Federal Agency for Nature Conservation

Genetic engineering, nature conservation and biological diversity

Boundaries of design

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Konstantinstr. 110
D-53179 Bonn

Tel.: +49 228 8491-0
E-mail: info@bfn.de
Internet: www.bfn.de

Tax ID Number: DE 122268582

With contributions from:

Kristin Hagen, Margret Engelhard, Mathias Otto, Samson Simon (Division I 2.6 Assessment of genetically modified organisms/Enforcement of Genetic Engineering Act)

Karl Stracke, Oliver Hendrischke, Philipp Blanke (Division I 2.1 Legal and Economic Issues in Nature Conservation)

Wiebke Züghart, Armin Benzler, Christina Hünig, Eva Willée (Divison II 1.3 Terrestrial Monitoring)

Further members of the "New genetic engineering and nature conservation" project group: Lars Berger (Division I 2.2 Nature Conservation, Society and Social Issues), Barbara Engels (Division I 2.3 International Nature Conservation), Karin Hornig (Division I 1.3 Import and Export of Animals and Plants and of Parts and Derivatives), Manfred Klein (Division I 2.4 Nature Conservation in Agriculture), Andreas Krüß (Nationwide Biodiversity Monitoring Centre), Annika Tiesmeyer (Division II 1.1 Wildlife Conservation), as well as Sandra Balzer (Directorate II 1 Ecology and Conservation of Fauna and Flora), Peter Finck (Division II 2.3 National Natural Heritage, Dynamic Systems and Climate Change), Christiane Schell (Directorate I 2 Fundamental Issues, Integrative Nature Conservation and Sustainable Use) und Axel Ssymank (Division II 2.2 Habitats Directive/Natura 2000).

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Summary

In the present paper, Germany's Federal Agency for Nature Conservation (Bundesamt für Naturschutz, BfN) presents its position on an international discussion surrounding research approaches to **the genetic modification of wild organisms.** These research approaches, which are being developed in part **for nature conservation purposes,** are new in that they propose

- **nature conservation as a purpose and justification** for the release and dissemination of genetically modified organisms (GMOs),
- the release and dissemination of GMOs **outside of agricultural areas** and
- the potential genetic engineering of **protected species**.

These approaches differ fundamentally from the agricultural uses of new genetic engineering technologies that are currently being widely discussed. This paper deals with scenarios for the use of genetic engineering in wild organisms and species conservation. **Nature conservation is thus particularly affected here.**

Due to the complexity of biological diversity – from the molecular to the ecosystem level – the **effects of genetically engineering wild organisms cannot be sufficiently assessed with the methods currently available**. This is already true at the level of genetic material (the genome). Although the intended changes can be incorporated with relative precision at molecular level using new methods of genetic engineering, there are often additional unintended molecular changes in the genome. Moreover, the genetic diversity of wild organisms is greater than in populations bred for uniformity and intended to be used in research and agriculture, and the different genotypes in wild organisms are often unknown. This compounds the problem of how difficult it is to predict the effects of the intended and unintended genetic changes on the complex metabolism of organisms, on their characteristics and on their interactions. The interactions of physiological and ecological mechanisms are also multifaceted and interlinked. This is also true for the affected natural and near-natural ecosystems. At the same time, predicting the impacts of genetic engineering interventions becomes even more uncertain with larger geographic areas and longer time spans (cf. section 2.2). The effects of genetic engineering on wild organisms can therefore not be predicted either in the short or long term, and it remains **difficult to assess whether the goals pursued with genetic modification can even be achieved.**

Due to the lack of predictability of environmental impacts and the complex causal interdependencies of GMOs in the wild, the possibility of meeting the requirements for environmental impact assessment and monitoring using the methods currently available is slim. However, these requirements must be satisfied under current German and European legislation for the authorisation of GMOs and are consistent with the precautionary principle (cf. section 3). **The fundamental and necessary discussions on the compatibility of genetically engineering wild organisms with the requirements and the objectives laid down in section 1 of the German Federal Nature Conservation Act must first be conducted. It is important to ensure that genetic authorisation procedures take these issues adequately into account.** The legislature has not yet evaluated the use of GMOs for nature conservation. In addition, new questions arise in the international context because genetically modified wild organisms can spread across borders, in some cases very quickly depending on the species and technology applied. **This could be reflected in international law at the level of the Convention on Biological Diversity (CBD) by expanding opportunities for participation and**

obligations to provide information prior to releases, but also effective protection measures to prevent impacts across borders (cf. section 8).

Global biodiversity loss is progressing with tangible consequences. We need suitable instruments to stop it. Nevertheless, wild organisms must not be genetically modified solely based on the assumption of a potential benefit to nature conservation and with uncertainty about possible harm. The urgency of combating biodiversity loss is no reason to abandon the precautionary principle (cf. section 4). On the contrary, the urgency of nature conservation issues justifies the implementation of effective measures to prevent the overuse and contamination of nature, and these measures may not be sidelined by technical solutions. In this respect, **social discourse is important on how synthetic biology, including new genetic engineering technologies, is understood in relation to nature** (cf. section 5).

Along with its diversity, beauty and utility, nature's uniqueness is a protected good in nature conservation that is firmly embedded in society and in legislation. Its intrinsic value imposes limits on the extent to which humans can intervene in nature to protect it. If permanent, far-reaching and inheritable genetic modifications of wild organisms, which go far beyond previous human interventions, become a reality and are accepted as legitimate instruments of nature conservation, the idea of *protecting* nature turns into the idea of *re-designing* nature. This would further limit the value of nature's unique character and, in the Federal Agency for Nature Conservation's view, would break with traditional understandings of nature, with higher-level protected goods, and with nature conservation objectives and practices (cf. sections 6 and 7).

1 Introduction

Most genetically modified organisms (GMOs) released to date worldwide are crops. They are grown on agricultural land, and their spread beyond this land is to be prevented as a precautionary measure. A new, additional paradigm is, however, attracting attention in research: **Increasingly, research is being conducted on GMOs that are intended to spread in nature outside agricultural production systems** (cf. e.g. Otto et al. 2020; Giese 2021). Another new aspect is that synthetic biology[1] is developing nature conservation applications for the new genetic engineering research, and bringing them to the attention of nature conservationists (cf. Redford et al. 2013b; Revive & Restore 2015; IUCN 2016, pp. 26-27). The approaches range from physiological modifications to make wild animal and plant species more resilient to stressors and diseases, through containing invasive species and reconstructing extinct species (cf. also section 2.1).

Some experts associated with the International Union for Conservation of Nature (IUCN)[2] were initially sceptical about the exchange with synthetic biology (Redford et al. 2013a), but have increasingly come out in favour of the new methods (Redford et al. 2014; Redford and Adams 2021). An IUCN report on synthetic biology and biodiversity conservation (Redford et al. 2019) was, however, highly controversial among the IUCN's members (cf. Düesberg 2020). The debate ultimately led to a Resolution[3] of the IUCN Members' Assembly. The resolution calls for the development of an IUCN Strategy on Synthetic Biology and Conservation by 2024, through a participatory process that attaches particular importance to members of civil society. **This is to involve both ecological aspects and potential socioeconomic and cultural impacts, as well as to analyse legal, conceptual and ethical issues.** The debate engaged in at the IUCN has hence shown that the controversies relate not only to the potential risks of using genetic engineering in nature conservation, but that it is also a question of assessing its potential benefit in the light of different ideas of engineering, nature and nature conservation.

