Putting gene drives into context: Risks, depth of intervention, and regulatory challenges

Engineered gene drives are an emerging technology for the large-scale genetic modification of natural populations of species. They are controversial due to high levels of uncertainty about their risks and benefits. We analyze gene drives in their social, natural, and technological contexts. We discuss their depth of intervention and compare gene drives to "conventional" genetic modification techniques and to other novel high-impact technologies. While gene drives might overpromise and under-deliver solutions for problems of sustainable development, they also represent a paradigm shift in human technological interference with nature, thus requiring broad discussion in society.

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Putting gene drives into context: Risks, depth of intervention, and regulatory challenges | *GAIA* 33/1 (2024): 165–169
Keywords: biotechnology, ethics, gene drives, governance, risk assessment

Gene drives: Causing or solving sustainability problems?

The recent and rapid advances of modern biotechnology, including molecular tools such as CRISPR-based technologies, ensure relatively precise and targeted genomic manipulations and facilitate the design of engineered gene drives in the laboratory. Gene drives are genetic elements that are transferred to offspring more frequently than expected under Mendelian inheritance. This enables genetic alterations to rapidly spread in a population (Burt 2003, Bier 2022).[1] We refer to genetically modified organisms (GMOs) which carry an engineered gene drive as gene drive organisms (GDOs). Hypothetically, engineered gene drives could become tools to alter, suppress, or eradicate animal populations, for instance, invasive species (Harvey-Samuel et al. 2017), agricultural pests (Legros et al. 2021), or disease-carrying insects (Sinkins and Gould 2006). In theory, gene drives thus have the potential to become a powerful technology in the fields of agriculture, medicine, and biodiversity conservation (Harvey-Samuel et al. 2017, Rode et al. 2019, Legros et al. 2021). At the same time, engineered gene drives are contentious due to their potential unintended ecological impacts and evolutionary consequences for natural systems (Hartley et al. 2023). Moreover, they raise complex social, ethical, and regulatory issues (Simon et al. 2018, Long et al. 2020, BfN 2022), including questions of democratic participation, free prior informed consent, and colonial legacies at proposed future field test sites in countries of the Global South (Taitingfong 2019).

In this article, we conceptualize gene drives as both a distinct, novel biotechnology and a member of a group of emerging technologies characterized by their substantial depth of intervention. We understand "depth of intervention" as a term that describes the power and range of a technological intervention in organisms, ecological and socio-ecological systems (cf. Frieß et al. 2019, pp. 3 f.). "Range" refers to both the temporal and the spatial extent of effects, whereby the tendency towards long impact chains is potentially also associated with a greater ignorance of desired and undesired effects. High depth of intervention can therefore be associated with social and environmental impacts, both adverse and beneficial, which are difficult to predict and control. This, in turn, poses complex challenges for anticipatory and precautionary governance. In organisms, a broad categorization based on the depth of intervention distinguishes changes >

1 For an example how this technically works, see figure 1 in Couto Pilz et al. (2024, in this issue).

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https://doi.org/10.14512/gaia.33.1.9
Received June 2, 2023; revised version accepted March 21, 2024 (double-blind peer review).

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occurring at the phenotype level from those at underlying control structures, which in "lower" organisms are represented at the most basic level by the genome and in "higher" organisms by the germline (Pfeifer et al. 2022, p. 1490f).

While gene drives are unique in the domain of biotechnology, they are only one example for various high-powered technological interventions that are currently advertised as response options to critical challenges of global sustainable development (Reynolds 2021, Rabitz et al. 2022). They accordingly raise fundamental normative questions about the management of natural environments as well as cultural concepts of nature (Neyrat 2019, BfN 2022), issues that have been debated long and controversially in nature conservation and environmental ethics (e.g., Minteer 2018, Potthast 2019, Toepfer 2020).

We start by explaining how GDOs differ from current GMOs and highlighting novel challenges for risk assessment procedures. After that, we situate GDOs in the broader context of emerging technologies with comparable intervention depths. We conclude by discussing the challenges of GDOs and similar technologies in the context of global sustainable development.

