National Gene Technology Scheme
An Australian, State and Territory Governments Collaboration

CONSULTATION DRAFT

National Gene Drive Policy Guide

DECEMBER 2023

Consultation Draft National Gene Drive Policy Guide

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 recognise the inherent strengths and knowledge Aboriginal and Torres Strait Islander peoples provide to the health and aged care system and thank them for their existing and ongoing contributions to the wider community. We extend this gratitude to all health and aged care workers who contribute to improving health and wellbeing outcomes with, and for, First Nations peoples and communities.

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.

Contents

1. Overview

Background to the development of the Policy 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 (Policy Guide) cannot be considered in isolation. Other intersecting Review Recommendations are integrally linked, including Recommendations 2, 19 and 21 which states:

- 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).

Genetically modified gene drive (GM gene drive) organisms

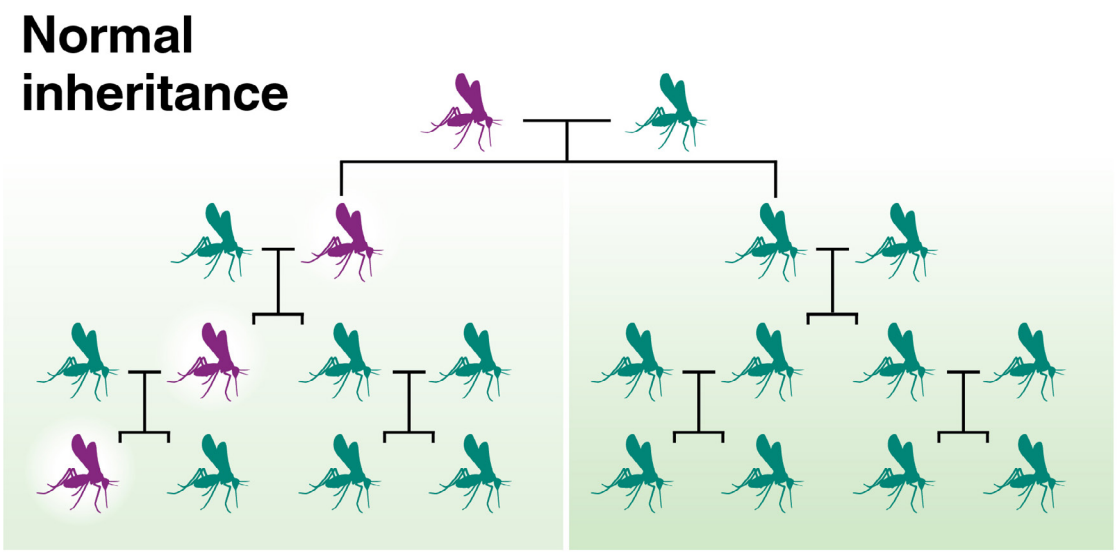
The term gene drive is used to describe organisms which have been genetically modified to increase the rate for a particular trait to spread through a sexually reproducing population, spreading the genes or traits through a species at a faster rate than normal inheritance. An example might be a trait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