The new genetic research approaches also brought up questions on the potential impact on nature, as well as conceptual issues, in the Ad Hoc Technical Expert Group on Synthetic Biology established under the Convention on Biological Diversity (CBD[4]; cf. CBD/AHTEG on Synthetic

[1] Research activity that is relevant to the topic largely originates from the synthetic biology community, and is at the same time technically genetic engineering. Genetic engineering is understood as the use of molecular biological techniques to modify DNA sequences in one or more genomes (Lanigan et al. 2020). The present paper hence largely equates synthetic biology with genetic engineering in terms of the technologies used, even though the terms are not synonymous. Genetic engineering methods form a central element of synthetic biology, which, however, also includes other methods such as protocell biology and xenobiology (which are less relevant in the present paper), and which frequently goes beyond traditional genetic engineering (cf. e.g. Sauter et al. 2015; Engelhard 2016). The operational definition of synthetic biology contained in the Convention on Biological Diversity (CBD) reads as follows: "[…] synthetic biology is a further development and new dimension of modern biotechnology that combines science, technology and engineering to facilitate and accelerate the understanding, design, redesign, manufacture and/or modification of genetic materials, living organisms and biological systems" (CBD/COP 2016, item 4; cf. also SCBD 2015, 2022).

[2] The IUCN is an international membership Union of civil society and government organisations of nature conservation and species protection, and is regarded as a worldwide authority in nature conservation; it also keeps the international Red List of Threatened Species.

[3] IUCN (2021): Towards development of an IUCN policy on synthetic biology in relation to nature conservation: www.iucncongress2020.org/motion/075

[4] The CBD is the most comprehensive worldwide agreement on the protection of nature and preservation of the natural resources which sustain human life.

Biology 2019). And just as within the IUCN, some stakeholders have also introduced the potential benefit ensuing from new genetic engineering methods for nature conservation into the international negotiations at CBD level as an argument for using genetic engineering in nature.

The present paper aims to supplement this fundamental debate by adding the German Federal Agency for Nature Conservation's outlook as a national nature conservation authority which is also involved in the GMO authorisation procedure. It furthermore seeks to illustrate the degree to which the genetic modification of wild organisms may be suitable and expedient for nature conservation. The sections below will start by briefly outlining key research agendas and analysing the potential to predict the impact of genetic modifications on wild organisms (section 2). Forecasting is one of the prerequisites for evaluating environmental risks (section 3). Section 4 will discuss the urgency of combating biodiversity loss as a potential justification for decreasing risk aversion with regard to the use of genetic engineering in nature conservation. This is followed by questions on technical feasibility as discussed in the public debate on nature conservation (section 5), on the compatibility of genetic modification with the protection of nature's unique and pristine character (section 6) and on the statutory foundations and values of nature conservation (section 7), as well as on the legal challenges posed by the genetic modification of wild organisms (section 8)[5].

2 Predictability of the impact of wild GMOs

Genetic modification of wild organisms outside closed systems can only be considered for the purposes of nature conservation if its impact can be predicted and verified, as it must be possible to specifically assess the feasibility, effectiveness and potential risks of the methods. There has, however, been little opportunity so far to effect a case-specific evaluation of specific interventions, since the research on nature conservation applications of GMOs is in the early conceptual or experimental phases (Otto et al. 2020; cf. also SCBD 2022, pp. 41-45). We will outline below several key aspects of application-orientated research (section 2.1) and basic constraints regarding the ability to predict the impact of genetic modifications in complex systems (section 2.2).

2.1 GMO research agendas in the context of biological diversity

One scenario for the use of the genetic modification of wild organisms in nature conservation is **genetically engineering endangered species to make them more resilient to stressors**. Research is for instance being carried out with the aim of making corals more resistant to warmer water, or giving amphibians better resistance to chytrid fungi (Redford et al. 2019, pp. 78 et seqq.; cf. also Rode et al. 2019). None of these examples has yet progressed beyond the experimental stage. By contrast, approval has already been applied for in the USA for a transgenic variant of the American chestnut (*Castanea dentata*) which is alleged to be more resistant to *Cryphonectria parasitica* fungus (Newhouse and Powell 2020). The associated risk assessment was, however, not able to take into account any periods corresponding to the long life-cycle of the trees, and was only able to consider the ecological interactions and

[5] The legal analysis in this paper takes German law as a starting point, while including the European and international legal framework.

evolutionary processes to a limited degree (Then 2020; Davis 2021). It is generally difficult to predict what the impact of a genetic modification might be in the long term, and whether it actually constitutes an improvement for the respective conservation objective. Even with relatively good experimental knowledge of all individual species, the competitive behaviour of species in an ecosystem cannot be deduced. What is more, only a small number of the range of species have been studied at all in most cases, or are sufficiently well known (cf. section 3).

Other research methods aim to **contain invasive species or pathogens using GMOs with a gene drive.** Synthetic gene drives involve genetic engineering tools (e.g. CRISPR/Cas) being incorporated as a part of the genetic modification. If organisms with synthetic gene drives are released, these genetic engineering tools are released too – one might say that the genetic engineering experiment is moved into the environment, a "lab in the field" (Simon et al. 2018). Gene drive organisms can interbreed with their wild relatives. The effect of the gene drive on inheritance is that the genetic modification (including the genetic engineering tools) is inherited by more than half, and up to all, of the offspring. Without the gene drive, according to Mendel's principles of inheritance, only half the offspring would inherit the modification. Gene drives are intended to enable the genetic modifications to persist more successfully in wild populations over time, and to also become prevalent under certain circumstances. The technique involved in synthetic gene drives thus theoretically permits GMOs to spread even where they possess characteristics which are disadvantageous for the organism and/or for its reproduction (for instance only bringing forth male offspring) and having the potential to cause a population to collapse or even become extinct.[6] This method is regarded for instance by the Genetic Biocontrol of Invasive Rodents consortium[7] as a potential contribution to combating rodents which people have introduced to other continents and which have become a threat to other species in their new ecosystem. Doubts have, however, been raised as to whether the method is feasible (Dolezel et al. 2019; Champer et al. 2021), and risk assessment of gene drives is highly problematic (cf. section 3).

Other research methods aiming to spread intended characteristics into nature make use of **genetically modified (GM) viruses**. These methods have been engineered for some time, such as when a transmissible GM virus was tested on rabbits in field trials as a vaccine.[8] Development of this technique was, however, not pursued intensively for a prolonged period, both because of virologists' view that the impact could not be controlled as the GM viruses lack stability, and because it is not clear how potential transboundary movements by the GMOs could be dealt with (CBD/COP 2007; Henderson and Murphy 2007). Transmissible GM viruses are, however, currently being engineered once more for a number of different purposes,[9] as the willingness to take risks has evidently increased (Lentzos et al. 2022). In order to introduce GM viruses to their target organisms, research is also underway on how to spread the viruses via insects so that they can transmit them to plants. The GM viruses in such applications are to contain molecular genetic engineering tools to be used in turn to drive genetic modifications in the plants. The aim of this is to allow genetic modifications to be implemented on the plants of an existing population, independently of reproduction ("horizontally"), and quickly.

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[6] Cf. originally Esvelt et al. 2014; taking a critical stance for instance CSS et al. 2019; Dolezel et al. 2019; specifically with regard to nature conservation e.g. Esvelt and Gemmell 2017; Redford et al. 2019; Rode et al. 2019.

[7] GBIRd website: www.geneticbiocontrol.org

[8] Wild rabbits on a Spanish island were vaccinated against myxomatosis and haemorrhagic rabbit disease using a GM virus (Torres et al. 2001).

