ABN: 67 104 140 918
PO Box 400, Emerald Vic 3782
T: 03 5968 2996
E: info@geneethics.org

March 10, 2024

Gene Technology Implementation Team
E: gene.technology.implementation@health.gov.au
T: 02 6289 2033

Re: GeneEthics comments on the draft National Gene Drive Tech Guide

Introduction

1 What is your name and surname?

Name: Bob Phelps

2 What is your email address?

[redacted]

3 Please select one of the following that best applies to you.

I represent a non-governmental organisation (NGO)

4 Are you providing your feedback representing your organisation or as an individual?

On behalf of my organisation

5 Name of your organisation

Organisation: GeneEthics Limited

Q2 - Purpose of the Guide

1 Does this section provide sufficient description to assist proponents, regulated entities and the public to understand the purpose of the Guide?

GeneEthics contests the legitimacy of the draft guide and its intentions. This guide is antidemocratic as it: “aims to provide clarity and certainty for investors, researchers, government agencies, and proponents who wish to develop this technology,” while disempowering and marginalising all other sections of civil society.

The guide offers preferential treatment and priority access that would enable gene drive proponents and their financial backers – including the US Department of Defense research arm, the Defense Advanced Research Projects Agency - to fast-track the research, development, and release of their novel organisms.

In contrast, a voice for the legitimate concerns and interests of the citizens and residents of this continent are systematically marginalised and excluded. Yet Australians are the owners and custodians of the biological and genetic diversity of the continent's life support ecosystems. The proponents 'may' consult First Nations communities, civil society generally, public interest advocates, and independent experts but the processes and outcomes will remain under proponent control.

Australian ecosystems are now so disrupted that many species of all descriptions are being driven to extinction. Genetically Manipulated gene drive organisms (GM GDOs) may have similar devastating impacts, yet the guide facilitates their release, without any demonstrated and compelling benefits. GM GDOs must all be banned until compelling scientific reasons for their release are demonstrated and agreed to by the whole society.

Those reviewing the National Gene Technology Scheme recommend that "Consideration of benefits (e.g. potential economic, environmental and health benefits) should not be introduced as an element of regulatory decision making at this time." (Rec 19) The community cannot be expected to accept the extreme risks of GM GDOs without any certainty of environmental or public health rewards.

Public servants, government departments, officials, and regulators have a responsibility to be impartial and serve the public interest. But this document preferentially advises gene drive proponents and regulated entities how to minimise public and regulatory participation, reduce well-founded resistance or delay, and to facilitate the research and deployment of GM GDOs.

The document admits that "gene drives may pose risks that are not yet fully understood, including the potential to alter the ecosystem in unpredictable ways." That is a big understatement as Australia has a multitude of very complex and fragile ecosystems that GM GDOs are intended to deliberately disrupt, by controlling or eliminating organisms that a proponent and their backers consider inconvenient, expensive or undesirable.

The guide goes on to say: "These risks should be acknowledged and managed in a structured and systematic way". The document does not attempt this as it includes very few requirements and uses "may" extensively when discussing public engagement processes in the place of genuine participation.

Q3 - Process Fundamentals

2 Does this section provide proponents, researchers, academics and regulated entities with a clear understanding of the process fundamentals that have been used to develop the Guide?

The "process fundamentals" are biased. No rational, integrated, comprehensive strategies are envisaged, except for a "risk management strategy for the release of a GM gene drive organism." Few risks are even acknowledged but the vast complexity of natural ecosystems and biological diversity are falsely assumed to be understood, foreseeable, and manageable. Huge data gaps still exist in science's comprehension

of nature and its millions of species. Moreover, the biotechnologists who may propose GM GDO release operate at the micro level in labs and have scant expertise or understanding of the macro level of ecosystems. Independent experts who comprehend ecosystem complexities must be enabled to participate.