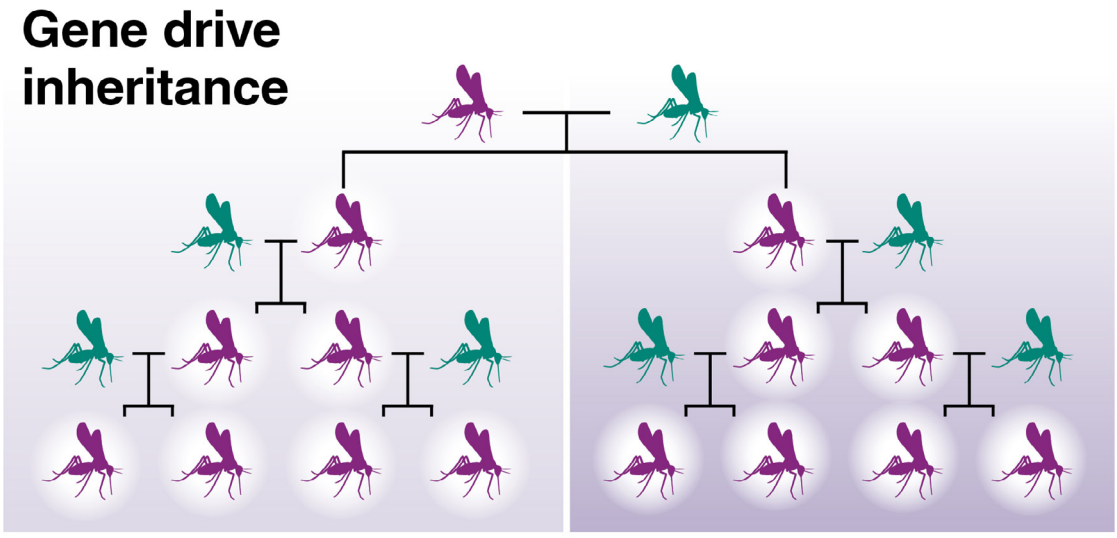
The concept of a gene drive is not a new one; these dominant genes – sometimes called selfish genes – are abundant in nature. However, GM gene drive organisms have the potential to be useful for addressing some of the environmental, agricultural, and public health challenges currently faced by Australia, such as 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.

What are gene drives?

The images below provide an example of what the difference between normal inheritance and gene drive inheritance may look like.





For more information and case studies visit www.genetechnology.gov.au

Regulation of gene drive organisms

Information on the operation of the Scheme and the regulation of GMO's generally is available on the National Gene Technology 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.

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 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 Regulator may impose conditions that are 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.

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 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.

2. 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. 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 need for clear guidance applies to proponents of this technology, the public, and particularly affected communities. It is intended to highlight roles and responsibilities and promote collaboration between 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 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 Section 3 – Process Fundamentals and Section 4 – Risk Considerations Under the GT Act.

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, https://www.ogtr.gov.au/sites/default/files/2022-02/gteccc-15-records-communique-21_september_5_and_21_october_2021.pdf

In addition to the existing regulatory requirements under the GT Act, Section 6 of this Guide 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 Scheme website provides an overview of a number of hypothetical different types of potential GM gene drive organisms which may assist proponents in identifying relevant considerations for their application of this technology.

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.

Q1: Does this section provide sufficient description to assist proponents, regulated entities and the public to understand the purpose of the Guide?

3. Process fundamentals

The process fundamentals below underpin the Guide and inform the considerations that are set out in Section 5 – *Criteria for Risk Assessment under the Gene Technology Act 2000*, and Section 6 – *Additional Risk Assessment considerations under the Scheme*. These fundamentals have been developed through targeted consultation with states and territories, experts, and regulated entities.

There is currently no specific policy guidance in the form of international standards or guidelines for the risk assessment of GM gene drive organisms. If international standards or guidelines are developed, the Guide will be reassessed, if appropriate.

3.1 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. For example, demonstration of the public good objective in the Northern Territory context should be guided by the Northern Territory Social Outcomes Framework.

3.2 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 GT Act, in the context of state/territory legislation and policies.

3.3 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 drives may require regulation and approval under separate environmental legislation, both at a Commonwealth level (*Environment Protection and Biodiversity Conservation Act 1999*) 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 and 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.

3.4 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 give consideration to the approval timeframes for all applicable regulatory authorisations.

3.5 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. They should establish reasonable social licence to proceed to a formal regulatory assessment. (Please refer to Section 7)

The GT Regulator undertakes consultation on identified risks and risk management for any GM gene drive application – through a Risk Assessment and Risk Management Plan (RARMP). 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.

Q2: 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?

4. Proposed assessment process

This Guide outlines criteria, requirements and additional responsibilities of a proponent wishing to use GM gene drive technology under current 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.