[9] e.g. PREEMPT research project: www.preemptproject.org

This method, which is also referred to as Horizontal Environmental Genetic Alteration Agents (HEGAAs) (Reeves et al. 2018; cf. also Frieß et al. 2020), is being developed as a crop protection strategy – funded by the US Ministry of Defense's Defense Advanced Research Projects Agency (DARPA)[10]. This and other virus-based strategies are also being discussed in connection with environmental and nature conservation (Lentzos et al. 2022). Given the millions of insect species, and indeed the large numbers of species which have so far not been described, and the fact that the biology and characteristics of the life of only a small number of species is well known, the impact and interactions would be particularly unpredictable.

A research field which explicitly arises from synthetic biology **is the attempt to replicate an extinct species in individuals of a related species that is still in existence**. The biologist George Church proposes in his book entitled "Regenesis", which appeared back in 2012, to reconstruct woolly mammoths in elephants (Church and Regis 2012).[11] The proponents argue that reconstructing extinct species could symbolise an appreciation of biodiversity and enhance public awareness of biological variety. It is, however, evident that this method, which has also been referred to as "de-extinction" (Shapiro 2015, 2017), cannot be considered as protecting species, as it is not an existing species which is being protected (Sandler 2013), but organisms are created that would be merely similar to the extinct one. The IUCN Species Survival Commission (SSC) interprets the restoration of extinct species using reconstructed "proxies" as a kind of re-settling, as is carried out in the context of renaturation (IUCN SSC 2016; Svenning et al. 2016). It also remains contentious whether such "reconstructed" neoforms can actually be brought into being, and whether the potential suffering of the test animals as a result of the necessary reproduction techniques is justifiable. It is furthermore questionable whether neoforms would actually be suited to renaturation, whether it would be possible to estimate the ecological risks that their release might entail, as well as whether they could be regarded as making any fundamental contribution towards biodiversity (Minteer 2014; cf. e.g. Rubenstein and Rubenstein 2016; Adams 2017; Genovesi and Simberloff 2020).

2.2 The methodological boundaries of genetic modifications at the level of complex systems

As the examples from section 2.1 show, research is underway on modifications in the genome of wild organisms, and nature conservationists are being approached to use these methods in order to protect species. The justification is that genetic engineering methods could make a major contribution here, whilst at the same time criticism is expressed that this has (so far) been prevented by an "ethos of restraint" (Brister et al. 2021). In the following section, we will explain why restraint continues to be advisable.

Individual sections of DNA (i.e. of the genome) can be modified, and with increasing precision. At the same time, unintended insertions of genetic material may also occur into other areas of the genome. This is not surprising if one considers that the evolution of living beings is based not only on point mutations, but also on the duplication of whole genes. This means that identical or similar sequences are likely to occur in the entire genome (Ohno 1970).

[10] Insect Allies research project: www.darpa.mil/program/insect-allies

[11] The idea is being pursued as part of the *Pleistocene Park* project (https://reviverestore.org/projects/woolly-mammoth), and by a company named *Colossal* (https://colossal.com/mammoth)

Parts of genomes which are naturally better protected against mutations, or which previous genetic engineering methods were unable to modify, are now more accessible if new methods are used (Kawall 2021). The range of species to which the genetic engineering methods can be applied has also grown massively as a result of technical development, so that genetic modifications can now be carried out in almost all taxonomic groups. The technology for this has been developed in the past few decades by bringing molecular biology together with bioinformatics: Genetic engineering methods can now be applied more quickly, cheaply, precisely and broadly. Digitalisation and automation make it possible to decrypt genetic material quickly, whilst at the same time offering major capacities for storing and efficiently processing the information that is obtained in this way. The large volumes of data make it possible to make plans to modify, edit or even create new genomes; standardised genome components and genetic engineering procedures make their implementation easier, ultimately facilitating highly complex DNA modifications.

Despite an increased level of precision for modifications at the level of individual DNA sections, it is, however, often not possible to predict the impact of these modifications more precisely or more reliably at the level of the entire genome, the organism and the environment. Even at genome level, genetic modifications can lead to additional, unintended molecular modifications (known as “off-target effects”); this is also valid for novel genetic engineering methods such as CRISPR/Cas (Agapito-Tenfen et al. 2018; BfN 2021; Eckerstorfer et al. 2021). Unintended modifications can be analysed in the laboratory, but not where genetic modifications take place outside laboratories, as would be the case with synthetic gene drives. Added to this is the impact of multiple regulatory mechanisms at genome level which modulate the effects of the genes and whose influence on the metabolism can vary as a result of the genetic modification. Then there is the fact that the genetic diversity of wild organisms is greater than in populations which were bred for uniformity and intended to be used in research and agriculture, and that the various genotypes in the wild organisms are often unknown. There are further physiological interactions and environmental influences to be considered at higher biological organisational levels (cell, tissue, organism, population, community of species): Large numbers of different interactions between the biota and the environment take place in natural and near-natural ecosystems – frequently with no geographical or time limits. It is precisely this vast diversity, networking and ability to react to environmental changes that form the basis for both the resilience and the dynamic adaptability of nature. Early statements on the question of releasing GMOs already referred to the **fundamental constraints on possible predictions as to the ecological impact arising from complexity** (Tiedje et al. 1989; Snow et al. 2005); **these statements are no less valid today.**

When the use of technology is envisioned in increasingly complex systems, the effects of missing data and insufficient knowledge about possible impacts are magnified (Gleich 2013). This makes it virtually impossible to reliably model and predict the impact. This also applies to undesired consequences (cf. section 3). Releasing functional elements of a genetic modification (for instance via gene drives) would exacerbate this effect further. Where biologically sound models of gene drives have been established, the results have been the opposite of what was expected in some cases (cf. e.g. Champer et al. 2021). It therefore remains unclear as to whether, and if so in what period, the anticipated phenotypic and/or ecosystem impacts would be attained by the modifications being carried out on the DNA, and whether any additional, perhaps undesired, phenotypic and/or ecosystem impacts might be the result. The increasing precision that is achievable when modifying individual sections of DNA cannot even be translated under laboratory conditions and in agro-ecosystems into precise modifications of an organism's characteristics, or indeed into reliable prognoses of the consequences in nature. **Any reference to novel genetic engineering processes as "precise" is misleading in this regard** (cf. also Shah et al. 2021).

The genetic modification of wild organisms in complex ecosystems goes far beyond current interventions. The knowledge that is needed in order to assess the effectiveness and risks can no longer be generated *at all* on a timescale relevant for action. The experiments that need to be carried out would go beyond the scientific framework of trial and error (Weizsäcker 1996). The practical implementation of the genetic modifications to wild organisms proposed for nature conservation would hence be a case of acting in the absence of knowledge, and an exploratory experiment in which the environment, nature and society would become playing fields for uncontrolled experimentation (Frieß et al. 2020). **Given the complexity of the ecosystems in question, it cannot be predicted what the impact of genetic interventions in wild organisms would be.**

3 Risk assessment, monitoring and risk management of wild GMOs

Given that the ecological impact of wild GMOs cannot be forecast to any satisfactory degree, the risk assessment of GMOs as prescribed by law is limited in its applicability for wild GMOs. The release of GMOs into the environment is regulated in Germany by the Genetic Engineering Act (cf. section 8.1), which is based on the stipulations of European law, rendering mandatory an **assessment of the risks for humans and for the environment**. Such an assessment must be carried out specifically for each GMO. Amongst other things, the gene constructs being used, and the characteristics of the GMO, need to be assessed, taking the specific environmental conditions into consideration. The environmental risk assessment and monitoring are tools implementing the precautionary principle, and are intended to prevent and avert damage to nature and to the environment. The European Deliberate Release Directive explicitly stipulates that long-term, cumulative effects must also be estimated and included in the monitoring.

