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Gene drives: A summary of legal and regulatory issues

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Introduction

Gene drives are an extremely powerful new genetic engineering technology designed to purposefully spread genetic modifications through populations by bypassing the rules of natural inheritance. While normal genes have a 50 percent chance of being passed on to the next generation, gene drive elements change the odds dramatically in their favour, theoretically up to 100 percent.

The genetic modifications spread by gene drives could either alter or suppress a population, resulting in permanent modification or potential eradication of populations, or even species (Heitman et al. 2016). Their impacts are likely to be irreversible. Gene drive organisms (GDOs) are not meant to stay where they are released. Of particular concern are 'global' gene drives, which can spread to all populations that are connected by gene flow, potentially across national borders.

The touted applications of gene drive systems range from potential interventions in the health sector (e.g., suppressing populations of malaria-causing mosquitoes), to conservation (e.g., eradicating invasive species such as rats, which are threatening endangered species on islands), to agriculture (e.g., making herbicide-resistant weeds susceptible to a herbicide again).

* This paper draws from a book chapter on the legal and regulatory issues relevant to gene drive organisms (Lim and Lim 2019), published in *Gene Drives: A report on their science, applications, social aspects, ethics and regulations* (www.genedrives.ch). See also TWN-ACB Biosafety Briefing on "Key elements in a legal and regulatory framework for gene drive organisms".

Africa is on the frontline of gene drive applications. Deploying 'global' gene drives for disease vector eradication is being suggested as the first potential application, specifically targeting the *Anopheles* mosquitoes that cause malaria. The most prominent project is being implemented by the Target Malaria consortium, led by Imperial College in the United Kingdom, but which operates in Burkina Faso, Mali, Uganda and Ghana.

However, the legal and regulatory landscape in many developing countries, particularly in Africa, is challenging. Many countries, although Parties to the Cartagena Protocol on Biosafety, lack national biosafety laws. There is furthermore a lack of capacity for important biosafety tasks such as risk assessment, risk management, assessing socioeconomic impacts, monitoring, and liability and redress.

The urgent need for legally binding international regulation

Working gene drives using the CRISPR[1] genome-editing platform were only recently demonstrated in several organisms in laboratory settings, in 2015. The pairing of gene drives with CRISPR has, however, accelerated the pace of gene drive development. Potentially far-reaching applications are in the pipeline, backed by huge financial investments, to which the United States' Defense Advanced Research Project Agency (DARPA) and the Bill and Melinda Gates Foundation are the biggest contributors. This means that there is real urgency in creating mechanisms to ensure that there is effective regulation in place before any release of GDOs into the environment. It is important to set out governance and regulatory arrangements well in advance so that would-be developers are informed of the requirements they must meet. The time to consider the legal and regulatory regime for gene drives and GDOs is, therefore, now.

GDOs are covered by existing international biosafety regulation for research, development and use of genetically modified organisms (GMOs), also termed living modified organisms (LMOs).[2] However, there is still an urgent need for specific strict regulation of GDOs that goes beyond existing biosafety regulation and that takes into account their unique features and effects. With GDOs, spread and persistence are their *raison d'être*, posing different legal and regulatory challenges, because of their high potential to spread beyond national borders, particularly in the case of 'global' gene drives. Moreover, GDOs will now deliberately move beyond cultivated fields, into wild populations and ecosystems. The complexity of the systems that could be affected and the impacts that could be realised increases scientific uncertainty manifold, requiring more precautionary approaches to regulation than already required with GMOs.

A regulatory regime for gene drives and GDOs must consider worst-case scenarios in order to be able to adequately deal with and to anticipate the full spectrum of possible adverse effects. While not all gene drives are global in nature, the advent of CRISPR-based gene drives, which have the potential to spread 'globally' and also to be invasive in certain contexts, certainly makes this a realistic concern. Mathematical models based on empirical data show that even the least effective gene drive systems are highly invasive (Noble et al. 2018). In addition, while there have been some mitigating proposals that claim to be able to restrict the spread of gene drive systems (for example, so-called 'local' or 'self-limiting' drives (Esvelt and Gemmell 2017, 4-5)), these remain largely theoretical and currently have not been demonstrated to work. Therefore, a legal and regulatory regime for gene drives and GDOs has to be designed to deal with the full implications of the technology. It has to be prepared to regulate global gene drives and all their potential impacts. This paper focuses largely on global gene drives and the resulting GDOs, in order to discuss their effective regulation.