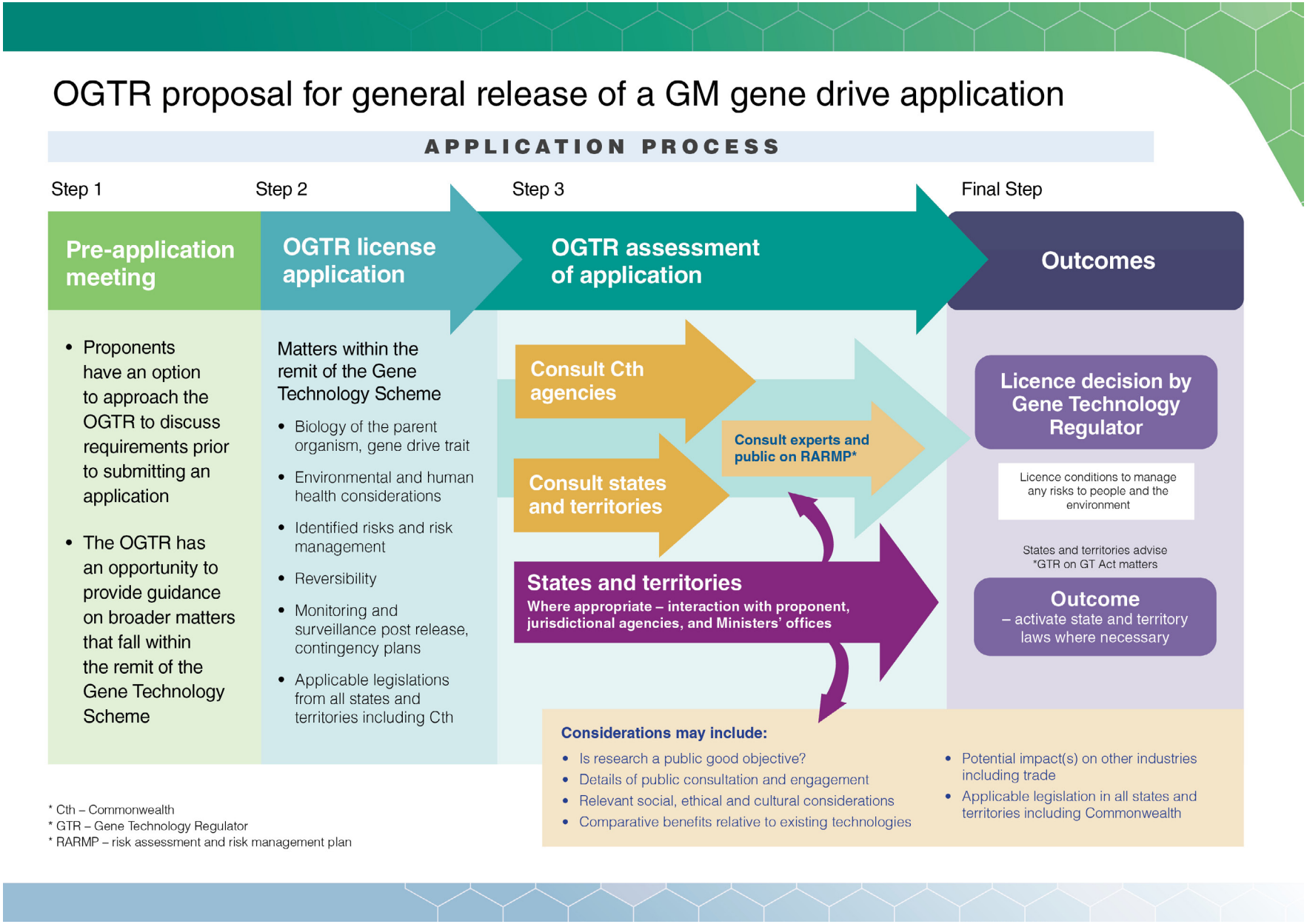
It should be noted that while the Guide aims to provide proponents with an understanding of what they need to consider, the list of considerations is not exhaustive, and they must take responsibility for fulfilling the conditions that their application(s) require.

A pre-application meeting between the OGTR and the proponent would facilitate timely and coordinated consideration of various matters included in the Guide. **Figure 1** illustrates the proposed process for assessing environmental release of GM gene drives.

This diagram represents existing OGTR processes relating to assessment of a licence application.

Q3: Does this diagram below assist proponents, researchers, academics, and regulated entities with understanding of the existing OGTR assessment process?

