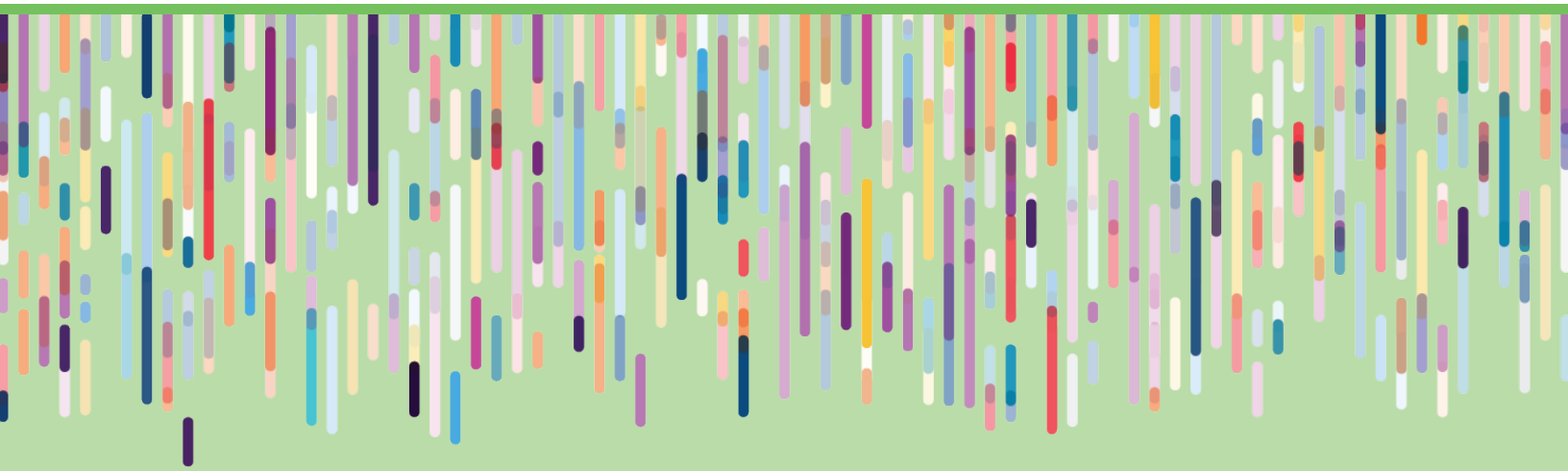
National Gene Technology Scheme

An Australian, State and Territory Governments Collaboration



National Gene Drive Policy Guide

December 2025

Acknowledgement of Country

We proudly acknowledge the Traditional Owners and Custodians of Country throughout Australia and pay respect to those who have preserved and cared for the lands on which we live, work, and benefit from each day.

We also recognise and respect Aboriginal and Torres Strait Islander peoples' continuing connections and relationships to the lands, waters, culture, and community; and pay respect to all Elders past, present, and emerging.

Acronyms and Abbreviation

Acronym	Meaning
CBD	Convention on Biological Diversity
CRISPR	Clustered Regularly Interspaced Short Palindromic Repeats
CSIRO	Commonwealth Scientific and Industrial Research Organisation
DAFF	Australian Government Department of Agriculture, Fisheries and Forestry
DCCEEW	Australian Government Department of Climate Change, Energy, the Environment and Water
DFAT	Australian Government Department of Foreign Affairs and Trade
DIR	Dealing Involving Intentional Release
EPBC Act	Environment Protection and Biodiversity Conservation Act 1999
FPIC	Free, Prior and Informed Consent
GM	Genetically Modified
GMO	Genetically Modified Organism
GT Act	Gene Technology Act 2000
GT Regulator	Gene Technology Regulator
GTECCC	Gene Technology Ethics and Community Consultative Committee
GTTAC	Gene Technology Technical Advisory Committee
IBC	Institutional Biosafety Committee
IUCN	International Union for Conservation of Nature
MHC	Major Histocompatibility Complex
NHMRC	National Health and Medical Research Council
OGTR	Office of the Gene Technology Regulator
PFA	Pest Free Area
Qfly	Queensland Fruit Fly (Bactrocera tryoni)
RARMP	Risk Assessment and Risk Management Plan
SIT	Sterile Insect Technique
WHO	World Health Organization
WTO	World Trade Organization

Contents

Overview

Background to the development of the guide

The Third Review (the Review) of the National Gene Technology Scheme (Scheme), endorsed by all Australian governments on 11 October 2018, recommended *"clarifying, and where necessary strengthening, the mechanisms for regulating the environmental release of GM gene drive organisms in Australia"* (Recommendation 7b).

Review Recommendation 7b and development of the National Gene Drive Policy Guide cannot be considered in isolation. Other intersecting Review Recommendations are integrally linked, including Recommendations 2, 19 and 21 which state:

- The object of the *Gene Technology Act 2000* (the GT Act) be maintained (Recommendation 2).
- 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 (Recommendation 19).
- Clarifying the intersection between the Gene Technology Regulator (GT Regulator), other regulators, and legislation, which may include: (a) identifying opportunities to enhance communication mechanisms and linkages, and (b) identifying any emerging areas where legislative or administrative changes can be made, to reduce any unnecessary duplication (Recommendation 21).

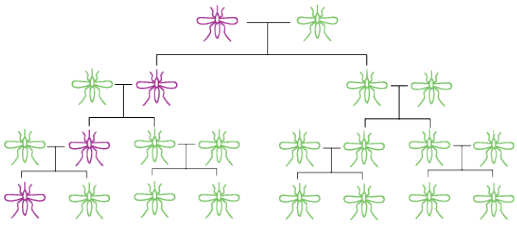
What are gene drives?

The term 'gene drive' is used to describe organisms which have been genetically modified to increase the rate for a particular trait to spread through a sexually reproducing population, spreading the genes or traits through a species at a faster rate than normal inheritance. An example might be a trait to increase likelihood of offspring to be female and thereby suppress the population of the targeted pest species.

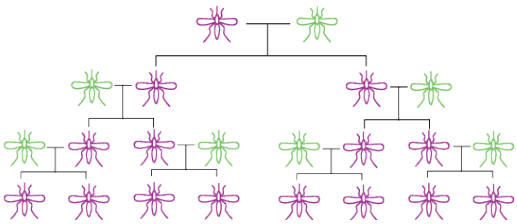
Figure 1 provides an example of the difference between normal inheritance and gene drive inheritance within a sexually reproducing insect population.

Figure 1

Normal inheritance



Gene drive inheritance



Genetically modified (GM) gene drive organisms

The concept of a GM gene drive is not a new one. These dominant genes - sometimes called selfish genes - are abundant in nature. However, GM gene drive organisms have the potential to be useful for addressing some of the environmental, agricultural, and public health challenges currently faced by Australia. For example, conserving native populations, controlling significant exotic pests, or providing public health benefits.