Therefore, GMOs are analysed in a step-by-step approach (laboratory/greenhouse – experimental releases in the open field – market approval). Data are collected for the risk assessment at each phase leading up to market approval. Experimental release is to be restricted over both time and area, and is accompanied by monitoring of the potential environmental impact. Release after market approval is initially restricted to ten years in Europe. Each authorisation for a release furthermore involves mandatory monitoring. Monitoring after market approval is intended to serve as an early warning system to identify unexpected negative impacts of release and to be able to counteract if necessary. The information from monitoring reports is also intended to identify previously unknown risks and include them in the risk assessment. In practice, however, the kind of monitoring currently being carried out is not far-reaching enough to record ecological impacts.

The **methods, assessment areas and evaluation strategies of environmental risk assessment and monitoring are currently focused on crops.** Many of the data generated by these means come from small-scale agricultural release trials. Were wild organisms to be genetically modified and released, these geographical and ecological dimensions would undergo profound changes. Most natural and near-natural ecosystems have greater biodiversity than agricultural landscapes, so that the interactions are more complex in the majority of cases.

What is more, the interrelationship in terms of time and place between release into nature and into the environment, and the anticipated effects of modifying wild organisms, are more complex and take place on a larger scale. Since the environmental risk assessment and the monitoring need to include the specific environments ("receiving environment"), the large number of new habitats and ecosystems which are relevant to the risk assessment constitute a new challenge. For instance, an assessment would require much greater volumes of data on species, genetic diversity, species composition and functional interrelationships in the ecosystem. At the same time, large quantities of such data can only be collected by expending considerable financial resources and large amounts of time, and are contingent on intensive long-term research, including the development of applicable methods.

In technical terms, an environmental risk assessment can only be carried out if a suitable range of methods has been validated and identified; this is not the case today for wild species of GMO. Existing assessment strategies and criteria would hence need to be fundamentally revised, or new ones established, before any release could take place (Otto et al. 2020). Even implementing an experimental release – which is an important step towards assessing the potential environmental repercussions of GMOs – is much more difficult with wild GMOs than with crops. This is directly linked to risk management, which with crops generally assumes that they cannot become permanently established in the environment without human assistance, so that the organisms can be "retrieved". But it has been shown that even where GM crops such as rapeseed are released, GMOs remain in the environment for an indefinite period, even if they are released subject to strict conditions. Experience with managing invasive species and with imported non-indigenous species for biological pest control shows that they cannot be expected to be retrievable, and that this way of managing invasive species involves risks. Initial experiences with releasing GMOs into wild populations confirm this through individual examples: It was found in the case of mosquitos of the *Aedes aegypti* species that genetic modifications have become established in local populations, contrary to the expectations and goals of the project (Evans et al. 2019). It is hence questionable whether a geographical and time limit on trial releases with genetically modified wild organisms is actually feasible. This would be tantamount to equating experimental release with unrestricted release, particularly when it comes to gene drive applications.

Gene drive applications, and the risks that their release involves, are the subject of intensive discussion on the international stage (NASEM 2016; CSS et al. 2019; Dolezel et al. 2019; EFSA GMO Panel 2020; Gleich and Schröder 2020). The European Parliament (EP) initially called for a moratorium on gene drives at CBD level (European Parliament 2020, item 13), and repeatedly confirmed that it should not be permissible to release genetically modified gene drives, even for nature conservation purposes (European Parliament 2021a, item 148; European Parliament 2021b, item 32). It cannot currently be estimated for concrete application scenarios of gene drives how long it would take until the gene drive would spread throughout the entire population. This makes it unclear for gene drives intended to eradicate a population how long they would remain in the population were they to be released. The longer a gene drive remains in nature, the more likely it, however, also becomes that unintended events and evolutionary changes will take place. There are theoretical considerations as to how a gene drive could be removed from a population, but it is completely unclear whether this would be realistic. It is therefore not currently possible to estimate the scale of the ultimate environmental risk that would be run were gene drives to be used in any specific manner. A concrete risk going by the example of invasive rodents on islands (cf. section 2.1) would exist beyond the local ecosystems if the gene drive were to extend beyond them, spread into the rodents' original natural habitat, and also decimate it there (cf. Dolezel et al. 2019; and models of the impact see also Champer et al. 2021).

To sum up, **recognised methods and strategies for risk assessment and monitoring of environmental impacts of genetically modified wild organisms are missing, as the latter differ widely from the classical GMOs (crops). It would be difficult to collect the requisite data. Trial releases can also not be carried out safely, as retrievability cannot be expected.**

4 Balancing problems and willingness to take risks

New application scenarios within genetic engineering are put forward for nature conservation based on the argument that they are indispensable given the major, urgent challenges arising when it comes to the protection of species (e.g. Piaggio et al. 2017; Phelan et al. 2021). Even the potential damage that might be caused by leaving efficient new technologies unused as a precaution should – as a common argument has it – be considered, and weighed up against risk avoidance and other reservations. In one of the calls to restrict the precautionary principle or to apply it less stringently it has been claimed that there is a need to replace an "ethos of restraint" with an "ethos of responsible conservation action" (Brister et al. 2021).

There is no doubt that nature conservation faces massive challenges, and that these are exacerbated by climate change; large sections of the population are also aware of this (for Germany: BMU and BfN 2020, 2021). That being said, neither the novelty of the approach, nor the urgent nature of the problem allow us to deduce the suitability, efficiency and, above all, the lack of alternatives to such a new technology-centred approach. The use of other technologies has repeatedly demonstrated that it is not easy to apply technical solutions in the complex system that is nature, and that such solutions may have unexpected detrimental effects (European Environment Agency 2001, 2013). The genetic engineering solutions which are currently being put forward for nature conservation are unsuited given the lack of predictability of their impact according to the current state of knowledge and in time periods relevant for action (cf. sections 2 and 3), and in addition they give rise to both ethical (cf. section 6) and legal (cf. sections 7 and 8) questions. With a view to major risks and unclear presumed benefits, this makes the application of the precautionary principle very much justified.

An evaluation of a potential solution must furthermore examine the primacy of tackling the causes: whether the approach addresses the underlying problems, or only addresses the consequences without solving the problem. The research methods applied in genetic engineering tend to tackle symptoms at the level of individual species, whilst addressing the causes has an impact at ecosystem level, thus generally creating a benefit for several species or communities of species. A dynamic that puts off tackling the causes whilst hoping for technical solutions is always problematic for nature conservation and climate change mitigation (cf. McLaren and Markusson 2020). **The urgent nature of many nature conservation problems does not justify a greater willingness to take risks, but calls for action to be taken with means that are appropriate and expedient in the long term, thus focusing on the causal level.**

5 Questions related to technical feasibility in the public debate on nature conservation

The debate on the use of genetic engineering in nature conservation has so far mostly been held within the scientific community. The controversies in the International Union for the Conservation of Nature IUCN (cf. section 1) have shifted the topic further into the political limelight, and the issue has been taken up several times at BfN events (Schell et al. 2019; Potthast et al. 2022). Little is known among the broader public at the moment about research agendas on wild GMOs (Kohl et al. 2019). A survey that was carried out as part of a nature awareness study, however, revealed that more than 80% of respondents in Germany had reservations when it came to deliberate genetic modifications of plants and animals in nature (BMU and BfN 2020, 61 et seqq.). Roughly three-quarters of the young people surveyed in the youth nature awareness study were against genetic engineering "messing around with nature" (BMU and BfN 2021, 66 et seqq.).