Figure 1:


OGTR proposal for general release of a GM gene drive application
APPLICATION PROCESS
Step 1
Pre-application meeting
• Proponents have an option to approach the OGTR to discuss requirements prior to submitting an application
• The OGTR has an opportunity to provide guidance on broader matters that fall within the remit of the Gene Technology Scheme
Step 2
OGTR license application
Matters within the remit of the Gene Technology Scheme
• Biology of the parent organism, gene drive trait
• Environmental and human health considerations
• Identified risks and risk management
• Reversibility
• Monitoring and surveillance post release, contingency plans
• Applicable legislations from all states and territories including Cth
Step 3
OGTR assessment of application
Consult Cth agencies
Consult states and territories
Consult experts and public on RARMP*
States and territories
Where appropriate – interaction with proponent, jurisdictional agencies, and Ministers' offices
Considerations may include:
• Is research a public good objective?
• Details of public consultation and engagement
• Relevant social, ethical and cultural considerations
• Comparative benefits relative to existing technologies
• Potential impact(s) on other industries including trade
• Applicable legislation in all states and territories including Commonwealth
Final Step
Outcomes
Licence decision by Gene Technology Regulator
Licence conditions to manage any risks to people and the environment
States and territories advise *GTR on GT Act matters
Outcome
– activate state and territory laws where necessary
* Cth – Commonwealth
* GTR – Gene Technology Regulator
* RARMP – risk assessment and risk management plan

5. 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 part 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

Proponent 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 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.

(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 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.

All proponents 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 certified laboratories or glasshouse facilities. However, this is not absolutely essential, and the GT Regulator would consider applications and their supporting information on a case-by-base.

In circumstances where proponents have undertaken initial research overseas, it would be beneficial to undertake research under Australian 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. 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 Department of Agriculture, Fisheries and Forestry (DAFF), and the Department of Climate Change Energy, the Environment and Water (DCCEEW), and GTTAC. DAFF and DCCEEW may also consider broader environmental impact of GM gene drive organism 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.

Q4: 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?

6. 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 fall under the remit of other regulators, the jurisdictions that are party to the gene technology 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 under their responsibility and communicate with other regulators, as necessary.

It should be noted that these 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.

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.

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 and establish appropriate safeguards.

A detailed description of the comparative benefits, relative to existing technologies, will be central to whether or not the proponent is able to establish reasonable social licence in advance of consideration by the state and territories.

This criterion falls with other regulators, national industry bodies, national environmental bodies, and state and territory governments or agencies may also play a role in assessing the comparative benefits of GM gene drives with existing technology.

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 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 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. State and territory governments may also play a role in assessing the potential impacts of GM gene drives on other industries. Proponents should anticipate that jurisdictions will 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
- Nongovernment agencies who have surveillance functions
- Special interest groups (e.g., veterinarians, Landcare 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 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 impact of a GM gene drive organism under their own legislation.

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 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.

Q5: Do the listed additional considerations provide sufficient detail on the range of factors needed to be taken into account for a potential application for environmental release of a GM gene drive?

Q6: Are there additional considerations that fall outside the remit of the Gene Technology Act or the remit of the Gene Technology Regulator that should be included to provide additional guidance?

Q7: In the context of environmental considerations, is there sufficient details on the additional factors for consideration that could be included?

Q8: Are there other factors to demonstrate comparative benefits that proponents should consider including in their applications?

The table below outlines who is responsible for consideration of each of these criteria.

	Proponent	GT Regulator	Other regulators[3]	State and territory governments	Commonwealth 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 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 *Gene Technology Act 2000*.

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.

Q9: Do you have any views on the criterion in the table or who is responsible for each criterion?

3 Other regulators can include APVMA

7. Social licence and public consultation

As highlighted above, proponents should be confident that they have established reasonable social licence to proceed to a formal regulatory assessment.

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*".

This will require a significant investment of time and effort on behalf 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 understanding (including modification where necessary) of new technology.

How a proponent goes about achieving social licence, and the appropriate timing for social licence, may vary between applications.

Guidance on establishing social licence may be provided by relevant state and territory governments and regulators. Proponents may also wish to engage with communications experts, or specialist ethicists (or ethics committees) from medical or Agricultural research facilities for advice on establishing social licence.