As an evolving technology, gene drives may pose risks that are not yet fully understood, including the potential to alter the ecosystem in unpredictable ways. These risks should be acknowledged and managed in a structured and systematic way if Australia wishes to be a future beneficiary of this technology.

Additional information on GM gene drives is available on the Scheme website (www.genetechnology.gov.au).

Regulation of GM gene drive organisms

Information on the operation of the Scheme and the regulation of GMO's generally is available on the Scheme website.

The Scheme is also complemented by numerous pieces of Commonwealth, state, and territory legislation, which may be triggered depending on the type of GM gene drive organism. State and territory legislation that may apply to an application for environmental release of a GM gene drive organism or GMO is available, as a non-exhaustive list, on the Scheme website and may be updated as appropriate over time.

There is community expectation that new technologies, such as gene drives, are safely managed in Australia through regulation. It is important to note that all dealings involving a GM gene drive organism are currently regulated under the Scheme and require a licence from the GT Regulator. Licences are issued according to the requirements of the GT Act, and the GT Regulator may impose conditions considered necessary to manage risks posed by the dealings or activities with the GMO. This is achieved through the Risk Assessment and Risk Management Plan (RARMP) prepared by the GT Regulator.

Gene drive technology is relatively new, with some contained research work being progressed in Australia under licences issued by the GT Regulator. Although no applications have yet been submitted for environmental release of a GM gene drive organism, as the technology matures, proponents may seek to move from contained research to environmental release.

Any environmental release of a GM gene drive organism will require significant consultation with state and territory governments, and other impacted bodies. These consultations will allow regulators from all levels of governments to identify potential impacts of environmental release and assign responsibility to manage those potential impacts through their respective pieces of legislation.

Some state and territory governments may consider implications relating to the *Gene Technology (Recognition of Designated Areas) Principle 2003,* where for trade and marketing purposes of crops, special areas may be designated GM-free or non-GM under state or territory law.

Before submitting an application for a licence to release a GM 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. However, proponents are strongly encouraged to seek their own specialist legal and regulatory advice in conjunction with this guide.

Purpose of the guide

This guide aims to provide guidance and awareness to assist proponents with identifying the numerous regulatory and policy considerations that currently exist to manage the risks posed by environmental release of GM gene drive organisms.

The guide provides information on risk considerations under the GT Act and broader considerations outside of the GT Act, which still fall within the scope of the Scheme. These broader considerations have been described in more detail in the Additional considerations for proponents under the Scheme section of this guide and cover a range of regulatory obligations in addition to those considered by the GT Regulator. At the same time, it aims to provide clarity and certainty for investors, researchers, government agencies, and proponents who wish to develop this technology.

The information within the guide is intended to highlight roles and responsibilities and promote collaboration between the proponent and regulatory (and potentially other) agencies. All stakeholders need confidence in the overall process for the evaluation and regulatory oversight of new technologies, such as GM gene drive organisms. This guide outlines a combination of administrative and legislative processes that currently exist and is intended to provide guidance to proponents to ensure that they have considered the complete range of risk considerations; and all relevant laws that may be activated at state, territory, or Commonwealth level.

The guide is not intended to provide proponents and researchers with an exhaustive list of regulatory requirements, or to prescribe data requirements for all agencies that may be involved in assessing an application for the environmental release of a GM gene drive organism. The guide does not impose any additional regulatory requirements. **Proponents are strongly encouraged to source their own specialised independent regulatory and legal advice**.

The Gene Technology Technical Advisory Committee (GTTAC) has provided advice on the types of information that may be applicable for environmental risk assessments of GM gene drive organisms. In the context of the Office of the Gene Technology Regulator (OGTR) Risk Analysis Framework, the Gene Technology Ethics and Community Consultative Committee (GTECCC) has also considered GM gene drives in the context of the National Ethics Framework.[1,2] The advice from GTTAC and GTECCC has helped inform the Process Fundamentals and Risk Considerations Under the GT Act sections.

In addition to the existing regulatory requirements under the GT Act, the References section includes a list of resources which may be valuable for proponents to identify obligations (regulatory and administrative) outside the remit of the GT Regulator.

The guide has been developed with information available at the date of its publication. It may be revised in the future to include updated information regarding risks and safety, possibilities and limitations, alignment between state and territories or other regulatory requirements.

A set of hypothetical GM gene drive case studies are included in the guide, providing several examples of different types of potential (hypothetical) GM gene drive organisms. This may assist proponents in identifying relevant considerations for their application of this technology.

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1 Gene Technology Ethics & Community Consultative Committee, 'National Framework of Ethical Principles in Gene Technology', 2012. Viewed on 1 June 2022, https://www.ogtr.gov.au/sites/default/files/files/2021-07/national_framework_of_ethical_principles.pdf

2 Gene Technology Ethics and Community Consultative Committee, Meeting of 21 September, 5 October and 21 October 2021 Communique. 2021, viewed on 1 June 2022, 09 Mar 2022 - Communique of GTECCC meeting of 21 September, 5 and 21 October 2021 | Office of the Gene Technology Regulator - Trove

The Scheme website also provides a list of Commonwealth, state and territory legislation which may be activated by the environmental release of a GM gene drive organism. It is important to note that this list is not exhaustive, and it is recommended that proponents seek independent expert advice from relevant agencies and legal advice to assist them with identifying all relevant regulatory and policy requirements.

Process fundamentals

The 5 process fundamentals below underpin the guide and inform the considerations that are set out in *Risk Considerations under the Gene Technology Act 2000,* and *Additional Risk Assessment considerations under the Scheme* sections of the guide. These fundamentals have been developed through targeted consultation with states and territories, experts, and regulated entities.

There has been considerable international research involving contained GM gene drive organisms. The World Health Organization (WHO) and the Cartagena Protocol on Biosafety[3]; have published guidance on the responsible use of gene drives. However, there is no single international standard when it comes to the regulation of gene technology, GMOs and risk assessment measures for the environmental release of GM gene drive organisms. If international standards or additional guidelines are developed, the guide will be reassessed, if appropriate.

1. Any proposals by proponents for environmental release of a GM gene drive organism should constitute a clear public good objective in terms of either pest control, disease control/public health or species conservation.

   Proponents are required to establish the case supporting the merits of their applications. Consideration should be given to the potential scale, scope, and likelihood of potential benefits, and any plausible alternatives and their respective impacts.

   In addition to benefits, negative consequences should be acknowledged and explicitly justified, and the strengths of risk minimisation measures described. Proponents should demonstrate they have given consideration to relevant economic, environmental, and social factors.

   Numerous entities may be able to assist proponents in establishing public good. These may include:

   - relevant regulators, including biosecurity
   - agricultural, livestock, environmental and health industry peak bodies
   - non-governmental organisations
   - traditional owners of the recognised country where the proposed environmental release applies.

   Some jurisdictions may have applicable policy frameworks to demonstrate public good objectives. For example, demonstration of the public good objective in the Northern Territory context should be guided by the Northern Territory Social Outcomes Framework[4].