The application scenarios in wild organisms that have been put forward conflict with fundamental values of nature conservation, such as the intrinsic value (cf. also sections 6 and 7) of natural processes, and the integrity of organisms. Moreover, a practice of higher-risk release of GMOs would place supraordinate goals and principles of nature conservation in question (including the precautionary principle) (Sandler 2019). The idea that genetic engineering is safe and controllable enough to be used in nature conservation can also pave the way for other applications of genetic engineering, such as a further expansion of industrialised agriculture. Indirectly, an instrumentally narrow understanding of nature may be promoted, which itself is frequently presumed to be one of the causes of the destruction of nature and of the environment (cf. Meyer-Abich 1997), by regarding organisms and ecosystems as production systems, genes as programming, and humans as designers of nature. There is a need to engage in a fundamental debate within society, and for a process of awareness-raising.

The foundation of nature conservation in society can only be shaped in ongoing discourse. A wide range of stakeholders are playing a role in shaping nature conservation as a civil society, scientific and political process. Furthermore, the different understandings of nature (conservation) must also be seen as directly linked to social justice (cf. BfN 2013; regarding the IUCN processes cf. also Comité français de l'UICN 2021). Issues regarding concepts of nature and technology in synthetic biology, including novel genetic engineering, should therefore be the subject of a broad societal debate: What images of nature are associated with the perceived need to protect nature? To what extent can humans perceive the consequences of their interventions in nature, let alone control and – if necessary – reverse them? Can and should nature be "improved" by human intervention? What does it mean to society to be able to rely on what is perceived as nature not being (in its entirety or largely) the result of human design, so to speak a constructed, open-air museum of nature? What right do future generations have to a natural world that has emerged from its own dynamic process?

6 Compatibility with the value of nature's uniqueness and dynamic processes

The debate on genetic engineering, synthetic biology and nature conservation involves assessing potential *consequences*, as well as addressing the question of whether the genetic modification of wild organisms is compatible with the *strategies and values* of nature conservation. In this context, it is important to recognise that in the course of natural evolution, various mechanisms have emerged that promote the resilience of ecosystems. Along with prudential arguments of protecting nature's intrinsic dynamic processes in humanity's own interest, biodiversity is understood to be a result of natural evolution, and at the same time as a value in its own right. This emerges from organisms' intrinsic value, in their networks with the ecological systems (Potthast 1999). This intrinsic value is stressed both in recital 1 of the Preamble of the CBD, and in the German Federal Nature Conservation Act (cf. section 7).

A contrasting argument that is put forward in defence of the far-reaching design of ecosystems and wild organisms is that there no longer is any pristine nature in the age of the "Anthropocene"[12], and an untouched state of nature is no longer possible (cf. e.g. Preston 2018). The conclusion is hence that attempts should no longer be made to preserve pristine nature and allow it to change on its own, but that nature should be actively designed.[13] However, this argument is not convincing. An extensive loss of pristine nature does not mean that the best strategy for nature conservation is to become an *agent* of even more profound interventions in nature ("*Anthropozän-Fehlschluss*"; cf. Sandler 2017; Toepfer 2020; Potthast et al. 2022). What is more, the very premise is incorrect that because there is no *completely* pristine nature, this means that there is no longer any pristine nature worthy of protection.

Pristine nature and wilderness have been understood in nature conservation for a long time as concepts that are subject to considerable cultural influence (cf. BMU and BfN 2014, 22 et seqq.). Many ecosystems can rightly be referred to as nature-culture hybrids, and some ideas of nature categorically reject any strict division or demarcation between humans and nature. Be that as it may, however, a purely binary distinction between natural and unnatural/artificial is inaccurate in both conceptual and empirical terms, given that different degrees of naturalness occur in most cases (Potthast 2019; cf. also hemeroby concepts in ecology). The protection of (largely) unused, non-fragmented areas that are used to make sure that natural processes can take place with a minimum of human influence is therefore very much practicable (cf. Finck et al. 2013), and also does not conflict with the conservation of less pristine nature, for instance in cultivated landscapes and urban natural settings.

[12] The concept of an age of the Anthropocene, a term originally proposed for a new geochronological epoch, alludes to the comprehensive, global consequences of human activity, such as climate change, light pollution and marine pollution, and fragmentation of the landscape. The concept is controversial , in part because it does not differentiate between ecosystems that are affected to different degrees, nor between the impacts of different economic systems (cf. Manemann 2014).

[13] To some extent, this promotes a new understanding of nature conservation, in which synthetic biodiversity supplements natural biodiversity (cf. e.g. https://reviverestore.org/what-we-do/). Visions of feasibility and a belief in the human capacity for design and judgement go so far that synthetic biologists strive to improve nature (e.g. Church and Regis 2012; Doudna and Sternberg 2017; cf. also Then 2020, p. 8).

The more pristine a protected good is, the more carefully nature conservation intervenes to preserve it. Activities to design near-natural ecosystems (e.g. via extensive use or active management activities) are generally used with more restraint than is the case in cultivated landscapes, and they are frequently avoided altogether in natural ecosystems; latitude is left here for the protection of natural processes and for natural evolution. In contrast to design measures that help to achieve a favourable conservation status, the wilderness objective is embedded in the German National Strategy on Biological Diversity. The wilderness objective seeks to ensure the natural occurrence of species, and re-settlements or planting are subject to strict conditions (BMU 2007; cf. Niebrügge and Wilczek 2011; Finck et al. 2013). Added to this is the challenge that protected areas operate as places in which networks of relationships are subject to constant dynamic adaptation.

Concepts such as untouched nature and wilderness can therefore be understood in the sense that, by stepping back from pre-defined purposes and objectives, space is left for *components* of natural dynamic processes, spontaneity or natural environments in their pristine and evolving state. Ecosystems that are (relatively) untouched by humans provide considerable scope for such natural processes, so that nature's unique character can often endure and evolve.

The genetic modification of wild organisms may at first glance follow on from tried-and-tested means of intervention in the interest of nature conservation. This point of view, however, ignores the fact that measures intervene in nature in different ways and to differing degrees. These graduations of the degree of intervention are central for the evaluation of the appropriateness of an instrument. A targeted modification at the level of the DNA of wild organisms is a much more encroaching and more profound intervention than for instance releasing a species into a new habitat (something which, in nature conservation circles, is regarded as a major intervention in itself). The natural mechanisms of evolution are overridden when functional elements of genetic engineering are inherited (e.g. via gene drives). **Where humans exert too great an influence through their interventions, no latitude is left for nature's unique character.** Many people also perceive an intrinsic *value* in nature that is independent of its utility. The different ethical justifications for nature conservation –nature's intrinsic value as well as instrumental value – form the foundation for different but frequently complementary understandings of nature conservation and protection strategies (Eser and Potthast 1999). **The value of nature's unique character, of natural environments in their pristine and evolving state and of the independent future dynamic development of natural processes impose boundaries on the degree to which humans can design nature.**

7 Compatibility with the goals and fundamental values set out in the German Federal Nature Conservation Act (*Bundesnaturschutzgesetz*)[14]