Claims of social licence should be underpinned with consideration of reasonable arguments and concerns, be receptive to evidence, be supported by logical explanation and include a realistic assessment of impacts.

Some effective ways to demonstrate social licence may include evidence of, and feedback from:

- public engagement through an appropriate combination of in-person and digital participation
- raising awareness through education and awareness campaigns
- engagement with relevant experts / peer reviewed processes
- engagement with impacted national industry bodies
- engagement with local communities and traditional owners.

Proponents should also consider the most appropriate time for engaging with the public to minimise the risk of creating adverse sentiment. Balancing timely progress with meaningful engagement is crucial. Early consultation builds trust and may help with achieving social licence. However, it may be recommended that the proponents risk assessment process has progressed to the point where all plausible risks are known, and mitigations actions identified before public consultation takes place.

Communication and engagement with the public should occur as early as practicable, be inclusive, and ongoing dialogue is encouraged. The consultation process should facilitate two-way communication, allowing stakeholders to ask questions, seek clarification, and provide feedback.

Proponents should ensure that sufficient evidence is available to support how any identified risks are to be managed. Additional scientific assessment and public consultation may be necessary to ensure that any further identified risks can also be managed.

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

The expectation is that proponents will have been through a structured process of consultation and engagement with the public and affected communities. 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.

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

Outcomes of public engagement and consultation should be presented in language that is inclusive and accessible. If consultation has occurred on a similar GM gene drive organism overseas, this information should also be presented if available.

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

Social, ethical, and cultural considerations

Proponents will need to give due consideration to 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 attaining free prior and informed consent with indigenous people. 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 communities including local Traditional Owners, Elders and Land Councils also falls within the remit of social, ethical and cultural considerations that may need to be undertaken. Sufficient time should be provided to allow for appropriate consultation.

Consultation with impacted industry and cultural groups may be undertaken in a number of ways including surveys and workshops with impacted social and cultural groups.

This is essential in order to realise the potential benefits of such technology. The approach must be guided by existing best practice strategies in science engagement employed by leading scientific and research organisations in Australia. The *Community Attitudes Report 2021* published by the Office of the Gene Technology Regulator may be a useful resource to support the development of an appropriate communication strategy.

Although social licence and public consultation does not fall within the remit of the OGTR, there is opportunity for its consideration by other relevant regulators.

8. References

General resources

Australian Academy of Science, May 2017. Discussion paper, Synthetic Gene Drives in Australia: Implications of emerging technologies.

Emerson, C., James, S., Littler, K., Randazzo, F., (2017) Principles for gene drive research. *Science* 358 (6367) 1135–1136.

Ethics resources

Gene Technology Ethics & Community Consultative Committee, National Framework of Ethical Principles in Gene Technology 2012

Gene Technology Ethics and Community Consultative Committee, Meeting of 21 September, 5 October and 21 October 2021 Communiqué

Australian code for the care and use of animals for scientific purposes (the Code) | NHMRC

Agricultural resources

National Carp Control Plan – Engagement Report (ACT)

The National Carp Control Plan (NSW)

AgTech Strategic Plan for South Australia (SA)

Agricultural Produce Commission Act 1988 (WA)

Agriculture and Related Resources Protection Act 1976 (WA)

Agricultural and Veterinary Chemicals Act 1995 (WA)

Animal Welfare Act 2002 (WA)

Biosecurity and Agriculture Management Act 2007 (WA)

Biodiversity Conservation Act 2016 (WA)

Biological Control Act 1986 (WA)

Conservation and Land Management Act 1984 (WA)

Environmental Resources

Advice on complying with the EPBC Act

Guidelines and procedures | EPA Western Australia

Framework for assessment procedures in EIA | EPA Western Australia

Referral of a proposal under section 38 of the Environmental Protection Act 1986 Instructions (WA)

How to prepare an Environmental Review Document Instructions – Environmental Protection Authority October 2021 (WA) Environmental Impact Assessment (Part IV Divisions1 and 2) Procedures Manual – Requirements under the Environmental Protection Act 1986 (WA)

Human Health Resources

WALW – Public Health Act 2016 – Home Page (legislation.wa.gov.au)

Q10: Are there additional resources that may be helpful?