2. Each proposal for the environmental release of a GM gene drive organism would be assessed by the appropriate state, territory, and Commonwealth regulatory bodies, considering the process fundamentals on a case-by-case basis. In parallel, the proposal must also undergo comprehensive risk assessment(s) addressing the risk elements outlined in the guide. The proponent must consider and consult with the appropriate jurisdictional bodies on risk elements that are beyond the scope of the GT Act, in the context of state and territory legislation and policies.

[3] Biosafety, Fundamental Tool to Promote Biosafety – Decisions of the 10th Meeting of the Conference of Parties to the Convention on Biological Diversity serving as the meeting of the Parties to the Cartagena Protocol on Biosafety, Part 1 Kunming, China 2021 and Part 2 Montreal, Canada 2022, https://www.cbd.int/doc/decisions/cp-mop-10/booklets/cp-mop-10-decision-booklet-en.pdf(cbd.int)

[4] Northern Territory Social Outcomes Framework, https://cmc.nt.gov.au/__data/assets/pdf_file/0003/1002747/social-outcome-framework.pdf

3. The proponent will be required to consult with and comply with any requirements of their respective state or territory regulatory bodies, as well as the GT Regulator. For example, a proposal for an environmental release of GM gene drive organisms may require regulation and approval under separate environmental legislation, both at a Commonwealth level *(*e.g. *Environment Protection and Biodiversity Conservation Act 1999* (EPBC Act)) and on a jurisdictional level.

   Due to the possibility of GM gene drive organisms crossing state and territory borders, applicable legislation and regulatory authorisations from multiple jurisdictions may apply. Proponents may need to consider submitting applications to relevant regulators and agencies in multiple states and territories to obtain timely review of their application(s). The Scheme website provides a non-exhaustive list of potentially applicable legislation to assist proponents in identifying all respective regulatory bodies. Proponents will also need to understand, and if necessary, obtain their own legal advice on potentially applicable penalty provisions in the event of misuse or unauthorised use of this technology.

4. Proponents must consider Australia's combination of applicable Commonwealth, state, and territory legislation and policies. Currently the GT Regulator consults with other prescribed Commonwealth, state and territory regulators and agencies as part of the risk assessment process.

   Proponents must consider the approval timeframes for all applicable regulatory authorisations.

5. For any proposals for environmental release of a GM gene drive organism, proponents have a responsibility to consult widely on the comparative advantages and disadvantages of the GM gene drive organism, relative to existing measures or technologies. Despite not being a legislated requirement, the importance of community engagement and obtaining community support cannot be understated. Proponents should consider developing a communications strategy or plan before proceeding to a formal regulatory assessment. (Please refer to the Community Engagement section for further information)

   The GT Regulator undertakes consultation on identified risks and risk management for any GM gene drive application through a RARMP. The RARMP process conducted by the GT Regulator is a mandatory consultation on all applications for dealings involving intentional release (DIRs) of GMOs into the environment. RARMP consultations are separate to the public consultation with affected communities and the public that is expected to be undertaken by proponents referred to in the Community engagement section of the guide.

   Other involved regulators and state and territory governments may consult on broader matters, such as comparative benefits to existing technology, and cost comparisons to existing control approaches (or no action). Proponents and involved regulator(s) are encouraged to advise the jurisdictions of their intention to commence public consultation as part of the risk assessment process at the earliest practical opportunity and discuss the approach in advance of any announcement.

Proposed assessment process

This guide outlines criteria, requirements and additional responsibilities of a proponent wishing to use GM gene drive technology under gene technology legislation. The additional responsibilities of a proponent outlined in the guide include the need to:

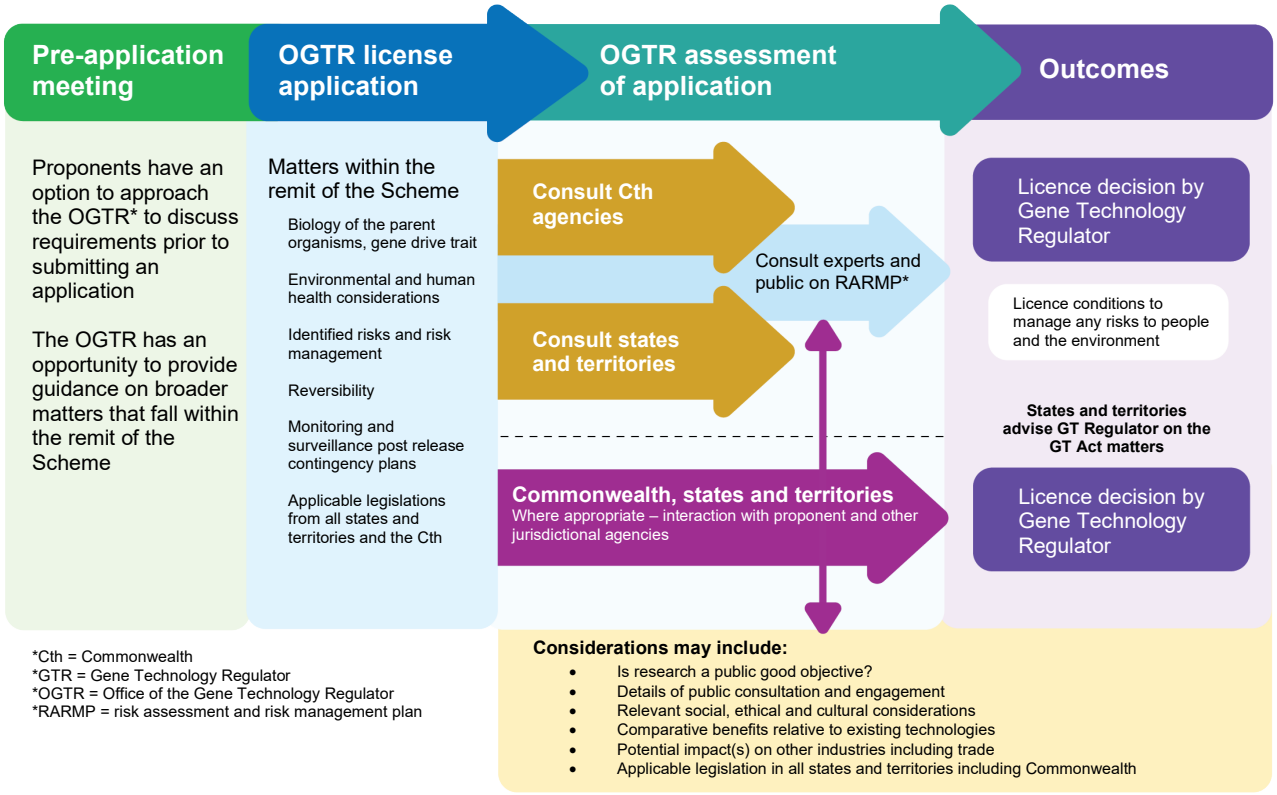
- consult with and apply to other relevant regulatory bodies for approvals
- understand obligations under other legislation which may be triggered, across all levels of government, on a case-by-case basis
- assess broader matters that are not within the remit of the Scheme and are the responsibility of a jurisdictional regulatory body.