Australia's woeful history of inadvertent and deliberate releases of foreign organisms that continue to cause profound ecological harm confirm how little is known. Invasive species are among the lead drivers of biodiversity loss in Australia and we have "lost more native mammal species than any other continent (with) more than 100 species listed as either extinct or extinct in the wild."[1] The deliberate release of GM GDOs carries every likelihood of failing to durably fix some claimed problem while accelerating the biodiversity losses.[2]

The draft is exclusionary, ignores the need for a required mechanism to fully and fairly canvass the concerns of all affected First Nations communities, civil society, independent experts, and public interest critics. Instead it merely suggests: "negative consequences should be acknowledged and explicitly justified, and the strengths of risk minimisation measures described." Such minimisation measures are likely be mere window dressing, to assuage genuine community concerns as GM GDOs cannot be retrieved from open environments and all proposed mechanisms for agent control remain undemonstrated.

The lack of robust evidence challenges the assumption that risk minimisation and management of a GM GDO is possible in open environments after release. The community must have guaranteed fora in which to exercise influence over the evidence of probable unforeseen collateral impacts, ecosystem disruption, species extinction, creation of new invasive species, or horizontal gene transfer from GM GDOs to non-target relatives

Though the document asserts that: "Proponents must undertake post-release surveillance activities on efficacy of the GM gene drive and collect data on downstream environmental and health effects of the released GM gene drive organism." That amounts to standing by to watch as ecological catastrophes unfold.

If GM GDO releases are uninsurable they should not be permitted. Responsibility for biodiversity disruption, loss, and compensation is not assigned. Also, there is silence in the guide on guarantees that the proponents, governments, or the regulators who issue the licences are required to ensure the availability of sufficient economic resources, expertise, and commitment to undertake any necessary clean up, for the foreseeable future.

Q4 - Proposed Assessment Process

3 Does the process diagram above assist proponents, researchers, academics, and regulated entities with understanding the OGTR assessment process?

---

[1] https://www.theguardian.com/environment/2023/sep/04/invasive-species-no-1-driver-of-biodiversity-loss-in-australia-and-feral-cats-have-biggest-impact-report-finds

[2] John Paull, Genetically Modified Organisms (GMOs) as Invasive species https://orgprints.org/id/eprint/33327/1/Paull2018GMInvasiveSpeciesJEPSD.pdf

Figure 1 reveals that systemic discrimination against the Australian public interest is inherent in this guide. The proponents are invited to discuss how to meet the OGTR's requirements and how the regulator will help them to navigate the process.

The graphic reflects the inherent unfair processes, where independent experts and communities are only allowed to briefly comment on the OGTR's pre-digested Risk Assessment and Risk Management Plan (RARMP) which is only published when the application is well advanced and everyone else has had the opportunity to make submissions. RARMPs amount to approval of the release, disclose the Regulators intention to grant a licence, and seeks to justify the decision.

Proponents are advised that: "Before submitting an application for a licence to release a gene drive organism into the environment, proponents should seek a pre-application meeting to obtain technical advice from the GT Regulator. This is intended to help reduce uncertainty for prospective applicants."

This is absolutely counter to any democratic or fair process. The GT Regulator also has the discretion and a responsibility to provide an open forum at such pre-application meetings for independent ecological, public health and safety experts, public interest advocates, and the interested general public. These groups must be able to also participate and contribute their expertise, evidence, and opinions in a meaningful and influential way, to the proponents and to the OGTR, before the application process begins.

All parties must hear what the proponents intend and have a decisive influence on whether or not the GM GDO proposal can even proceed to assessment.

Q5 - Risk considerations under the Gene Technology Act 2000

4 Is there additional information on existing OGTR processes that might be helpful to provide proponents, researchers, academics and regulated entities with a clear understanding of their existing obligations under the GT Act?

Obligations under the GT Act extend to observing the Precautionary Principle, which imposes the burden of proof for safety and efficacy on proponents. When the OGTR and applicants ignore these requirements they fail to serve the public interest, with precautionary measures to protect natural environments and public health.

A broader approach to risk assessment that does not merely consider a limited suite of ecological risks, in isolation from broader considerations, is essential.