Proposals for self-regulation by scientists, such as guidance documents for best practices, are clearly not enough to ensure adequate oversight and governance of a technology as powerful as gene drives. While such 'rules of the road' (Adelman et al. 2017) can certainly play a role, these will have to be rooted in a legal and regulatory system that is specific and responsive to all the particular challenges raised by GDOs. Given that GDOs have the potential to cause serious harm to the environment, a public good, it would not be appropriate to place regulation and decision-making about the technology solely in the hands of private actors (Sustainability Council of New Zealand 2018, 20). As such, a legally binding regime is needed.

1 'CRISPR' is short for 'clustered regularly interspaced palindromic repeats'.

2 In this paper, we generally use the term 'genetically modified organism' (GMO), unless we refer specifically to the Convention on Biological Diversity, the Cartagena Protocol on Biosafety, the Nagoya – Kuala Lumpur Supplementary Protocol on Liability and Redress, or the International Plant Protection Convention, which all use the term 'living modified organism' (LMO).

Governance and regulation of gene drives and GDOs must furthermore be international in nature because of the potential for transboundary spread of GDOs. This is because even a small number of GDOs introduced in one country is very likely to have ramifications well beyond its borders (Esvelt and Gemmell 2017).

At the same time, while a significant number of countries are party to the Cartagena Protocol on Biosafety and thus would likely also have national biosafety laws or regulations governing the use of LMOs (which should apply to GDOs), these are not explicit or specific to GDOs. National laws can be developed, or amended, if national biosafety laws already exist, to specifically take into account gene drives and GDOs.

Regulation of contained use is critical

The contained use of GDOs warrants further urgent scrutiny. Research and development of GDOs is currently occurring in the laboratory, with no reported releases into the environment yet. However, there are no internationally agreed rules on contained use research. As such, ensuring that contained use laboratory research on GDOs is well regulated is a priority.

The concept of 'contained use' aims to ensure that contact with the environment is prevented by physical means and associated personnel practices. For example, the Cartagena Protocol on Biosafety defines contained use as "any operation undertaken within a facility, installation or other physical structure, which involves living modified organisms that are controlled by specific measures that effectively limit their contact with, and their impact on, the external environment" (Article 3).

However, the risk of accidental or unintentional release from contained use into the environment remains, through either laboratory accidents or human mistakes. A series of recent incidents[3] at high-containment laboratories draw attention to the inevitability of containment failure.

For GDOs especially, the consequences are great, because even a small unintentional release, particularly of a global gene drive, can result in an extensive spread of the gene drive (Esvelt and Gemmell 2017, 2; Noble et al. 2018; Simon et al. 2018, 3), possibly throughout an entire species. The very properties that make GDOs of interest– spread and persistence – mean that contained use will need to be especially stringent.

Indeed, that subset of GDOs that are designed to eradicate populations or species may far more closely resemble dangerous pathogens than other types of GMOs. Such GDOs, currently under development, are intended to be 'infectious' (through mating), lethal (i.e., severe in consequence), and difficult (probably impossible) to treat or to remove from the environment. They have the capacity, indeed are designed, to spread widely through a population or entire species. These are key characteristics that traditionally define dangerous organisms (usually pathogens) that are assigned to higher-risk groups, and which in turn typically require high-containment facilities and associated stringent personnel practices.

Despite this great need, however, "there are currently no dedicated guidelines on the required risk assessment and minimal control measures applicable to gene drive organisms in contained use" (van der Vlugt et al. 2018, 25).

Towards an effective international legal and regulatory regime

Our review of existing international legal and regulatory instruments and processes relevant to gene drives and GDOs shows that there are serious gaps (Lim and Lim 2019). Table 1 summarises these instruments and processes, as well as their key advantages and gaps in relation to GDOs.