While the guide aims to provide proponents with an understanding of what they need to consider, the list of considerations is not exhaustive, and they must take responsibility for fulfilling the conditions that their application(s) require.

A pre-application meeting between the OGTR and the proponent would facilitate timely and coordinated consideration of various matters included in the guide. **Figure 2** illustrates existing OGTR processes relating to assessment of a licence application for environmental release of a GMO, with additional content for the extra considerations associated with a GM gene drive organism.

An application may not be approved if it does not satisfy the regulatory requirements or risk assessment process(es). Proponents may be required to consult with regulatory agencies or governments on a number of occasions and may be requested to provide additional information.

Figure 2: Proposed OGTR application process for general release of a GM gene drive organism



Risk considerations under the *Gene Technology Act 2000*

This section provides proponents with a general list of risk assessment criteria for a GM gene drive licence application made to the OGTR. The risk considerations and criteria outlined in this section fall within the remit of the GT Regulator. These are established requirements that currently apply to licence applications to the GT Regulator, and do not comprise additional regulatory requirements.

In respect to some of the listed criteria below, there may be overlap with the risk considerations of other regulators. The considerations would be applied in a general sense. However, additional case-by-case risk criteria may also apply depending on the nature of the GM gene drive organism.

(i) Full details of the proponent, including all collaborators/contributors

Proponents will need to disclose details of all collaboration and contributors, given that research in this area is often conducted jointly by several organisations. Institutional Biosafety Committees (IBC) and other bodies involved in assessing the proposals for GM gene drive applications will need to demonstrate and maintain the necessary technical expertise to effectively identify risks specific to the proposal.

Where the intent is intentional release of the GM gene drive organism to the environment, the proponent should include members or collaborators/contributors that have the appropriate scientific knowledge and skills to model and assess the ecological consequences, as an integral part of the research program.

(ii) Detailed description of the purpose of the GM gene drive organism

The description would include details of reasons for selecting the target organism, or whether it is the disease vector which is the target.

(iii) Detailed description of the gene drive mechanism to be deployed

The description would provide detail of the type of gene drive mechanism being used providing schematics of the gene drive design being introduced and describe any genetic safeguards incorporated into the design.

(iv) Detailed description of the biology of the parent organism, prior to genetic modification

Detailed information on the biology of the parent organism includes any information that would inform the design of risk management practices. It also includes standard risk management practices applied to the parent organism.

(v) Detailed description of the trait to be spread through a sexually reproducing population

Similar to (iv), detailed information on the trait includes any information that would assist the design of an effective risk management strategy for the release of a GM gene drive organism.

(vi) Results of initial research, [preferably under the OGTR licence] for contained dealings within certified laboratories or glasshouse facilities

It is recommended that applications for environmental release of a GM gene drive organism should be preceded and informed by the results of initial contained research in Australia, under OGTR licence conditions, within contained certified facilities. However, this is not absolutely essential, and the GT Regulator would consider applications and their supporting information on a case-by-case basis.

In circumstances where proponents have undertaken initial research overseas, it would be beneficial to undertake research simulating Australian environmental and ecosystem conditions or justify why this is not necessary.

Proponents would be required to provide comprehensive details of the results of the initial research.

(vii) Remaining uncertainties

Risk assessments will need to recognise uncertainties and consider how those unknowns or uncertainties will be addressed.

The results of early, contained research, conducted under a license from OGTR within certified facilities, could be used in the risk assessment and address uncertainty in later work.

(viii) Environmental considerations

In the absence of direct experimental results, environmental considerations could include ecosystem modelling, reflecting the complex biological systems and their interrelationship with dynamic ecosystems. Providing detail of the organism's natural ecology, including information on relevant food webs, migration/dispersal processes, and relevant roles in the ecosystem, will assist with demonstrating potential ecological flow-on effects. 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.

This criterion may also fall with other regulators. The GT Regulator would seek the advice of other regulators, including the Australian Government Department of Agriculture, Fisheries and Forestry (DAFF), and the Australian Government Department of Climate Change, Energy, the Environment and Water (DCCEEW). DAFF and DCCEEW may also consider broader environmental impact of GM gene drive organisms under their own legislation. The statutory advisory committee GTTAC would also be consulted.

(ix) Human health considerations

Human health considerations depend on whether these issues are applicable to the particular GM gene drive organism in the proposal. Proponents would be expected to demonstrate that the release would not have a negative effect on human health.

(x) Identified risks and risks management

Proponents would address physical, reproductive, and ecological containment measures and any other safeguards which can be employed to mitigate potential ecological and environmental risks.

(xi) Reversibility

Proponents would disclose whether or not the GM gene drive organism has been designed to stop after a few generations, in order to limit the ability of the organism to spread. Any other attributes related to reversibility, or molecular confinement, must be included as these will be central to assessing the risks.

(xii) Compliance monitoring post release

Proponents must undertake to comply with licence conditions imposed by the GT Regulator.

(xiii) Contingency plan

Information regarding a contingency plan would be considered as part of developing the OGTR RARMP.

Additional considerations for proponents under the Scheme

Proponents wishing to use GM gene drive technology have additional regulatory responsibilities they must satisfy outside the purview of the GT Act, but within the scope of the Scheme. These are obligations which currently apply in numerous pieces of Commonwealth, state and territory legislation. These are not requirements for a licence application with the OGTR. However, these requirements may apply as part of the assessment by other government departments and agencies.

The responsibility to assess the considerations outlined in this part of the guide fall under the remit of other regulators, the jurisdictions that are party to the Scheme, and ultimately users of the technology.

With respect to some of the listed considerations, there is some overlap with the GT Regulator. It is the responsibility of the relevant bodies to separately assess whether the proponent has satisfied the specific criteria within their responsibility and communicate with other regulators, as necessary.

It should be noted that these considerations are not additional regulatory obligations, and the listed criteria are not exhaustive. Additional factors may be required to be considered by proponents to proceed with their applications on a case by-case basis. Detailed and case specific data requirements can be obtained through consultation with the OGTR.

Due to the intersection of Commonwealth, state and territory legislative and policy requirements, regulation is highly complex and evolving. This list is not exhaustive, and proponents are strongly encouraged to seek their own specialist legal advice in conjunction with this guide.

The following are some of the risk assessment considerations which must be addressed by proponents, but which fall outside of the responsibility of the GT Regulator.

(xiv) Statement of Intent

A clear statement attesting to the aim of the proponent to pursue research which promotes public good and social value. Such research should demonstrate high quality science, ethical integrity and respect for the broader ecosystem.