Gene drives, genetically modified organisms, risk assessment, and governance

GDOs are technically a novel type of GMOs. In difference to "conventional" GMOs, GDOs are engineered to pass on the genetic modification to their offspring at a higher rate than natural Mendelian inheritance allows for. By doing so, GDOs can "drive" a modification into a wild population even if it has a fitness cost (Burt 2003). Gene drives can be designed to either spread a new genetic trait throughout a population (replacement drive), or to suppress a population, by spreading a genetic modification that will inhibit further reproduction. In particular suppression gene drives have been proposed as alternative tools for pest or disease control. To date, GDOs have not been released outside the laboratory. However, a wide variety of potential gene drive designs have been proposed (Long et al. 2020, Frieß et al. 2023). While recently attempts have been made to develop "localized" gene drives which would spread only within a specified area or population, we concentrate our analysis on non-localized gene drives, which may spread through connected populations from a single release of a low number of gene drive individuals (Long et al. 2020).

Self-propagation sets GDOs apart from conventional methods of biological control, such as Sterile Insect Technology (SIT), first applied in the 1950s. A more recent method based on the transfer of a Dominant Lethal Allele (RIDL, see, e.g., Alphey 2014) uses gene technology to transmit a lethal gene. In contrast to GDOs, however, sterile insects – released repeatedly in large numbers to compete with wild mating partners – are designed to not reproduce and therefore not persist in the population. GDOs are also distinct from "conventional" GMOs in several aspects (Simon et al. 2018). Like conventional GMOs, engineered gene drives are designed and developed in the laboratory. GDOs, however, may bring the "lab in the field" (Simon et al. 2018, p. 2) as the genetic machinery to achieve the drive is inherited and the modification will take place – for each successive generation – in the field. In contrast to most currently released GMOs, most engineered gene drives are proposed to target wild species instead of cultivated ones. Therefore, GDOs will interact with more complex ecosystems on geographical and time scales much larger and more difficult to define (Harvey-Samuel et al. 2017).

Risks associated with GDOs depend on a combination of multiple factors such as the gene drive mechanism, its molecular setup, the specific trait that it propagates, the ecology of the recipient organism and its manifold interactions in the ecosystem. Thus, general statements about the risk potential (hazard and exposure) of GDOs are likely too superficial to serve as a basis for prospective risk assessment. Also, case-by-case assessment will be challenging given the long-term functioning of the molecular setup and the complex interactions with the environment bearing the potential to be highly time-lagged. Thus, information on uncertainties would be an important part of the risk assessment. Modelling gene drive behavior is an option to assist risk assessment and to identify key uncertainties. However, current models use simplified assumptions on the genetics of the GDO and are not designed to predict ecological effects (Frieß et al. 2023). Directing future efforts to modelling the interaction of GDOs with the environment may improve the predictive power of such models.

In the case of non-localized GDO designs, a small, single initial intervention (release) may cause large, long-term, and irreversible impacts. Consequently, GDOs will be difficult to test experimentally in the field, as field releases, even under controlled conditions, are prone to the risk of unintended escapes. This would mean that the experimental release may not be confined in space and time. Super-Mendelian self-propagation is a major concern because it may lead to ecological and evolutionary knock-on effects (Rode et al. 2019). Depending on the connectivity of populations, the worst-case risk scenario for a gene drive is the eradication of a species. The prospect that GDOs may not be controllable in time and space is a critical issue for the risk management of GDOs and respective monitoring efforts. In this context, it may be instructive to consider similar past and present cases. For example, the persistence of chemicals, in conjunction with their bioaccumulation potential and toxicity, is already recognized as a cause for concern in a growing number of jurisdictions worldwide (for a historical development of persistence criteria in regulation see Matthies and Beulke 2017).