After consideration of the various relevant treaties, regulatory bodies and other instruments currently in place, it would appear that the Convention on Biological Diversity (CBD) and its Protocols – the Cartagena Protocol on Biosafety and the Nagoya – Kuala Lumpur Supplementary Protocol on Liability and Redress – are the best overall structure in which to locate development of international law pertaining to GDOs. This would include responsibility for international contained use regulations, given the potential species and ecosystem implications should escapes from the laboratory occur. The objectives of each of the three CBD instruments are multifaceted, but all of them include in their aims the conservation and sustainable use of biological diversity.

3 Recent examples include accidental distribution of potentially pandemic influenza viruses by the US Centers for Disease Control and Prevention (CDC 2014a), the discovery of improperly stored and forgotten samples of viable smallpox virus at the US National Institutes of Health (CDC 2014b; Christensen 2014), and numerous incidents of accidental distribution of viable anthrax bacteria by the US Army's Dugway Proving Ground (Chappell 2015).

Table 1: Summary of relevant international legal and regulatory instruments and processes

Instrument	Application	Legally binding?	Number of Parties/ members	Key advantages in relation to gene drive organisms	Key gaps in relation to gene drive organisms
Convention on Biological Diversity	Conservation and sustainable use of biodiversity, fair and equitable benefit sharing	Yes	196	Near-universal membership Already begun to address GDOs Precedence with wider policy issues on GDOs/new technologies	Lack of implementation and enforcement US not a Party
Cartagena Protocol on Biosafety	LMOs that may have adverse effect on biodiversity, taking into account risks to human health	Yes	171	Subject matter includes GDOs Already begun to address GDOs Specific regulation of GDOs, in so far as they are LMOs	Developed for conventional LMOs Focused on decision-making by a country in the context of intentional transboundary movements Inadequate provision for socioeconomic assessment No elaboration of contained use rules Lack of enforcement US not a Party
Supplementary Protocol on Liability and Redress	Liability and redress rules for damage from LMOs	Yes	45	Subject matter includes GDOs Liability and redress rules important for GDOs Damage resulting from unintentional and illegal transboundary movements is included	Damage must result from LMOs/GDOs from another country Administrative approach places burden on authorities No financial guarantees Limited number of Parties currently US not a Party
WTO Agreement on Sanitary and Phytosanitary Measures	Sanitary and phytosanitary measures that affect international trade	Yes	164	Economic aspects included in risk assessment Ability to take temporary precautionary measures with low likelihood of WTO challenge	Context of trade liberalisation Focused on narrow scientific risk assessment with high tests to meet Limited relevance to GDOs currently
International Plant Protection Convention	Plant pest risks from international trade	Yes* * IPPC itself is legally binding, but its standards are not	183	Applies to plant pest risks from all LMOs, which may be plants, insects, fungi, bacteria, etc. Addresses unintentional pathways of introduction	Limited relevance to GDOs currently
World Organisation for Animal Health standards	Animal health and zoonoses from international trade	No	182	Specific focus on animal health and animal disease agents	Limited relevance to GDOs currently
Biological Weapons Convention	Biological weapons	Yes	182	Mandate clearly addresses hostile use with clear prohibition on development, use and stockpiling for such purposes	No oversight framework on biotechnology research Lack of political will to develop implementation mechanisms
Environmental Modification Convention	Environmental modification techniques	Yes	78	Prohibits hostile and military use	Moribund; limited membership and political will High 'troika' threshold to meet
UN Declaration on the Rights of Indigenous Peoples	Rights of indigenous peoples, including free, prior and informed consent	No	150*	Universal framework of minimum standards, sets international norms Free, prior and informed consent an established right	* Not legally binding, but endorsed by 150 members of the UN General Assembly
Guidance Framework for Testing of GM Mosquitoes	Testing of GM mosquitoes	No	N.A.	Specific focus on GM mosquitoes	Not developed intergovernmentally Flaws in approach to gene drive mosquitoes

The CBD and the Cartagena Protocol on Biosafety have near-universal application, with the United States as the most notable exception. There are currently 196 CBD Parties and 171 Parties to the Cartagena Protocol. The Nagoya – Kuala Lumpur Supplementary Protocol on Liability and Redress has recently entered into force, with 45 Parties.