Section 1 of the Federal Nature Conservation Act contains a legal definition of "nature conservation" which also draws from the many-dimensioned ethical rationale of nature conservation. Section 1 subsection (1) of this Act plays a standard-setting role for the focus of nature conservation and landscape management in Germany (Frenz and Müggenborg 2021, section 1 para. 8). The provision aids interpretation when enforcing the stipulations contained in this Act (Schlacke 2017, section 1 para. 2), and defines the purpose of nature conservation (to protect nature and the landscape), identifies its grounds for protection (the intrinsic value attaching to nature and the landscape, as well as its importance as a basic necessity for human life and health), lists the actions that are permissible in the interest of nature conservation (protection, management, development and restoration), and defines three conservation objectives to be safeguarded in equal measure: biological diversity, the performance and functioning of the natural balance, as well as the diversity, unique character and beauty of nature and the landscape. **It is doubtful for a variety of reasons that using genetic engineering on wild animals and plants is compatible with the statutory understanding of nature conservation as defined in section 1 subsection (1) of the Act.**

Doubts may arise, first of all, as to whether such deployment would serve to protect "nature" within the meaning of the Federal Nature Conservation Act. This precise entity to be protected would in fact undergo substantive modification. "Nature" within the meaning of the Act refers to the living and non-living world not created by humans, and the creatures living in it with the exception of humans (Schumacher and Fischer-Hüftle 2021, section 1 para. 7). This understanding of nature does not presuppose a complete detachment from civilisation, but emphasises that the animals or plants to be protected are in essence characterised by their untouched nature and the absence of human control. (Frenz and Müggenborg 2021, section 1 para. 13). Genetically modifying wild animals or plants would, however, entail humans changing and impacting this very essence, that is the genetic make-up that emerged through natural evolution.

It must also be taken into account that nature is to be protected both on grounds of its intrinsic value, and by virtue of it forming a foundation for human life and health (section 1 subsection (1), first sentence, of the Federal Nature Conservation Act). **Reservations also arise with regard to the ground for protection consisting in the intrinsic value of nature when it comes to modifying wild animals and plants.** The intrinsic value of nature definitely demands respect for nature, regardless of any potential benefit to humankind, as well as keeping open the options for future generations when it comes to how they deal with nature (Frenz and Müggenborg 2021, section 1 para. 25). **Genetic interventions targeting wild animals and plants, however, lead to nature being permanently designed in accordance with human purposes subject to a given zeitgeist.**

What is more, the deployment of genetic engineering exceeds the applicable understanding of what action may be taken in nature conservation (protection, management, development and restoration). True, development and restoration of nature and landscape as a matter of

[14] The legal analysis in this chapter refers to German law.

principle permit a dynamic understanding of nature conservation, and are by no means corralled into purely conservatory protection. But intervention should stop short of attempting to radically re-design and re-shape nature (Meßerschmidt 2022, section 1 para. 42). The development of nature does not aim to technically or artificially re-shape natural states, but primarily to expand the stock of such states – for instance via renaturation (Meßerschmidt 2022, section 1 para. 40). Genetically modifying wild animals and plants, however, has the potential to trigger a profound re-design and re-shaping of nature, to be achieved with technical means, that is both permanent and irreversible. Restoration as subsidiary vis-à-vis the other types of action should also be narrowly defined. It is not to be regarded as being at the same level as the other types of action, and makes it possible to restore a previous state that is, however, no longer extant because of circumstances that have arisen (cf. Bundestag printed paper [BT-Drs.] 14/6378 2001, p. 34). Whether this state can and indeed should be restored in order to achieve nature conservation objectives should not be determined in general abstract terms, but by examining all the circumstances of the individual case (Schlacke 2017, section 1 para. 9).

All in all, it appears to be highly questionable whether the deployment of genetic engineering in nature conservation is compatible with the conservation objectives under the Federal Nature Conservation Act. All three conservation objectives can be compromised in equal measure by genetically modifying animals and plants. The objective of conserving biological diversity is to preserve the totality of species of animals and plants in their natural geographical diversity, with diversity of species of animals and plants being understood as including diversity within species, and diversity of types of communities (section 7 subsection (1) number 1 of the Act), including naturally occurring genetic diversity (Meßerschmidt 2022, section 1 para. 46). This diversity is to be safeguarded under conditions of natural selection in such a way that evolution can advance with as few obstacles as possible (Blab et al. 1995, p. 13). The genetic modification of wild animals and plants would, by contrast, aim to modify naturally occurring genetic diversity. **If functional elements of genetic engineering are transmitted to the next generation (for instance with gene drives), such genetic intervention overrides the unconfined progress of evolution.**

The performance and functioning of the natural balance relates to the natural components of soil, water, air, climate, fauna and flora (section 7 subsection (1) number 2 of the Federal Nature Conservation Act), and aims to protect the structures, functions and outputs of ecosystems typically characterised by close interaction and interdependence (Bundestag printed paper 14/6378 2001, p. 34). **The complexity of natural ecosystems makes it impossible to predict the long-term impact of genetically modified wild animals or plants on the performance and functioning of the natural balance according to the current state of scientific knowledge over periods of time relevant for action, and it is questionable whether this will be possible at any time in the future (cf. section 2.2).**

The protection of the nature's unique character is intended to also protect "individual creations" of animal and plant species (Schumacher and Fischer-Hüftle 2021, section 1 para. 58), and facilitate the value-neutral protection of characteristic features of animals and plants (such as their colourings or calls, or the behaviour of a bird) (Frenz and Müggenborg 2021, section 1 para. 46). **The objective pursued in genetic modification is, however, not the value-neutral protection of natural characteristic features, but rather changes based on human values.**

What is more, it should be borne in mind that equal priority attaches to the nature conservation objectives defined in section 1 of the Federal Nature Conservation Act, that they may not be regarded in isolation from one another, and that goal conflicts arising within nature conservation need to be weighed up against one another in such a way that they each take on equal significance (section 2 subsection (3) of the Federal Nature Conservation Act). In light of this, it is particularly problematic that it is not currently possible accurately predict the risk potential threatening the goal of protecting the performance and functioning of the natural balance.

To sum up, there are fundamental reservations regarding the compatibility of the use of genetic engineering on wild animals and plants with the statutory understanding of nature conservation defined in section 1 subsection (1) of the German Federal Nature Conservation Act. The reason is that genetically engineering wild animals and plants may compromise the legally defined conservation objective, what action may be taken and the ground for protection and protection objectives established in nature conservation.

8 Legal and regulatory challenges concerned with using genetic engineering in nature conservation[15]

It should be stressed first and foremost that neither national nor European law on genetic engineering was originally enacted with the aim in mind of regulating the deployment of genetic engineering *in nature conservation*. The law on genetic engineering has primarily been used to regulate the use of GMOs in agricultural plant and animal breeding in order to take advantage of the potential economic benefits offered by nature (Erbgut and Schlacke 2014, section 14 para. 1). The Deliberate Release Directive, for instance, was therefore not founded on the EU's environmental competence, but solely with an eye to the economic harmonisation of the Internal Market.

The legislature has yet to explicitly address the question of whether the use of genetic engineering in nature conservation is desirable from a legal standpoint, and whether it is suited to the objectives of nature conservation. The use of GMOs in nature conservation, as envisaged in the new research paradigms, has not yet been evaluated by the legislature. If a request is filed to release genetically modified animals, plants or microorganisms for use in nature conservation, the competent authorisation authorities would therefore have to decide on these fundamental questions for the first time and on the basis of legal criteria alone. This is because the preconditions in Germany for releasing GMOs not related to food and feed are based on the general stipulations of the national Genetic Engineering Act (*Gentechnikgesetz* – GenTG), regardless of the intended use of the genetic modification, which is aligned with European law as a result of the stipulations set out in the Deliberate Release Directive.