The quality of potential risks and the constraints on risk assessment bring gene drives into the ambit of the precautionary principle. Moreover, challenges of GDO risk governance apply at the international level due to the high likelihood of cross-border diffusion. Therefore, the Convention on Biological Diversity (CBD) with its Cartagena Protocol on Biosafety applies to GDO regulation including transboundary issues. This would require authorization decisions from the affected countries, possibly based on prior risk assessment (Rabitz 2019). With risk assessment being a keystone of the international regulatory architecture, the CBD's *15th Conference of the Parties* decided, in December 2022, to develop corresponding guidance materials for consideration by *COP 16* in October/November 2024. Moreover, the International Union for Conservation of Nature (IUCN) is expected to present a policy document on the issue of synthetic biology (including GDOs) in 2025.

Finally, GDOs differ from GMOs in important ethical aspects. The United Nations provides normative frameworks into which the ethical analysis of GDOs needs to be embedded. These include human rights and sustainable development goals, as well as the values of biological diversity (IPBES 2022): intra- and intergenerational justice, the priority of the basic needs of the poorest, and multiple values of nature provide a normative basis for further debates and policymaking (Potthast 2014). Such reflections must include debates about the implications the release of GDOs would have on how we view nature and nature conservation (BfN 2022). Even though the agricultural use of "conventional" GMOs already led to heated debates about the definition and moral value of "naturalness", these interventions have primarily taken place in organisms with a long history of conventional breeding. By contrast, the proposed use of GDOs for the genetic modification of "wild" populations would mark a considerable expansion of the depth of human intervention in natural systems. Hence, in terms of their functionality, risk profile, as well as their governance and ethical implications, GDOs differ considerably from "conventional" GMOs.

genetic information. However, instead of vertical transmission through inheritance from one generation to another, viruses can spread horizontally, between members of the same generation. This allows for much faster dissemination. As demonstrated by the COVID-19 pandemic, small initial doses can lead to global spread. As with gene drives at the current stage of development, there is no proven technique for controlling self-spreading viruses. In the case of gene drives, there are concerns about the potential spread to non-target populations or related species through hybridization (Quilodrán et al. 2020). For self-spreading viruses, there are similar concerns, for example, that transmissible vaccines could infect people who are not suitable for this type of vaccination. The evolutionary dynamics of viruses due to their comparatively high mutation rate and the possibility of exchanging genetic material with other viruses complicate applications and reduce their reliability (Giese 2021).

Nanocarriers have been used for decades for the transport and release of substances. New approaches to this technology in agriculture aim to transport information instead of chemical agents. For example, RNA interference (RNAi) can be used as a pesticide to protect plants from insect pests and viruses (Rank and Koch 2021). Interventions at the level of (genetic) information promise to be much more specific than chemical substances. However, little information is available on potential impacts on non-target organisms and on the fate of RNA stabilized by a nanocarrier in the food chain and the environment. There is even the idea of using plant viruses to edit the genome of plants in the field (Reeves et al. 2018). These viruses could be distributed via insects that suck plant sap, such as aphids. If this approach is seen as a sophisticated nanocarrier system, it is associated with a much greater depth of intervention than classic nanocarrier technologies. Reeves et al. (2018) call such approaches Horizontal Environmental Genetic Alteration Agents, HEGAA. These agents are meant to rapidly alter plants outside of laboratories, and if they work as designed, they could significantly increase the power and reach of genome editing approaches, but at the same time their complex design makes them prone to failure and difficult to control (Pfeifer et al. 2022).

These proposed technological solutions potentially divert attention away from more effective measures that target the causes of planetary environmental problems, such as overuse and pollution of natural resources.

Gene drives and other high-impact technologies

As we proposed above, GDOs are characterized by a significant depth of intervention. Therefore, there is a need to broaden the social and political debate over GDOs rather than considering them as an incremental innovation of "conventional" GMOs. The governance challenges and ethical dilemmas that often arise for other technologies characterized by great depth of intervention could therefore meaningfully inform the discourse on GDOs and vice-versa. In this section we discuss three examples: engineered viruses, nano-carriers, and solar geo-engineering.