It is clear that GDOs are currently covered by the scope of the CBD, the Cartagena Protocol and the Supplementary Protocol, in so far as GDOs are LMOs, and in so far as GDOs are likely to have a significant adverse impact on biological diversity. GDOs have also begun to be specifically addressed by the CBD and the Cartagena Protocol. As such, the CBD and its Protocols can be said to be already 'seized of the matter'. However, GDOs pose challenges and risks not foreseen when the Convention and its Protocols were negotiated, since LMOs were what the first drafters had in mind. As such, much needs to be done to enable the CBD and its Protocols to adequately address the governance of GDOs beyond governance of LMOs.

The ongoing work on synthetic biology and risk assessment and risk management by the respective Ad Hoc Technical Expert Groups (AHTEGs) addresses GDOs, but is preliminary and needs to be taken further. Decisions of the Conference of the Parties (COP) to the CBD and the Conference of the Parties serving as the Meeting of the Parties (COP-MOP) to the Cartagena Protocol are also necessary to give effect to their recommendations.

In the Cartagena Protocol, work has been undertaken on other issues particularly relevant to GDO governance: in the AHTEG on Socio-economic Considerations; by the Network of Laboratories for the Detection and Identification of LMOs; and on unintentional transboundary movements of LMOs. Additional work on these issues specific to GDOs should be undertaken further.

COP decisions on synthetic biology, including GDOs, have stressed the importance of the precautionary approach but have not required mandatory risk assessment, risk management or regulatory procedures specific to GDOs to be in place or undertaken before any release occurs. The time is ripe for the COP to decide on this as well as on any potential suspension of GDO activity, especially considering the absence of binding and effective regulation of GDOs at local, national or international levels to date. The COP 14 decision (14/19) already moves in this direction (see section below). As such, implementation of these governance aspects, at international and national levels, should be a priority.

Explicitly locating broader governance of GDOs under the CBD and allocating more specific regulatory governance to the Cartagena Protocol, with the Supplementary Protocol addressing liability issues, seems to be the obvious way to begin the serious work of ensuring that there are specific and binding international rules on GDOs. Critical steps forward that should be initiated urgently include a thorough review of how the provisions of the Cartagena Protocol and the Supplementary Protocol may become actively responsive to the specificities and risks of GDOs. In addition, serious efforts need to be made to ensure that the implementation of and compliance with the CBD and its Protocols are improved.

Other international agreements, regimes and fora present opportunities for specific aspects of gene drive and GDO regulation. In particular, the issue of potential dual use of gene drive technologies has to be addressed by the Biological Weapons Convention, whose mandate clearly prohibits the hostile use of GDOs, and includes development, production, acquisition, transfer, retention, stockpiling and use for such purposes. Furthermore, the United Nations Declaration on the Rights of Indigenous Peoples sets the international norms and standards on the issue of free, prior and informed consent, which can be applied to the release of any GDO into the lands and territories of indigenous peoples, or that may affect their resources.

Key elements in a legal and regulatory framework for GDOs

A legal and regulatory regime that is responsive to the particular challenges posed by GDOs will need to build on existing biosafety law, address the prevailing gaps and put in place specific elements that address these challenges. We consider the following elements as fundamental in a legal and regulatory regime for GDOs:

- Strict contained use standards specific to GDOs to regulate its laboratory research, as well as strict containment measures for transport
- Joint decision-making, in terms of operationalising prior informed consent for all countries potentially affected by a particular environmental release
- Effective measures for dealing with unintentional transboundary movements
- Genuine public participation and obtaining the free, prior and informed consent of indigenous peoples and local communities
- Adapted risk assessment and risk management approaches for GDOs, including acknowledgment when such approaches are not possible
- Full assessment of socioeconomic impacts including ethical concerns
- A technology assessment approach, including consideration of alternatives
- Rigorous monitoring and detection
- Stringent liability and redress rules

For a full discussion of these elements, please refer to the TWN-ACB Biosafety Briefing on "Key elements in a legal and regulatory framework for gene drive organisms".

These elements are not fully in place and urgent efforts need to be undertaken to ensure they are translated into effective rules that are binding on all countries in order to remedy the serious gaps identified, *before* any release of GDOs is even contemplated.