(xv) Comparative benefits relative to existing technologies

Gene technology that enables the propagation of modified gene drives within a wild or domestic population of plants or animals, presents new opportunities for pest and disease control. While precautions should apply where environmental or economic risks cannot be mitigated, it is possible that in some instances the introduction of modified gene drives may be relatively uncontentious. However, in all instances it will be important to understand the linkages between environmental, economic and social impacts, in order to understand the possible outcomes of environmental release of a GM gene drive organism and establish appropriate safeguards.

A detailed description of the comparative benefits, relative to existing technologies, will be central to demonstrating value during community engagement. Building trust through ongoing engagement will also be important in advance of consideration by relevant regulatory agencies at the Commonwealth or state and territory level.

Other regulators, national industry bodies, national environmental bodies, state and territory governments or agencies may play a role in assessing the comparative benefits of GM gene drives compared to existing control measures.

In demonstrating comparative benefits to existing technology, proponents will need to consider the scope, duration and scale of potential benefits. This may include economic assessment comparing the cost of alternatives (including no action), and consideration of stakeholder input.

Some factors which may be required to demonstrate comparative benefits include:

- species dispersal information
- impacts on agricultural production
- impacts on human health
- impacts on trade
- impacts on biological diversity
- impacts on threatened species.

(xvi) Potential impact on other industries, including effects on international trade and the effect on any industries, either directly or indirectly affected by the release of a GM gene drive organism

Proponents will be required to consult extensively with potentially affected national trade and industry bodies on the real or perceived impacts that the environmental release of a GM gene drive organism could have on international trade. Various Commonwealth agencies, including the Australian Government Department of Foreign Affairs and Trade (DFAT) and DAFF, may have applicable regulatory requirements which must also be considered.

Consideration also needs to be given to other relevant factors, including impact on the livestock sector, risks posed by modified virus vector to impact on wildlife, domestic or wild populations, and any impact that would have on relevant trading partners.

Examples include fruit flies and how the release of a GM gene drive fruit fly would be received in Australia's major fruit export markets. Trade considerations include both direct effects as well as indirect effects. If the GM gene drive organism could be present in export commodities as a 'contaminant', this could still have the potential to create trade sensitivities.

It is important to note that current monitoring of sanitary and phytosanitary measures under the WTO agreement may not be considered sufficient by all international trading partners. In addition to international trade, proponents may need to consider relevant state and territory trade, border and biosecurity requirements.

This criterion also falls with other regulators. Relevant state and territory agencies may also play a role in considering the potential impacts of GM gene drives on other industries. Proponents should anticipate that states and territories may provide additional scrutiny and feedback on matters pertaining to trade.

(xvii) Monitoring and surveillance post release

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. Post-release surveillance should be planned and executed to detect movement and introgression of the genetic construct within targeted species, ongoing efficacy, and any unintended changes in the biology of the target species that may result in adverse effects on health or the environment.

Some aspects of this requirement fall within the remit of the GT Regulator. However, there is opportunity for its consideration by other regulators, agencies and bodies including:

- Commonwealth and state government biosecurity and environmental departments
- non-government agencies who have surveillance functions
- special interest groups (e.g., veterinarians, land care groups, farmers).

(xviii) Contingency plan

A contingency plan will assist proponents to prepare for any foreseeable incidents that could eventuate from an identified risk, by providing background information on the biology of the GM gene drive organism and available control measures for that organism.

(xix) Applicable legislation from all states, territories and the Commonwealth

Proponents will be required to identify relevant pieces of legislation that need to be considered by the proposal. As owners of the technology, the proponents should be aware of the regulatory requirements that apply to their research operation. The Scheme website provides a non-exhaustive list of potentially applicable legislation.

(xx) Environmental and human health considerations

In addition to falling within the responsibilities of the GT Regulator, this criterion also falls with other regulators. The GT Regulator would seek the advice of other regulators including DAFF and DCCEEW, as well as obtaining advice from GTTAC. The DAFF and DCCEEW may also consider broader environmental and human health impacts of a GM gene drive organism under their own legislation.

Human health considerations depend on whether these issues are applicable to the particular GM gene drive organism in the proposal.

At a jurisdictional level, departments and agencies responsible for agriculture, environmental protection and wildlife management may be involved in assessing environmental considerations.

The potential for inter-species transfer should be considered. For example, release of a GM gene drive organism to address population of field mice should ensure that there is no possibility of impacts on *Antechinus spp*. (marsupial mouse) populations.

Some environmental factors that proponents will need to consider include:

- closely related species
- species that may directly interact with target species, including predators and prey
- known parasites and species also affected by the same species of parasites
- target animal diseases and other species affected by the same target animal disease
- impacts on the extended ecosystem
- impacts on the food system.

The following types of information could support proponents' applications in demonstrating they have addressed environmental considerations:

- environmental assessment reports
- small greenhouse assessment data
- data generated by specialist consultancy
- relevant peer reviewed data
- overseas data (where relevant).

The results of early, contained research, conducted under a license from OGTR within certified facilities, could be used to identify and reduce uncertainty in later work. For example, uncertainties identified in the initial risk assessment process need to be scientifically assessed during the contained dealings and the findings used to best inform the risk assessment plans for proposed environmental releases.

Table 1: Parties who may be involved in considering certain criteria

	Proponent	GT Regulator	Other regulators	State and territory governments	Australian Government Portfolio Agencies
Statement of intent	✓				
Details of public engagement and consultation*	✓	✓	✓		
Social, ethical and cultural considerations	✓		✓	✓	✓
Comparative benefits relative to existing technology	✓		✓		
Potential impact on other industries including international trade ##	✓		✓	✓	✓
Monitoring and surveillance post release **	✓	✓	✓	✓	✓
Contingency planning	✓	✓	✓	✓	✓
Applicable state and territory legislation	✓			✓	
Environmental considerations ***	✓	✓	✓	✓	✓
Human health considerations	✓	✓	✓	✓	✓

* The GT Regulator also has responsibility for this criterion through consultation on the RARMP only.

** The GT Regulator also has some overlapping responsibilities for this criterion.

*** Environmental considerations also fall within the scope of the GT Act.

Portfolio agencies may include biosecurity, environment, industry.

National industry bodies may play a role in potential impacts on other industries including international trade, communication, advocacy and system development

Community Engagement

Community engagement plays a critical role in the successful approval and implementation of scientific innovations and applications. It ensures that affected communities and stakeholders are informed, consulted, and involved in the decision-making process. This not only helps to build understanding and trust but also fosters transparency and accountability.

Engaging with the community early and consistently allows proponents to identify concerns, values, and expectations, which can then be addressed through project design and communication.

Community engagement is often referred to as obtaining a 'social licence to operate' - a term used to describe the informal, ongoing approval and acceptance granted by the public and stakeholders. Unlike formal regulatory approvals, social licence is earned through meaningful relationships, responsiveness, and demonstrated benefit to the community.

