. As far as genetic engineering and the environment are concerned, the respective applications should be examined for their usefulness and necessity. The ability of society to predict the long-term consequences of new risk technologies must be improved.

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