The COP 14 decision

The Parties to the CBD at COP 14 in 2018 adopted a decision (14/19) that spelt out strict precautionary conditions for GDOs. These conditions should be met before any introduction into the environment of GDOs, including for experimental or research and development purposes. The precautionary conditions stipulated directly in Decision 14/19 relate to (i) carrying out risk assessments; (ii) having in place risk management measures; and (iii) obtaining the free, prior and informed consent (or equivalent at national level) of potentially affected indigenous peoples and local communities.

That decision also recalls previous COP decisions that laid out additional elements. These collectively include:

- effective regulatory systems consistent with the principle in international law of States' responsibility to ensure that activities within their jurisdiction or control do not cause damage to the environment of other States (which is very relevant to GDOs given the high potential for transboundary spread);
- addressing issues such as food security and socioeconomic considerations with the full participation of indigenous peoples and local communities;
- establishing the right to take precautionary measures (which could include bans and moratoria), even in a situation where scientific knowledge is lacking;
- environmental impact assessment and allowing for public participation in such procedures;
- dealing with the consequences of extra-territorial impacts by promoting reciprocity, notification, exchange of information and consultation;
- immediate notification as well as action to prevent imminent or grave danger or damage beyond national jurisdiction;
- emergency responses and international cooperation for joint contingency plans when there is a grave and imminent danger to biological diversity; and
- examining liability and redress, including restoration and compensation for damage to biodiversity.

Taken together, the Parties to the CBD have effectively raised the bar for any releases into the environment of GDOs. Importantly, the international community has pointed to the serious issues that must be addressed before any releases are even considered. This would mean that there has to be requisite time set aside to deliberate, and adequate processes put into place, to properly address these precautionary conditions.

The CBD decisions place implementation obligations on Parties, to which the United States – a non-Party – and any would-be developer operating in good faith, should also adhere. Gene drive research and development is not an unregulated space that can be experimented in at will. In practice, it is simply not acceptable to the international community for anyone to release a GDO without properly addressing the issues that Parties to the CBD have laid down. Neither would it be right for one country to approve a release without the consent of other potentially affected countries and the local communities concerned.

Critical steps forward

In order to allow for the space and time to put in place legally binding governance arrangements at the international level, which should include the establishment and operationalisation of the elements identified above and build on the CBD decisions, the following are critical steps forward in the interim:

Firstly, there should be **no intentional releases into the environment, including field trials, of any GDO**. There remain serious concerns at the intergovernmental level about any release into the environment of GDOs, however small or isolated, as evidenced by the recent COP 14 decision (14/19). For there to be well-considered, internationally agreed rules and procedures for the governance of gene drives and GDOs, there has to be a thorough pause during which no field trials are conducted, because even small or isolated releases of GDOs can spread, thus defeating the purpose of this important waiting period.

Secondly, there should be **strict contained use standards applied to existing research and development in the laboratory, as well as strict measures for any transport of GDOs, to prevent escape**. The best available standards should be applied immediately while an intergovernmental process should be established to develop mandatory international laboratory safety standards for contained use research involving GDOs. At the same time, there should be full transparency regarding ongoing research projects; a register should be established and maintained to keep track of developments. At the national level, governments can improve oversight by requiring the licensure of experiments with GDOs in contained use.

Thirdly, **monitoring and detection for unintentional releases and unintentional transboundary movements of GDOs have to be conducted during this period, with emergency response plans in place.** This has to be done both by the authorities that have oversight and by entities conducting the research and development. Such monitoring is necessary, as unintentional releases may occur at any time and governments should remain vigilant even during a period where no environmental releases are officially permitted. The tools and materials for detection of unintentional releases of GDOs must be quickly developed and/or adapted, in order to enable effective and timely detection and identification.

Finally, the **international rules for this period of constraint, including for their enforcement and for liability and redress should there nevertheless be damage, must be effectively operational, including at national level.** This is necessary because even during such a pause period there is a need for enforcement and to ensure that any unintentional and also rogue releases are adequately dealt with, particularly if any damage results.

Giving pause will allow governance arrangements at the international level to be established and made operational, including mechanisms for joint decision-making by all potentially affected countries. All governments need to engage in fully informed discussions about the seriousness of this issue, aided by the relevant expertise and genuine public participation. In addition, the issue of dual use of gene drives must be effectively addressed at the appropriate fora. Ultimately, political will is required to ensure that the world puts in place effective, legally binding and enforceable rules that are necessary for gene drive technologies.

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