For the purposes of this guide, the term 'reasonable social licence' is taken to mean *"evidence that a proponent has taken the necessary steps to disclose and secure broad public support for three overarching elements: **validity** of their proposal based on comparative benefits over existing technology, the **credibility** based on science and **trust** based on the way they operate as a public entity".*

It is important to recognise that community engagement and efforts to obtain social licence are not requirements under gene technology legislation. These activities are separate to the mandatory public consultation undertaken by the OGTR. It is the responsibility of the proponent to demonstrate the value of their project and secure community support. Social licence is not a formal or legal 'licence' that is granted or approved, but rather is a concept that reflects the extent of community engagement with an organisation's operations or specific proposals. Achieving this will require a significant investment of time and effort on the part of proponents. However, lessons learnt from the previous release of new technologies have shown that public engagement and industry involvement is critical to the longer-term community understanding (including modification where necessary) of new technology.

It should be noted that community engagement is not just a procedural step, it is a strategic and ethical imperative for sustainable innovations. It is strongly recommended that proponents have an ongoing communications strategy to provide transparency and build trust with potentially impacted communities and the broader public. Without community engagement, even scientifically sound and legally compliant projects may face delays, opposition or reputational risk.

How a proponent goes about engaging the community, and the appropriate timing for consultation activities or communications, may vary between applications.

Guidance on community engagement or engagement with other advisory bodies may be provided by relevant regulators. Proponents may also wish to engage with communications experts, or specialist ethicists (or ethics committees) from medical or agricultural research institutions for advice on establishing social licence.

Public engagement and consultation on the GM gene drive organism undertaken by the proponent

Obtaining community support for the release of a GM gene drive organism requires building trust through meaningful engagement, transparency, and responsiveness to community concerns. In Australia, this typically means engaging First Nations communities, local stakeholders, and the broader public, early in the development process.

Approaches such as co-design, public consultation, and independent ethical reviews can help ensure that scientific technologies align with societal values and expectations. For example, Commonwealth Scientific and Industrial Research Organisation's (CSIRO) consultation on gene drive technologies for pest control has featured extensive community engagement and ethical assessments to address concerns around ecological impact and consent. By prioritising dialogue over regulatory compliance alone, developers can foster a sense of shared ownership and legitimacy - key ingredients for earning and maintaining social trust.

There will be an expectation by potentially impacted communities and governments that proponents have been through a structured process of public consultation and engagement, especially in the areas likely to be impacted if the application for a GM gene drive is intended for environmental release. It should be noted that the quality of, and commitment to, the public consultation process is as important as the technical and scientific considerations associated with the GM gene drive organism.

Good community engagement requires a proactive, inclusive, and transparent approach. Proponents should ensure they have considered reasonable arguments and concerns, presented sufficient evidence and information, and that any information shared with the community is clearly explained.

Key steps may include:

- Early engagement – initiate dialogue with affected communities prior to finalising project planning
- Stakeholder mapping – identify all relevant and affected groups, including First Nations communities, local residents, councils, and environmental organisations
- Transparent communication – share clear, accessible information outlining the project's purpose, risks, and benefits
- Feedback mechanisms – provide multiple channels for community input (e.g. surveys, town hall meetings, online platforms) and ensure responses are acknowledged
- Benefit-sharing – identify if the application offers tangible benefits, such as local employment, infrastructure investment, environmental benefits, or community grants
- Ongoing engagement – maintain communication throughout the project lifecycle and adapt plans in response to community feedback.

Effective methods to engage with the community may include:

- public forums that combine in-person and digital participation
- education and awareness campaigns to inform the community
- consultation with relevant experts and use of peer reviewed processes
- engagement with national industry bodies impacted by the project
- direct engagement with local communities and traditional owners.

Proponents should also determine the most appropriate timing for community engagement to avoid adverse sentiment arising from the community having insufficient visibility of risk assessments having been conducted. Early consultation helps builds trust and may facilitate community support as well as help to inform risk management measures. Proponents should ensure that sufficient evidence is available to support how any identified risks will be managed. Further scientific assessment and public consultation may be necessary to ensure that any additional identified risks can also be managed.

Proponents should be able to demonstrate that they have made efforts to identify and consult meaningfully with all relevant stakeholders and have allowed sufficient time for appropriate consultation processes. The use of interpreters may be appropriate in some circumstances.

Outcomes of public engagement and consultation should be presented in language that is inclusive and accessible. If international assessments or consultations have been conducted on a similar GM gene drive organism overseas, this information should also be presented if available.

Where groups or individuals raise specific ideological concerns without plausible mechanisms for negative impact, these should be respectfully acknowledged and addressed with relevant information.

Social, ethical, and cultural considerations

Proponents should carefully consider the social, ethical, and cultural dimensions of the environmental release of a GM gene drive organism. This may include consideration of relevant international conventions, ethical research principles, and securing free, prior and informed consent[5] from First Nations peoples. Some relevant international conventions may include the United Nations Convention on Biological Diversity, and the United Nations Declaration on the Rights of Indigenous People. Comprehensive consultation with First Nations peoples – including local Traditional Owners, Elders and Land Councils – should form a key part of these considerations. Sufficient time should be allocated to ensure that consultation is thorough and culturally appropriate.

The approach to consultation should be guided by existing best practice strategies in science engagement employed by leading scientific and research organisations in Australia. The various *Community Attitudes Reports* published by the OGTR may be a useful resource to support the development of an appropriate communication strategy.

[5] *Articulating 'free, prior and informed consent' (FPIC) for engineered gene drives* Dalton R George, Todd Kuiken and Jason A Delbourne 2019. https://pubmed.ncbi.nlm.nih.gov/31847781/

Hypothetical GM gene drive case studies

Different applications of GM gene drives could have different regulatory requirements. The GT Regulator will assess applications based on the specific circumstances, including any unique risks they may pose.

These hypothetical case studies provide an example of the many different considerations and how these may vary depending on the application of a GM gene drive (or other applications for environmental release of GMOs).

Note that the hypothetical case studies below are examples only. Proponents would need to consult the GT Regulator about their individual requirements.

Hypothetical GM gene drive / environmental release case study 1

Scenario 1: Gene Drive Fruit Fly

These scenarios have been developed to provide guidance to proponents and are hypothetical only. These scenarios are intended to demonstrate the regulatory requirements and risk considerations which may apply depending on the GM gene drive organism that is proposed to be deployed.

Introduction

Australia has two economically significant fruit fly species - the Queensland fruit fly *(Bactrocera tryoni* 'Qfly') and the Mediterranean fruit fly *(Ceratitis capitata* 'Medfly'). According to DAFF, fruit flies cost Australia hundreds of millions of dollars per year in control measures and lost access to international markets.[6]

Fruit fly management is carried out by the Commonwealth and jurisdictional governments under the guidance of the Australian National Fruit Fly Management Protocols. This includes the maintenance of Pest Free Areas (PFAs) in Tasmania and the Riverland region of South Australia.[7]

The aims of the *National Fruit Fly Strategy 2020-2025*, developed by the National Fruit Fly Council, are "reducing the risk of exotic fruit fly incursion, effective and efficient management of established fruit fly species, and a robust national system to manage risk and underpin market access."[8]

Fruit fly management usually involves the use of agrichemicals and/or netting. This includes cover spraying[9], bait spraying, and other methods.