8.1 Authorisation procedure under the law on genetic engineering

In accordance with the Genetic Engineering Act, GMOs may be released in Germany if, based on the current state of scientific knowledge – relative to the purpose of the release – no unjustifiable impacts are expected on the legal interests designated in section 1 of the Genetic

[15] The legal analysis in this chapter takes German law as a starting point, while including the European and international legal framework.

Engineering Act (inter alia the environment in the complexity of its interactions, as well as animals and plants) (sections 14 subsection (1) and 16 subsection (1) of the Genetic Engineering Act).

The current state of scientific knowledge suggests that, where wild animals and plants are released into complex ecosystems, the challenge exists that it is not possible to adequately assess, due to the lack of predictability, whether or not the planned release may be anticipated to have unjustifiable impacts on the environment. It must, however, be evaluated in detail in the environmental impact assessment required under the law on genetic engineering representing the state of scientific knowledge, as stipulated in section 6 subsection (1) of the Genetic Engineering Act, what impact the planned release can be anticipated to have on the environment, including the cumulative long-term impact on animals and plants (section 5 subsection (1), first sentence, number 4 of the Rules of Procedure for Genetic Engineering – *Gentechnik-Verfahrensverordnung* – GenTVfV). Questions arise as to what this means for a request that involves the release of wild animals and plants. Even if a specific ad hoc decision is required in each case, where the scientific basis for evaluation is unclear, release may certainly not be authorised on grounds of any particularly important purpose, such as nature conservation. **For one thing, avoiding major negative environmental impacts always takes priority over the purpose of the release** (cf. Art. 4(1) of the Deliberate Release Directive). For another, there may be doubts as to whether the deployment of genetic engineering can at all be qualified as a purpose promoting nature conservation, given the understanding of nature conservation within the meaning of section 1 of the Federal Nature Conservation Act (cf. sections 4 to 6).

What is more, the precautionary principle needs to be adhered to in this regard, in line with which protective measures already need to be taken, where there is scientifically justified uncertainty, not based on mere presumptions, as to the existence or extent of significant risks, before the actual existence and seriousness of the potential risks have been proven (CFI T-13/99, para. 139). In accordance with the case-law of the European Court of Justice (CJEU), a particularly stringent precautionary standard needs to be applied in the law on genetic engineering in accordance with which it is always necessary to presume uncertainty and danger until scientific clarification has been carried out where the state of scientific knowledge is uncertain, and where this might lead to a resulting potential danger to the environment (CJEU C-528/16, para. 47 et seqq.). **As long as the uncertain state of scientific knowledge makes it impossible to reliably predict the impact of genetically modified wild animals and plants on the environment, any request for authorisation in this regard cannot be expected to be approved.**

8.2 Nature conservation law

Expanding the scope of genetic engineering to nature conservation would raise new challenges in nature conservation law – for instance as to how the stipulations of national site conservation law with regard to wild genetically modified animals can be adhered to. The Federal Nature Conservation Act so far only stipulates an assessment of the impact of the release of GMOs for European Natura 2000 sites.

8.2.1 European site conservation

In the event of GMOs being released in or close to Natura 2000 sites, the law on genetic engineering requires that the environmental impact assessment be supplemented to include an assessment under the Habitats Directive (section 34 subsection (1) in conjunction with section 35 of the Federal Nature Conservation Act). **Given that it is not currently possible to predict the impact genetically modified wild animals and plants have on complex ecosystems, there are doubts as to how significant adverse effects on Natura 2000 sites or their conservation objectives can be ruled out.** The assessment under the Habitats Directive sets out to analyse whether releasing GMOs is likely, individually or in combination with other projects or plans, to have the potential to affect a Natura 2000 site or its conservation objectives significantly. The expanded precautionary principle under the case-law of the CJEU needs to be taken into account in this context, in accordance with which the permissibility of a project submitted for authorisation must rule out any reasonable doubt of **adverse effects on the conservation objectives of the** protected site under the Habitats Directive (CJEU C-127/02, paras. 58 and 59). **A request for authorisation to release GMOs cannot therefore be approvable where justifiable doubts exist that releasing GMOs could have adverse effects on the conservation objectives of a conservation site under the Habitats Directive (section 34 subsection (2) of the Federal Nature Conservation Act).** The authorisation procedure under the law on genetic engineering does not provide for a possibility to carry out a derogation procedure under site conservation law in accordance with section 34 subsections (3)-(5) of the Federal Nature Conservation Act.

8.2.2 National site conservation

The genetic modification of wild animals and plants is prohibited within national conservation sites whose declaration as a conservation site stipulates that they be kept free of GMOs. This is because conservation sites may also be created under national site conservation law to keep free and protect spaces for natural processes to take place with a minimum of disturbance (for instance nature conservation areas and national parks, cf. sections 23 and 24 of the Federal Nature Conservation Act), in whose declarations as a conservation site it is possible to explicitly stipulate that they be kept free of all and any GMOs in order to protect their natural dynamic processes (Winter 2007, p. 636; Schlacke 2017, section 23 para. 42). **In the same manner, however, it would also have to be guaranteed prior to authorising genetically modified wild animals or plants that they cannot enter such conservation sites.** Section 23 subsection (2) of the Federal Nature Conservation Act prohibits not only actions inside the site which may destroy, damage, change or cause disturbance to the site, but also those outside which may have an impact on the site as long as they affect the site and its elements directly or indirectly (Schlacke 2017, section 23 para. 30). GMOs are to be prevented from entering such a protected area in the case of genetically modified agricultural plants by establishing protection zones around this site. The question would, however, arise in the case of a genetic modification of wild animals and plants as to whether and how they could be effectively prevented from entering national conservation sites at all.

8.2.3 Definition of species

It is furthermore both unclear and contentious whether genetically modified wild animals or plants can still be attributed to the same species as the non-genetically modified wild types of the original species. The matter of belonging to a species is for instance significant for one of the most important tools of nature conservation, that is general and special protection of species (sections 39 et seqq. of the Federal Nature Conservation Act). **Genetically modified species might therefore no longer have protective status under the law on special protection of species subsequent to the genetic modification.** Section 7 subsection (2) number 3 of the Federal Nature Conservation Act defines a species as any species, subspecies or subpopulation of a species or subspecies, whereby a species is identified by its scientific name. The Act therefore does not define the concept of “species”, but applies it in the same way as in natural science (Schumacher and Fischer-Hüftle 2021, section 7 para. 46). In natural science terms, as a rule all individuals are considered to belong to a species which share essential characteristics and are capable of interbreeding (Lütkes and Ewer 2018, section 7 para. 22).