Allowing communities to belatedly comment on the OGTR's Risk Assessment and Risk Management Plans (RARMP), after everyone else has set the agenda is an inherent unfairness in the OGTR's modus operandi. RARMPs are pre-digested justifications for the approval of proposals, when the Regulators intend to grant a licence.

6 - Additional considerations for proponents under the Scheme

5 Do the listed additional considerations provide sufficient detail on the range of factors needed to be taken into account for a potential application for the environmental release of a GM gene drive organism?

The document mostly makes ‘may’ suggestions instead of impressing ‘should’ or ‘must’ on proponents. It is unclear and confused about what: “factors needed to be taken into account”. Proponents, regulators and civil society may have diverse public interest priorities but proponents are given the advantage of deciding on the mode of their engagement with civil society and reporting on the outcomes.

The limited scope does not account for the wide range of foreseen and unforeseen risks and the paucity of tools for risk minimisation. The document provides no clear processes available to civil society by which a GM GDO could be prevented if it were seen as too high risk, against the public interest, or an unreasonable threat to biodiversity or public health.

The draft recommends that: “A contingency plan will assist proponents to prepare for any foreseeable incidents.” But ecosystem disruptions and the harm done are rarely foreseen or predictable. Yet they may have very long term or permanent, and extensive impacts. Any contingency plan is likely to be grossly under-resourced and impossible to deploy as shown with invasive red fire ants, feral rabbits, cane toads, European carp and dozens of other organisms that impose huge imposts forever on the biodiversity and finances of the nation.

6 Are there additional considerations that fall outside the remit of the Gene Technology Act or the Gene Technology Regulator that should be included to provide additional guidance?

Crafting this document exclusively with advice for the proponents is unacceptable. Extensive advice and guidance to civil society about its legitimate and crucial role, and scope for full participation, must also be included.

As gene drives have the capacity to spread regionally, nationally or globally, all jurisdictions must play a role in ensuring that their communities are fully and fairly informed about any applications. They should also ensure that their constituents are empowered to participate in decisions on the application, from research and development to potential release.

7 In the context of environmental considerations, is there sufficient detail on the additional factors for considerations that could be included?

The guide proposes a recipe for ecological disaster, with complete disregard for independent scientific evidence and precaution on environmental protection, as the following quote shows. It is completely unacceptable that the guide proposes:

“In the absence of direct experimental results, environmental considerations could include ecosystem modelling, reflecting the complex biological systems and their interrelationship with dynamic ecosystems. Modelling can assist with predictions of how GM gene drive organisms will interact with native populations and ecosystems. Modelling should also include how GM gene drive organisms could change or evolve over time in different environments. An environmental consideration may include examination of non-target species that are at risk of breeding with GM targeted species.”

GeneEthics asserts that the OGTR must reject any gene drive application on the basis of such gaping evidence vacuums. Ecosystems rate just four mentions in the whole guide, as if they were not of central importance.

8 Are there other factors to demonstrate comparative benefits that proponents should consider including in their applications?

The proposal for “A detailed description of the comparative benefits, relative to existing technologies,” is too limited to be effective, rational or meaningful. Moreover, the meaning of “comparative benefits” is undefined and unclear.

Technology is far from the only option for protecting or enhancing environments and public health. Effective management systems are more likely to produce durable and lower impact results than technologies.

For instance, instead releasing a GM GDO to eliminate disease-causing mosquitoes, they could be modified with benign and common bacteria to prevent Aedes aegypti from transmitting pathogens. “When Aedes aegypti mosquitoes carry natural bacteria called Wolbachia, they reduce the mosquitoes' ability to transmit viruses like dengue, Zika, chikungunya and yellow fever.”[3] Using GM GDOs to eliminate Aedes aegypti mosquitoes would unnecessarily remove their important ecological roles and functions as plant pollinators and as food for insectivores.

9 Do you have any views on the criterion in the table or who is responsible for each criterion? (Table below)

The public, broadly defined, must also have a responsible, participatory role in considering the criteria set out in the table. The proponents and their backers must not be allowed to drive the review and approval processes without civil society having similar influence.