[6] Fruit fly economic studies - DAFF
[7] Managing fruit flies in Australia - DAFF
[8] National-Fruit-Fly-Strategy-2020-25.pdf (preventfruitfly.com.au)
[9] Control methods | National Fruit Fly Council (preventfruitfly.com.au)

The Sterile Insect Technique (SIT) has also been very effective for managing fruit fly populations. It involves rearing sterile male flies by irradiating the pupae with x-rays and releasing them into the wild to mate with wild type females, leading to a reduction in fruit fly populations. SIT have been used to eradicate Qfly and Medfly from NSW, VIC, SA and WA, and to control fruit fly outbreaks, including in PFAs.[10] Whilst irradiation is not classed as genetic modification under the GT Act, the use of SIT establishes a precedent for the release of modified fruit fly into the environment to control fruit fly numbers.

Gene Drive

In 2021, Meccariello et al.[11] published the first demonstration of a gene drive in Medfly. This gene drive works using the 'X-shredding' system, which interferes with the transmission of the X-chromosome to offspring by introducing multiple DNA double-stranded breaks during male meiosis. This results in predominantly male progeny.

The authors noted however that the male to female ratio achieved by this gene drive would not be sufficient for use in the field, necessitating further work to improve the gene drive system.

Other gene drives systems have been developed in fruit fly not found in Australia, such as in the model organism *Drosophila melanogaster*[12], and the crop pest *Drosophila suzukii.*[13]

The OGTR issued a licence in 2021 authorising contained research to explore split gene drive designs in Australia using *Drosophila melanogaster* as a model organism.

[10] https://www.agriculture.gov.au/biosecurity-trade/pests-diseases-weeds/fruit-flies-australia/management/sterile-insect-technique
[11] https://bmcbiol.biomedcentral.com/articles/10.1186/s12915-021-01010-7
[12] A nickase Cas9 gene-drive system promotes super-Mendelian inheritance in Drosophila – PMC (nih.gov)
[13] https://www.pnas.org/doi/10.1073/pnas.1713139115

Hypothetical GM gene drive / environmental release case study 2

Scenario 2: Gene Drive Mouse

These scenarios have been developed to provide guidance to proponents and are hypothetical only. These scenarios are intended to demonstrate the regulatory requirements and risk considerations which may apply, depending on the GM gene drive organism that is proposed to be deployed.

Introduction

High mouse populations can cause significant crop damage, with Australia's worst ever mouse plague in 1993 causing an estimated $96 million worth of damage. Higher populations of mice are becoming a persistent problem, rather than the previous boom and bust population trends.[14]

Baiting is the primary strategy used to manage mice in Australia.[15] Zinc phosphide is commonly used for mouse baits and is highly toxic if acute exposures occur to humans through preparation and handling of baits. Baiting can be expensive, with baiting costs exceeding $150,000 for some farmers during the 2021 eastern Australia mouse plague[16]. Whilst financial support is available for farmers affected by mice infestation[17], there is no centralised management strategy for mouse management in Australia.

[14] https://www.csiro.au/en/research/animals/pests/mouse-control
[15] Managing mice on your property - DAFF
[16] Emergency permit allows farmers battling Australian mouse plague to use double-strength bait | Rural and regional Australia | The Guardian
[17] Financial assistance and support for farmers - DAFF

Gene Drive

Researchers at the University of Adelaide have developed the first gene drive in mammals, which introduces female infertility in the common house mouse *(Mus musculus).* This gene drive modifies a naturally occurring gene drive element, known as the f haplotype, to spread faulty copies of a female fertility gene.

This means that females are progressively reduced from the population, leading to the suppression of mouse numbers. However, the authors noted that many other factors, such as possible resistance, still require thorough exploration before deployment.[18] The authors also used computer modelling to determine the effectiveness of the system.

It was predicted that introducing 256 gene drive mice into a population of 200,000 mice on an island would lead to eradication of all mice from the island in approximately 25 years.[19]

The OGTR issued a licence in 2020 authorising contained research into genetic methods to control invasive pest mice by spreading mutations that cause infertility, embryonic death or bias the sex of offspring.

[18] https://www.pnas.org/doi/10.1073/pnas.2213308119
[19] https://www.abc.net.au/news/2022-11-10/university-of-adelaide-gene-drive-technologymice-control/101639638

Hypothetical GM gene drive / environmental release case study 3

Scenario 3: Gene Drive Mosquito

These scenarios have been developed to provide guidance to proponents and are hypothetical only. These scenarios are intended to demonstrate the regulatory requirements and risk considerations which may apply depending on the GM gene drive organism that is proposed to be deployed.

Introduction

Ross River virus (RRV) infections are the most common mosquito-borne infection in Australia with the largest recorded epidemic occurring in 2014-2015, with 9544 cases reported in 2015.[20] At least 40 mosquito species are thought to carry RRV, including several *Aedes* mosquitoes.[21]

Another mosquito-borne illness is dengue virus infection (also called dengue fever). It is commonly more severe than RRV, with symptoms that are similar to a serious case of the flu. It is carried by either the *Aedes aegypti* or the *Aedes albopictus* mosquito[22]. The number of cases of dengue fever per year in Australia is quite low since vector mosquitoes are only found in limited areas in Queensland,[23] with the WHO reporting 188 cases in 2022 as of 6 October.[24]

Clinical trials are being conducted using live vaccines containing attenuated dengue virus. However, currently mosquito-borne diseases in Australia, RRV and dengue fever are controlled by preventing bites and managing mosquito numbers.

[20] https://bmcinfectdis.biomedcentral.com/articles/10.1186/s12879-020-05411-x
[21] https://bmcinfectdis.biomedcentral.com/articles/10.1186/s12879-020-05411-x
[22] https://www.cdc.gov/dengue/index.html
[23] https://www.health.qld.gov.au/clinical-practice/guidelines-procedures/diseases-infection/diseases/mosquito-borne/dengue/virus-fever
[24] https://www.who.int/docs/default-source/wpro---documents/emergency/surveillance/dengue/dengue-20221006.pdf?sfvrsn=fc80101d_124

Protective[25] measures include wearing protective clothing and mosquito repellent, avoiding mosquito ridden areas especially at dawn and dusk, and using insecticides.

There has also been a trial in Northern Queensland to minimise mosquito numbers by releasing male mosquitoes infected with *Wolbachia,* bacteria that is harmless in humans but affects reproduction in mosquitoes.[26] This project has had a significant impact on dengue transmission, with no evidence of transmission in areas with high *Wolbachia* levels.[27]

Gene Drive

Gene drive mosquitoes are probably the most extensively researched gene drive system, with CRISPR gene drives investigated for both population suppression and to reduce pathogen transmission.[28] Whilst much of the research to date relates to the *Anopheles* mosquito, the vector for malaria, there has been some research into the use of gene drives for dengue fever suppression.