In a closely related development, genetically engineered self-spreading viruses have been envisioned for several years as a means to control pest species (Lentzos et al. 2022). Viruses for animals have also been proposed as transmissible vaccines to reduce animal reservoirs of transmitted diseases, and even human applications for vaccination are being considered (Bull et al. 2018). Like gene drives, this technology is based on the spread of

Parallels also exist between gene drives and solar radiation modification for climate engineering, a set of proposed methods for redirecting sunlight in order to slow down or halt global warming (see Irvine et al. 2016). These methods would reflect a small percentage of solar energy before it reaches the planetary surface, possibly allowing international temperature targets to be reached even if global efforts at greenhouse gas mitigation remain inadequate (Rabitz et al. 2022). Proposals for solar radiation modifi- >

cation techniques promise the manipulation of global temperatures for costs which are marginal compared to decarbonization or climate adaptation. However, these approaches also have a considerable depth of intervention. As with gene drives, there are substantial constraints on the risk assessment of solar geoengineering techniques, as it is hardly possible to extrapolate their interactions with the atmosphere and other components of the Earth system from limited field trials. Its propensity for complex causal interactions with uncertain outcomes that could include significant adverse impacts makes solar geoengineering difficult to address via conventional precautionary regulation.

The ethical and governance-related challenges raised by these technologies with great depth of intervention tend to be relatively similar and frequently revolve around risk-risk trade-offs in the presence of significant uncertainty: environmental challenges and potential technological solutions each pose distinct risks that are, to some extent, unknown or even unknowable, thus leading to complex decision problems (Reynolds 2021, Rabitz et al. 2022). In that sense, they may provide better inputs for thinking through the social, political, and moral implications of GDOs than the comparison with conventional GMOs which have been at the center of various public debates and controversies since the 1990s.

Conclusions

The discussion above suggests that the field release of GDOs could amount to a paradigm shift in human technological interference with nature, rather than to an incremental biotechnological innovation. GDOs differ from "conventional" GMOs more in type than in degree. At the same time, due to their potential to serve as a powerful tool for managing nature and protecting public health, debates about GDOs showcase the typical hype associated with emerging technologies, possibly raising too high hopes of solving pressing challenges in global sustainable development. The IUCN report *Genetic Frontiers for Conservation* (Redford et al. 2019) may serve as an example. GDOs fall into the category of "techno-fix" (p. 93), that is, technological solutions to problems that have been generated, or exacerbated, by human (often technology-based) activities. To make sure that such high-powered emerging technologies are accompanied by legitimate, effective, and precautionary governance structures, it is necessary to draw on scientific and technological knowledge and rigorous technology assessment methods. It is strongly advised to ensure public participation and deliberation, specifically by local communities with potentially high degrees of risk exposure. There is also a need for ethical reflection on underlying values and goals. This requires time and spaces for broad and inclusive debates about conflicting notions of human-nature relations, concerns about animal ethics, and the role of emerging technological options in addressing the planetary environmental crisis. The international governance framework of the United Nations is one important arena where debates around GDOs have to take place. In this context, the continuously evolving notion of sustainable development, which stresses the importance of global intra- and intergenerational justice, and the values of biological diversity (IPBES 2022) can serve as points of departure (Potthast et al. 2022). At the same time, it is important not to lose sight of the larger picture: many new technologies have an ever-greater depth of intervention. They provide humans with increasing leverage to cause beneficial, but also adverse, planetary impacts and therefore raise ethical and governance-related challenges. Finally, these proposed technological solutions potentially divert attention away from more effective measures that target the causes of planetary environmental problems, such as overuse and pollution of natural resources.

Acknowledgements: This manuscript resulted from discussions at the symposium *Novel Natures? New technologies and conflicts in nature conservation* which took place in July 2022 in Hannover, DE. We thank the participants for their contributions to our discussions. We would also like to thank two anonymous reviewers for their helpful comments.
Funding: We thank the VolkswagenStiftung for funding the symposium (Az 9B 457).
Competing interests: The authors declare no competing interests.
Authors' contributions: All authors contributed equally to the manuscript.

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