Citing the APVMA as another regulator that may be consulted about gene drives is not reassuring as it is captive of the industries it is supposed to regulate. A Clayton Utz report[4] to Agriculture Minister Murray Watt found the APVMA has “prioritised regulatory performance in relation to registrations, assessments and approvals over regulatory performance in relation to monitoring, compliance and enforcement,” and “found instances where the APVMA's approach appears focused on assisting industry,” that “appears to be embedded into the APVMA's regulatory priorities and culture.” Further, “Of the 10 ongoing chemical reviews, eight have been in progress for over 15 years or more, with seven ongoing for nearly 20 years.” Several chemicals now widely banned or restricted overseas have been on the APVMA’s priority review list since 1995 with little progress!

Environmental considerations must also be within the purview of other regulators, as well as state and territory governments. The unique environments of Tasmania and other offshore territories may require special protection from GM GDOs.

Another topic is necessary. The legal obligations to ensure sufficient economic resources, expertise, and commitment are guaranteed for any feral GM GDO clean

[3] World Mosquito Program. https://www.worldmosquitoprogram.org/en/work/wolbachia-method/how-it-works#:~:text=When%20Aedes%20aegypti%20mosquitoes%20carry,Zika%2C%20chikungunya%20and%20yellow%20fever.
[4] Clayton Utz, APVMA Strategic Review Report - July 2023

up, for the foreseeable future. Compensation for the loss of environmental amenity, economic loss, and other harms must also be guaranteed.

7 - Social licence and public consultation

10 Does this section provide proponents, researchers academics and regulated entities with a clear description and model for how they might demonstrate social licence?

Gene drive research and deployment is everyone's business. The Earth's life support systems are at risk and require the stewardship of all citizens. If released, GM GDOs are certain to radically alter and undermine our continent's genetic and biological diversity, very likely producing extensive local, regional, national or even international ecosystem disruptions and species extinctions. Humans and other species all depend on biodiversity for our survival so gene drives pose unpredictable existential threats that cannot simply be 'managed' as the draft guide proposes.

This section includes undefined terms which further signal that the document's intention is to facilitate gene drive deployment. For example, the guide suggests that proponents seek "reasonable social licence" and "to minimise the risk of creating adverse sentiment." Who will decide what is "reasonable" – those denied a voice in the future of their life support systems? "Adverse sentiment" would have a positive outcome if it prevented a release that became a disaster.

In the engagement, there are no requirements for any particular processes, with only cosmetic roles for First Nations, the public, independent experts, and public interest advocates. Yet these voices are the canaries down the mine.

Every step is at the discretion of the proponents and their backers, encouraging exploitative and dominant dynamics. The guide would allow a proponent to engage in token community talks and retain control over reporting the processes and outcomes.

Worse, the GT Regulator only engages with the community after announcing its intention to allow release, justified in its RARMP. Industry alone has appeal rights if its appeals are rejected but community concerns are generally dismissed without further correspondence and minimal published refutation.

This document does not enable or encourage full and frank discussion among all parties. It proposes second-rate "public engagement and consultation". These are weak substitutes for genuine, broad and deep, civil society participation in processes, from the inception of the research and development through to any possible release.

Gene Drives could catastrophically disrupt environments as they can make more species endangered or extinct. The community, including First Nations people, must be full participants (not just consultants) in any proposals to fund and begin GD research. From a Pacific perspective "A more reciprocal model of engagement was proposed, where unidirectional 'science communication' is not conflated with participatory community engagement, and 'consent' is not a guaranteed outcome of partnership."[5]

[5] https://www.nature.com/articles/s42003-024-05896-1

Amend the guide text on page 18 from “This will require a significant investment of time and effort **on behalf of** proponents.” to “This will require a significant investment of time and effort **on the part of** proponents.”

8 - References

11 Are there additional resources that could be helpful?

Australia already has several examples of biocontrol organisms, microbial pathogens, and other agents being mismanaged, threatening our genetic and biological diversity and public health. They should be in the references, to augment those proposed for inclusion.