In 2020, Ming *et al.*[29] reported a gene drive system in *Aedes aegypti* mosquitoes, the principal vector for dengue virus. This gene drive uses CRISPR to spread anti-pathogen effector genes through the mosquito population and has transmission rates of up to 94%. In addition, it is a “split gene drive”, meaning two critical components of the gene drive are split into different organisms. This reduces the chance the gene drive will spread into neighbouring mosquito populations and means the gene drive can be eliminated from the population over time. The authors suggested that these features could enable safe testing in the field prior to release of a non-split gene drive.

Whilst Ming *et al.* focused on the ability for the gene drive to prevent dengue virus infections, it may also be applicable to RRV, which can be spread by *Aedes aegypti* mosquitoes.[30]

[25] https://journals.asm.org/doi/10.1128/CVI.00546-14?url_ver=Z39.88-2003&rfr_id=ori:rid:crossref.org&rfr_dat=cr_pub%20%200pubmed
[26] https://ecos.csiro.au/preventing-mosquito-borne-diseases/
[27] World Mosquito Program in Australia: Combating Mosquito-Borne Diseases with *Wolbachia*
[28] https://www.nature.com/articles/s41467-021-24654-z
[29] https://elifesciences.org/articles/51701
[30] https://pubmed.ncbi.nlm.nih.gov/7325287/

Hypothetical GM gene drive / environmental release case study 4

Scenario 4: Rescue drive for frogs

These scenarios have been developed to provide guidance to proponents and are hypothetical only. These scenarios are intended to demonstrate the regulatory requirements and risk considerations which may apply, depending on the GM gene drive organism that is proposed to be deployed.

Introduction

The chytrid fungus *Batrachochytrium dendrobatidis* causes the amphibian disease chytridiomycosis, which has resulted in huge population losses and local extinctions, having a 100% mortality rate in some populations.[31] Chytridiomycosis was first identified in 1993 in Queensland, but has since been shown to be found in cool and wet areas throughout Australia, with exception of the NT. The chytrid fungus has been directly linked to the extinction of 4 frog species in Australia and has been implicated in the decline of at least 10 others, including the southern corroboree frog.[32]

The strategies to mitigate the impacts of the chytrid fungus are incredibly limited[33], and in Australia largely focus on preventing the spread of the disease to unaffected areas.[34] This leaves populations that are currently affected vulnerable. The chytrid fungus is listed as a key threatening process under the Commonwealth *EPBC Act.* A national Threat Abatement Plan was developed in 2016, which included four main objectives, two of which pertained to building scientific capacity and developing research around chytrid fungus management.[35]

[31] https://journals.plos.org/plospathogens/article?id=10.1371/journal.ppat.1000550#:~:text=One%20of%20the%20most%20dramatic,and%20local%20extinctions%20%5B3%5D

[32] https://www.dcceew.gov.au/sites/default/files/documents/c-disease_1.pdf

[33] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5095549

[34] https://www.dcceew.gov.au/sites/default/files/documents/c-disease_1.pdf

[35] Chytrid amphibian fungus – Chytridiomycosis - DCCEEW

Gene Drive

Whilst the gene drives discussed in the other scenarios involve eliminating a pest species or removing an undesirable trait, gene drives may also have a possible function to conserve threatened species by introducing beneficial alleles.[36] These gene drives are known as ‘rescue drives'.

The chytrid fungus reproduces mainly asexually so cannot be targeted with a gene drive. However, it may be possible to use a gene drive to introduce resistance to the fungus into affected frog species.[37] It has been shown that introducing changes to the Major Histocompatibility Complex (MHC) increases the likelihood that infected frogs will survive fungal infection.[38] If changes to the MHC could be made into a gene drive, it would be possible to rapidly spread resistance to the chytrid fungus throughout frog populations.

However, these changes have yet to be converted into a gene drive system. Even if a gene drive could be generated, there are several other factors that may influence the use of such a gene drive. Firstly, reducing diversity of the MHC gene within a frog species may have the unintended consequence of making the frogs more susceptible to other pathogens.[39] In addition, it is possible that making genetic changes to native species, rather than pest organisms, could be viewed more negatively by the general public.

[36] https://royalsocietypublishing.org/doi/10.1098/rspb.2019.2709
[37] https://link.springer.com/article/10.1007/s10592-019-01165-5
[38] https://www.pnas.org/doi/10.1073/pnas.1106893108
[39] https://link.springer.com/article/10.1007/s10592-019-01165-5

Potential regulatory touchpoints

Table 2 outlines the potential regulatory touchpoints of the various case study scenarios.

Table 2

		Scenario 1	Scenario 2	Scenario 3	Scenario 4
Regulatory Touchpoints	**Explanation**	**Gene Drive Fruit Fly**	**Gene Drive Mouse**	**Gene Drive Mosquitoes**	**Rescue Drive for frogs**
Gene Technology Regulation	The GT Regulator will consider all gene drive applications in accordance with the GT Act. However, jurisdictional gene technology regulation may also be triggered or enacted by the environmental release of gene drives, including under the Designated Areas Principle, which is the ability for the jurisdictions to designate 'GM areas' and 'non-GM areas.	✓	✓	✓	✓
Agricultural implications	Gene drive pest control, and the control of agricultural pathogens, will have a considerable impact on the agricultural sector. As such, agricultural legislation, on both a Commonwealth and jurisdictional level, may be enacted or triggered by the environmental release of gene drives. This may include relevant Animal Ethics Committee approvals.	✓	✓		✓
Food implications	Whilst at this point it is unlikely GM gene drives will be used in food crops/animals, there is the possibility that GM gene drive organisms could interact with food products, potentially triggering food legislation or regulation by Food Standards Australia New Zealand.	✓	✓		

		Scenario 1	Scenario 2	Scenario 3	Scenario 4
Regulatory Touchpoints	**Explanation**	**Gene Drive Fruit Fly**	**Gene Drive Mouse**	**Gene Drive Mosquitoes**	**Rescue Drive for frogs**
Environmental implications	The environmental release of gene drives is likely to impact environmental legislation and regulation, both on the Commonwealth and on a jurisdictional level. For example, GM gene drive organisms may fall under the EPBC Act. Examples of the environmental impacts of GM gene drives include: • If a GM gene drive causes the elimination of a particular species from an ecosystem, this could have serious implications for the broader biodiversity of that ecosystem, especially if the GM gene drive organism is a species. • There is a remote potential for gene drives to jump to other species, including native species.	✓	✓	✓	✓
Trade implications	Gene drives may also impact on trade, as regulations in other countries may prohibit the purchase of products that could be affected by gene drives (e.g. fruit that could potentially contain gene drive fruit fly larvae).	✓	✓		
Human health implications	Gene drives have the potential to impact on human health if the GM gene drive organism is a vector for human disease, or if the GM gene drive organism can cause human disease.			✓	

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