It is hence denied in some cases that affiliation to a species might change due to a genetic modification since the scientific name is said to relate solely to the taxonomic classification system of biology, which was sub-divided into domains, kingdoms, phyla, classes, orders, families, genera, species as well as sub-species and populations, but not to differentiate according to genetic characteristics. It is said that the concept of “species” relates solely to the phenotypical appearance, but not to the genetic material (Ekardt et al. 2011, p. 30). A species that could be classified according to the taxonomy would hence be said not to become another species, even if essentially derogating characteristics were anchored in its genepool (Lemke 2003, p. 210; Ekardt and Hennig 2011, p. 99). It is, however, argued in contrast to this that diversity within species, that is a concrete population, was also covered by section 7 subsections (2) and (3) of the Federal Nature Conservation Act, and hence also the genetic level (Lütkes and Ewer 2018, section 7 para. 22). Both the protection of biological diversity in accordance with section 1 subsection (1) number 1 of the Federal Nature Conservation Act, and the interpretation of the definition of “species” in accordance with section 7 subsection (2) number 3 of the Federal Nature Conservation Act, as well as the CBD, according to which a species is defined as any species, subspecies or subpopulation of a species or subspecies (CBD/COP 2002, Decision VI/23, footnote 57) suggest such an interpretation (Frenz and Müggenborg 2021, section 40 number 2). According to this viewpoint, the genetic characteristics of a species are therefore to be taken into account when defining a species (Schlacke 2017, section 40 para. 41).

8.2.4 Invasive species

The definition of a “species” is furthermore also relevant for identifying invasive species. In accordance with section 40 subsection (1), first sentence, of the Federal Nature Conservation Act, the release of plants the species of which does not occur in the affected area, or has not done so for more than 100 years, and of animals, is subject to authorisation. If the definition of a “species” also encompasses the genetic level, section 40 also applies to genetically modified species which might pose a risk to biological diversity (Frenz and Müggenborg 2021, section 40 para. 2). **A genetically modified species which might pose a risk to biological diversity becomes an invasive species that is subject to authorisation.** In accordance with section 40 subsection (1), third sentence, of the Federal Nature Conservation Act, authorisation to release must be denied if threats to ecosystems, biotopes and species of the Member States cannot be ruled out. As is already made clear by the wording (“not ruled out”), authorisation can already be denied if there are serious indications of a risk – it is not necessary to positively prove the risk (Meßerschmidt 2022, section 40 para. 20). It is sufficient if the action may pose a threat to the stock or the spread of individual populations or species (Bundestag printed paper 10/5064, p. 19).

8.2.5 International nature conservation law

Several GMOs have already been released outside agro-ecosystems on a trial basis in various parts of the world, most recently GM mosquitos in Burkina Faso (Pare Toe et al. 2021), Brazil (Evans et al. 2019) and Florida (Waltz 2021). There is no doubt that further releases are planned (Adams and Redford 2021), and this also gives rise to new legal issues in the international context. It is open, for instance, how organisms that have been modified via gene drives, or GM viruses which were released into the wild, can be prevented from spreading over national borders (CBD/AHTEG 2019, Annex 1, 48). Art. 17 of the CBD's Cartagena Protocol on Biosafety (CPB) only provides for notification and information obligations in the event of unintentional transboundary movements of GMOs (SCBD 2000). In order to ensure an adequate level of protection (cf. Art. 1 CPB), there would, however, be a need to create participation opportunities in the run-up to such a release where this involves the long-term, uncontrolled spread of GMOs (as particularly intended with gene drives), as well as to establish effective protective measures in order to prevent them impacting foreign territories.

9 Conclusion

The challenges in nature conservation are particularly urgent given the biodiversity and climate crises. New attempts at solutions offered from biotechnological research and development are, however, not *per se* suited or indeed indispensable for nature conservation just because of this urgency, but rather need to be judged by looking at the whole picture as well as at the details. Such a view currently shows neither the usefulness nor the permissibility or desirability of the application scenarios for genetic engineering in nature conservation. The approaches which have been proposed are not suited to achieve the objectives that have been postulated, given that the prospects for success are unclear, and at the same time would entail taking virtually inestimable risks. What is more, the approaches are in contradiction to the overarching goals of nature conservation, particularly with regard to nature's unique character and intrinsic dynamic processes, and also pose a great variety of legal questions. Both the cost involved in such a development, and the efforts employed to reverse biodiversity loss via purely technical means (which the BfN considers to be unrealistic), could deny nature conservation resources for other activities. In order to safeguard the network of species, habitats and landscapes in the long term, above all the causes of biodiversity loss and of advancing climate change need to be eliminated. It is in this sense even more urgent that nature conservation continues to implement appropriate measures. Moreover, society must engage in an open debate on perceptions of nature and value and of the means and objectives of nature conservation.

Abbreviations and statutes

Abbreviation or statute	Explanation
Federal Nature Conservation Act	Federal Nature Conservation Act of 29 July 2009 (Federal Law Gazette [BGBl.] Part I p. 2542), most recently amended by Article 1 of the Act of 18 August 2021 (Federal Law Gazette Part I p. 3908)
CBD	Convention on Biological Diversity of 5 June 1992
CPB	Cartagena Protocol on Biosafety to the Convention on Biological Diversity (CBD)
CFI	Court of First Instance (since 2009 General Court)
CJEU	European Court of Justice
Habitats Directive	Council Directive 92/43/EEC of 21 May 1992 on the conservation of natural habitats and of wild fauna and flora, Official journal L 206 of 22 July 1992 pp. 0007-0050
Deliberate Release Directive	Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC, Official journal L 106 of 17 April 2001 pp. 0001-0039
GenTVfV	Rules of Procedure for Genetic Engineering in the version of the promulgation of 4 November 1996 (Federal Law Gazette Part I p. 1657), most recently amended by Article 3 of the Ordinance of 12. August 2019 (Federal Law Gazette Part I p. 1235)
GenTG	Genetic Engineering Act in the version of the promulgation of 16 December 1993 (Federal Law Gazette Part I p. 2066), most recently amended by Article 8(7) of the Act of 27 September 2021 (Federal Law Gazette Part I p. 4530)
GM	Genetically modified
GMO	Genetically modified organism
IUCN	International Union for the Conservation of Nature

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In this paper, Germany's Federal Agency for Nature Conservation (Bundesamt für Naturschutz, BfN) presents its position on an international discussion surrounding research approaches to the genetic modification of wild organisms, which are being developed in part for nature conservation purposes. These research approaches are *new* in three ways: They propose nature conservation as a purpose and justification for the release and dissemination of genetically modified organisms (GMOs), the release and dissemination of GMOs outside of agricultural areas and the potential genetic engineering of protected species. The BfN's position is that wild organisms must not be genetically modified solely based on the assumption of a potential benefit to nature conservation and with uncertainty about possible harm.

Since the effects of genetically engineering wild organisms cannot be predicted in the long term, it is a matter of speculation whether the goals pursued with genetic modification can even be achieved – at the same time, there are potential undesirable, often irreversible effects. Due to the complexity of the receiving ecosystems, it is nearly impossible to conduct an environmental risk assessment in the wild in accordance with the precautionary principle and in compliance with current legislation. This gives rise to fundamental concerns as to whether nature conservation requirements can be adequately reflected in the authorisation procedure under genetic engineering law. Since genetically modified wild organisms can cross national borders, opportunities need to be expanded for participation prior to releases, but also effective protection measures to prevent impacts on a foreign territory at the level of the Convention on Biological Diversity (CBD).

Along with its diversity, beauty and utility, nature's unique character is one of the priority protected goods of nature conservation – and its intrinsic value imposes limits on the extent to which humans can intervene in nature. Permanent, far-reaching and inheritable genetic modifications of wild organisms are contrary to nature's intrinsic value and, in the BfN's view, are not compatible with the current understanding of nature, with higher-level protected goods and with nature conservation objectives and practices. Broad social discourse should address how synthetic biology, including new genetic engineering technologies, is understood in relation to nature.

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