- The rabbit calicivirus escaped from a field trial on Wardang Island off the South Australian coast and was soon on the mainland, apparently through insect vectors or wind transmission. https://www.newscientist.com/article/mg14820021-000-deadly-rabbit-virus-out-of-control/
- Mousepox virus being developed as a biocontrol agent inadvertently killed all the project’s experimental animals. The gain-of-function methods that made the virus so virulent were reported as a possible means for developing biowarfare agents. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2816623/
- Testing the concept of virally vectored immunosterilisation for the control of wild rabbit and fox populations in Australia A J Robinson, M K Holland https://pubmed.ncbi.nlm.nih.gov/7779038/
- John Paull, Genetically Modified Organisms (GMOs) as Invasive species https://orgprints.org/id/eprint/33327/1/Paull2018GMInvasiveSpeciesJEPSD.pdf
- A worker at the High Containment PC4 facilities in Geelong was sent home with the highly contagious Newcastle (poultry) Disease in her eye. Date unknown. https://www.csiro.au/en/about/facilities-collections/acdp/pc4-zoonsis-suite-and-bioimaging-facility
- Possible dual-use of gene drives (DARPA is their chief funder globally) and potential convergence of gene drive and gain-of-function research, must be resisted. An NHMRC review of Australian gain-of-function research identified 17 projects, after concerns that SARS-Cov2 may have originated from experiments in a Wuhan lab. https://www.nhmrc.gov.au/about-us/publications/gain-function-research-review-report
- Australia harbours many zoonotic organisms with pathogenic potential so we must avoid any repetition in synthetic microbes too. For instance, Queensland has the Hendra virus which crossed from the excreta of bats roosting in trees, infected horses grazing below, which then passed the virus to some people working with the horses, several of whom died. https://www.who.int/health-topics/hendra-virus-disease#tab=tab_1
- The long-proposed release of carp herpes virus as a biocontrol agent, into the Murray Darling river system, is hotly contested. European carp biocontrol would be temporary and partial but huge negative and permanent impacts on river ecology are foreseen, especially as millions of native fish would also be killed. https://www.agriculture.gov.au/biosecurity-trade/pests-diseases-weeds/pest-animals-and-weeds/national-carp-control-plan
- Boersma, K., Bovenkerk, B. & Ludwig, D. Gene Drives as Interventions into Nature: the Coproduction of Ontology and Morality in the Gene Drive Debate. *Nanoethics* **17**, 4 (2023). https://doi.org/10.1007/s11569-023-00439-0
- Chennuri PR, Adelman ZN, Myles KM. Genetic Approaches for Controlling CRISPR-based Autonomous Homing Gene Drives. Front Bioeng Biotechnol. 2022 Jun 15;10:897231. doi: 10.3389/fbioe.2022.897231. PMID: 35782500; PMCID: PMC9240394.https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9240394/

- ETC Group. Gene Drive Organisms. An introduction to a dangerous new technology putting Africans at risk. https://etcgroup.org/content/gene-drive-organisms

Privacy information and consent to publish

The Department of Health and Aged Care, on behalf of the National Gene Technology Scheme (the Scheme), intends to publish submissions, including the name of the individual or organisation that made the submission, on the Scheme website. Please indicate your willingness for your details to be published by selecting the appropriate response below. The following question requires one answer to be selected.

I CONSENT to publication of my submission on the Scheme website.

By making submission, I acknowledge that:

Yes: I understand that the giving of my consent is entirely voluntary.

Yes: I am over the age of 18 years.

Yes: I understand the purpose of the collection, use, publication or disclosure of any submission.

Yes: I understand that, where I have provided consent to my submission being published, the Department has complete discretion as to whether my submission, in full or part, will be published.

Third Party personal information and evidence of consent to publish(Please select all that apply.)

Yes. Please tick this box if none of the above options apply.

If you have indicated above that you have attached written evidence of third-party consent please attach it here Please make sure your file is under 25MB: