

# Tasmanian Gene Technology Guidelines

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The import, use and development of Genetically Modified Organisms (GMOs) in Tasmania, along with any other dealings, are regulated by numerous laws at both Commonwealth and State levels, depending on the particular application of gene technology and the end products.

The *Tasmanian Gene Technology Policy 2019-2029* is an overarching document that outlines the Government's intention to maintain a GMO moratorium.

The Guidelines describe the dealings that may be authorised under the *Genetically Modified Organisms Control Act (2004)* ("the Act").

These Guidelines also provide the operational details on how the Policy will be implemented by DPIPWE, as the lead Agency for GMO policy for primary industries in Tasmania. These Guidelines may be amended by Cabinet.

The Guidelines will be published on the Department's website ([www.dpipwe.tas.gov.au](http://www.dpipwe.tas.gov.au)). The Policy and these Guidelines do not have the force of law in the same way that legislation does, however both would be taken into account as a guide for decision making under the relevant laws.

## Definitions:

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**Adventitious Presence** – an event where GM material is unintentionally or inadvertently introduced into the State.

**AgriGrowth Tasmania** - a Division of the Primary Industries, Parks, Water and Environment Department.

**Commercial Release** – intentional release of GMOs into the environment for commercial rather than research purposes which take place outside of containment facilities.

**Dealings with GMOs** – activities involving GMOs that include conducting experiments with GMOs, developing or manufacturing GMOs, transporting and importing GMOs, and disposing of GMOs. A complete definition of "deal with" is provided in the *Genetically Modified Organisms Control Act 2004* (<https://www.legislation.tas.gov.au/view/whole/html/inforce/current/act-2004-045>).

**Genetically Modified Organism** – (GMO or GM) an organism that has been modified by gene technology, or an organism that has inherited particular traits from an organism (the initial organism) being traits that occurred in the initial organism because of gene technology. The Commonwealth *Gene Technology Regulations 2001* specifies other techniques that do not constitute gene technology, and can declare those things that are a GMO.

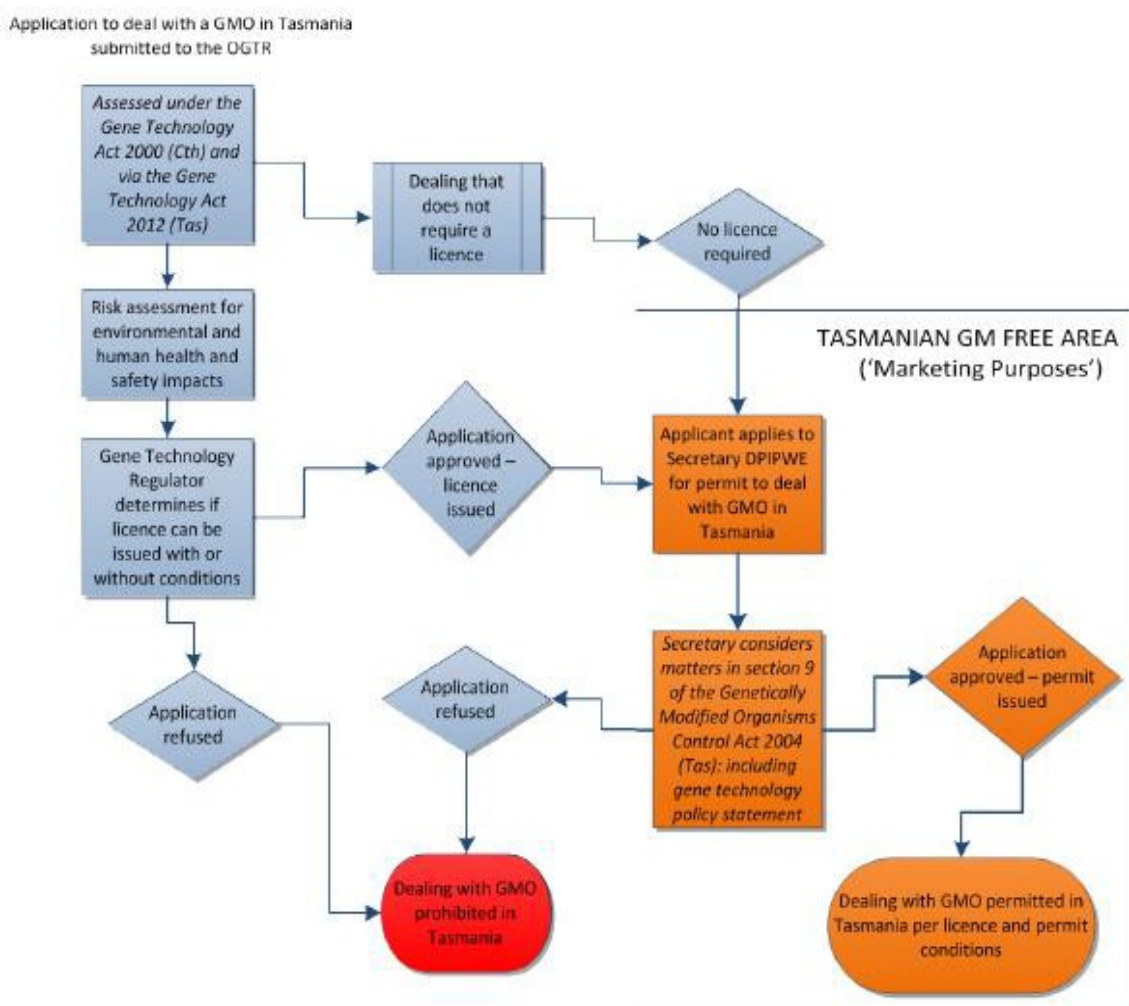
**Gene Technology** – any technique for the modification of genes or other genetic material, but does not include sexual reproduction or homologous recombination.

**Limited and Controlled Release** - research and development outside of Physical Containment Facilities. These can range from small scale field trials (i.e. under field conditions. This is also known as open-air research).

**Physical Containment Facilities** – certified facilities, such as laboratories, that are designed to prevent the release of viable organisms into the environment.

## Regulatory System:

The diagram below tracks how an application submitted to the Office of Gene Technology Regulator (OGTR) to 'deal' with a GMO in Tasmania would be assessed.



Tasmania's GMO regulatory and legislative framework fundamentally aligns with that of the Australian Government's *Gene Technology Act 2000 (Cth)*. In the Tasmanian context, the *Gene Technology (Tasmania) Act 2001* was enacted, and in 2012, the 2001 Act was repealed and replaced with the *Gene Technology (Tasmania) Act 2012*.

The *Gene Technology Act 2000 (Cth)* is, however, modified in Tasmania by prohibiting the operation in Tasmania of any licence granted by the Regulator for dealing with a GMO, if the dealing is in contravention of a GMO-free order (section 7 *Gene Technology (Tasmania) Act 2012*).

The *Genetically Modified Organisms Control Act (Tas)* came into effect in 2004. Its objective is to provide for the whole or any part of Tasmania to be declared a GMO-free area for the purpose of preserving the identity of non-genetically modified crops and animals for marketing purposes and to provide for persons to be allowed to deal with GMOs under permits.

The power of the Minister to declare GMO-free areas is provided in section five of the *Genetically Modified Organisms Control Act 2004 (Tas)* and is only exercisable if the Minister considers that declaring a GMO-free area would aid in preserving the identity of non-genetically modified crops and animals for marketing purposes.

The whole of Tasmania was made a GMO-free area by the *Genetically Modified Organisms Control (GMO-free Area) Order 2005 (Tas)* on 31 October 2005.

Part two of the *Genetically Modified Organisms Control Act (Tas)* prohibits a person from knowingly dealing with a GMO in a GMO-free area unless that person has a permit (granted under section 9) of the Act by the Secretary, Department of Primary Industries, Parks, Water and Environment (DPIPWE) and a license from the Regulator, or a permit when dealing with a GMO that does not require a license.

### **Administration costs**

The costs of administering a prohibition on use of gene technology in primary industries, such as import control and eradication of GMOs, either as a result of barriers breaches or from former GM canola trial sites in Tasmania, can be substantial. Moreover, quarantine barrier and incursion response costs can be expected to increase in the event that more of Tasmania's domestic and international trading partners adopt GM crops and perhaps GM production animals.

The Tasmanian Government acknowledges this situation. Accordingly it will endeavour to administer the Policy and these Guidelines in a manner sensitive to the potential cost burdens on business and the community. The impact of increasing demands on biosecurity resources and the costs on agencies, business and consumers will be considered as part of the Government's budget development processes.

## **Administration**

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The responsibility for effective implementation of GMO policy across Government falls to DPIPWE because of its legislative obligations.

DPIPWE is responsible for administering the *Genetically Modified Organisms Control Act 2004*. The role involves:

- Assessment of and preparation of advice on applications for authorization to deal with GMOs;
- Oversight of authorisation to deal with GMOs, including contained laboratory research, field trails, processing to a non-viable state, disposal;
- Oversight of clearance of GM material from former GM canola trial sites, and regular status

- reporting;
- Oversight of clearance of GM material from properties affected by the 2005 Grace canola GMO contamination incident;
- Oversight of clearance of GM material from farm properties affected by inadvertent dealing;
- Import policy formulation, including in regard to commodities potentially contaminated with viable GM material;
- GMO incursion response; and
- Review and amendment of the *Genetically Modified Organism Control Act 2004*.

In addition, DPIPWE administers the *Gene Technology Act 2012* Tasmania's legislative component of the national scheme for gene technology regulation. DPIPWE also has an interest in national food safety regulation, in cooperation with the Department of Health and Human Services. Accordingly, DPIPWE undertakes:

- Preparation of advice in relation to participation in the national scheme for gene technology regulation via the Legislative and Governance Forum on Gene Technology (previously known as the Gene Technology Ministerial Council [Ministerial Council]), including review of GMO risk assessments and procedures and protocols generated by the national Office of the Gene Technology Regulator (OGTR); Review and amendment of the *Gene Technology Act 2012* and
- Preparation of advice in regard to GM food safety regulation, via Food Regulation Ministerial Council, including review of safety assessments conducted by Food Standards Australia and New Zealand (FSANZ), and labelling arrangements for GM food, under the *Australia New Zealand Food Standards Code*.

As well as carrying out its legislative duties, DPIPWE also engages locally and abroad by:

- Responding to requests from the public for information, or other correspondence; and
- Monitoring national and international scientific, legal and policy developments relevant to use of gene technologies in primary industries.

While DPIPWE has primary carriage for policy administration, certain measures require expertise that lies with other agencies. Implementation of those measures is agreed with other agencies as required.

## Implementation

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Development and use of Gene Technology that may be authorised under the Policy and these Guidelines is as follows.

Category	Research Contained Facilities**	Research Limited and Controlled Release**	Commercial Release**
GM Food Crop	Yes*	No	No

GM Non-Food Crop <i>Pharmaceuticals not intended for food or feed</i>	Yes*	Yes*	Yes*
GM Non Food Crop <i>Other</i>	Yes*	No	No
GM Animal	Yes*	No	No
GM Microbes	Yes*	No	No

Note: Refer to definition section for clarification in *Physical Containment Facilities, Limited and Controlled Release and Commercial Release*.

\*Provided approval by OGTR and approval conditions by DPIPWE are met.

\*\* The Policy on any of these areas may be subject to review by the Government as a result of the monitoring program by DPIPWE.

To deal with a GMO in Tasmania, a license from the Commonwealth is required (unless the dealing is classed as an “exempt dealing” refer [www.ogtr.gov.au](http://www.ogtr.gov.au)).

Any applications for a permit to develop and use of gene technology in Tasmania must stipulate the necessary precautions to be taken to minimise potential risks to the environment and health and safety of people. The applicant must demonstrate satisfactory capacity for compliance otherwise the permit will not be granted.

## Food Plants

Importation, distribution, use or any other dealing that facilitates release of GM food plants, viable seeds or other propagules intended for use as food or feed to the Tasmanian environment is prohibited. The prohibition covers all dealings, including those for commercial purposes, and limited and controlled release.

### Research in Physical Containment Facilities

Dealings relevant to research or other activities in contained facilities involving GM food or feed plants, viable seeds or other propagules may be authorised under the *Genetically Modified Organisms Control Act 2004*. However authorisation will be subject to:

- Prior approval by the national Office of Gene Technology Regulator (OGTR) as required;
- Assessment by DPIPWE of the likelihood of GMO entry into the broader environment, other plants, or human or animal food supplies; and
- Conditions as required.

### Former GM Canola Trial Sites

Sites in Tasmania previously used to trial GM canola will continue to be regulated under the *Genetically Modified Organisms Control Act 2004* to eradicate residual GM seed and prevent spread of GM material off-site.

DPIPWE will continue its cooperative approach with affected farmers and the biotechnology companies responsible for the trials to ensure compliance with site management plans and progression to site clearance and sign-off with least possible disruption to normal farming activity.

#### Grace canola sites

DPIPWE will continue to assist landholders affected by Grace canola GMO contamination to eradicate residual seed and prevent spread of GM material off-site commensurate with risk, and with least possible disruption to normal farming activity.

#### GMO inadvertent dealings

In the event of a land holder(s) being affected by any inadvertent dealings contamination (for example, through breaches of the *Plant Quarantine Act 1997*) DPIPWE will assist the landholder to eradicate residual seed and prevent spread of GM material off-site commensurate with risk, and with least possible disruption to normal farming activity.

## **Non-Food Plants**

#### Release to the Environment

Release of plants, viable seeds or other propagules genetically modified for pharmaceutical purposes and not intended for use as food or feed, to the Tasmanian environment for limited and controlled release or commercial purposes may be authorised under the *Genetically Modified Organisms Control Act 2004*. However authorisation will be subject to:

- Prior approval by the national OGTR as required;
- Assessment by DPIPWE of the likelihood of GMO entry into the broader environment, other plants, or human or animal food supplies;
- Conditions as required.

Importation, distribution, use or any other dealing that facilitates release of GM plantation, amenity, ornamental or novelty plants, viable seeds or other propagules to the Tasmanian environment is prohibited. The prohibition covers all dealings, including those for commercial purposes, and limited and controlled release.

#### Research in Physical Containment Facilities

Dealings relevant to research or other activities in contained facilities involving GM plants not intended for use as food or feed may be authorised under the *Genetically Modified Organisms Control Act 2004*. However authorisation will be subject to:

- Prior approval by the national OGTR as required;
- Assessment by DPIPWE of the likelihood of GMO entry into the broader environment, other plants, or human or animal food supplies;
- Conditions as required.

## **Contamination of Non-GM plant stocks with GM material**

### Tolerance thresholds

Zero tolerance for the adventitious presence of viable GMO contamination in imported canola seed and whole grain will continue to apply.

The Tasmanian Government will accept as evidence of zero contamination, a negative result from a test capable of detecting one GM canola seed in 10 000 non-GM canola seeds with 95% confidence, or an alternative import proposal which achieves an equivalent level of assurance that GMOs are absent.

The same zero tolerance approach may be applied to other imported seeds and whole grains if these are also likely to be contaminated with viable GM material, for example, as a result of increased plantings by trading partners.

### Co-existence

DPIPWE's evidence-based monitoring program will continue to assess developments in gene technology as well as market and branding implications. The monitoring will include:

- arrangements for co-existence between GM and GMO free canola and other crops on the Australian mainland with particular regard to level of potential GMO contamination; and
- mainland and overseas co-existence experience including biosecurity measures and equipment and resources for segregation along the entire supply chain, particularly as relevant to potential importation of viable product from those systems to Tasmania; and
- court decisions in Australia and overseas regarding liability for GM contamination.

The Tasmanian Government will work with industry and key stakeholders on appropriate co-existence strategies for managing potential risks to ensure that measures to safeguard Tasmania's GMO free status remain appropriate to a changing risk environment.

## **Animal Feed derived from plants**

### Dealings with viable GM seed prohibited

Importation, distribution, use or any other dealing with animal feed containing viable GM seed capable of producing a GM plant is prohibited. The prohibition encompasses grain, grain mixes, fodder and any other plant product used for animal nutrition.

Animal feed containing viable GM seed may be authorised under the *Genetically Modified Organisms Control Act 2004* for processing in Tasmania to a non-viable state in an approved facility prior to further distribution and use. However authorisation will be subject to:

- Prior approval by the national OGTR as required;
- Approval of the facility by DPIPWE; and
- Conditions as required.

#### Dealings with non-viable GM seed

Importation, distribution, use and any other dealing with animal feed containing material derived from GM plants that is not viable and hence incapable of producing a GM plant (e.g. meal, substantially cracked or crushed grains, chaff) is not prohibited. However DPIPWE may require, or undertaken to obtain, evidence demonstrating GM material in that feed is non-viable.

### **Animals**

Importation, distribution, use or any other dealing that facilitates release of viable GM livestock, fish, invertebrates, or other animals to the Tasmanian environment is prohibited. The prohibition covers all dealings, including those with commercial purposes, and limited and controlled release research, including in aquatic environments.

Notwithstanding, dealings relevant to release of live GM animals intended for bioremediation or biological control of pests or diseases may be authorised under the *Genetically Modified Organisms Control Act 2004*. However authorisation will be subject to:

- Prior approval by the national OGTR as required;
- Assessment by DPIPWE of the likelihood of GMO containment in the target environment, or restriction to the target pest or disease, and GMO entry to human or animal food supplies; and
- Conditions as required.

#### Research in Physical Containment Facilities

Dealings relevant to research or other activities in contained facilities involving GM animals not intended for use as food or feed may be authorised under *the Genetically Modified Organisms Control Act 2004*. However authorisation will be subject to:

- Prior approval by the national OGTR as required;
- Assessment by DPIPWE of the likelihood of GMO entry into the broader environment, other plants, or human or animal food supplies;
- Conditions as required.

Proposals must stipulate the necessary precautions to be taken to minimise potential risk. Any research project will not proceed if the capacity for compliance cannot be satisfactorily demonstrated.



## Microbes

Importation, distribution, use or any other dealing that facilitates release of viable GM microbes to the Tasmanian environment is prohibited. The prohibition covers all dealings, including those for commercial purposes, limited and controlled release research, including in aquatic environments.

Notwithstanding, dealings relevant to release of live GM animal vaccines, or microbes intended for bioremediation or biological control or pests or diseases may be authorised under the *Genetically Modified Organisms Control Act 2004*. However authorisation will be subject to:

- Prior approval by the national OGTR as required;
- Assessment by DPIPWE of the likelihood of GMO entry into the target environment, or restriction to the target pest or diseases, and GMO entry to human and animal food supplies; and
- Conditions as required.

### Use in food manufacture

Importation, distribution and use in Tasmania of live GM micro-organisms to generate food processing aids or food additives is prohibited.

Dealings with food processing aids and food additives derived from GM micro-organisms are not prohibited unless the GMO remains alive and viable in the final food product.

### Research in Physical Containment Facilities

Dealings relevant to research or other activities in contained facilities involving GM microbes may be authorised under the *Genetically Modified Organisms Control Act 2004*. However authorisation will be subject to:

- Prior approval by the national Office of Gene Technology Regulator as required;
- Assessment by DPIPWE of the likelihood of GMO entry into the environment;
- Conditions as required.

# Exemptions

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To enable efficient operation of the Act, certain persons may be exempt from requiring a permit under the Act.

There is a current exemption in place (under Section 19(2) of the Act) for persons employed by agricultural contracting companies who may conduct activities at contaminated sites and for persons who unintentionally deal with GM canola. The current exemption can be found at [http://gazette.tas.gov.au/editions/2008/april\\_2008/20831\\_-\\_Gazette\\_09\\_April\\_2008.pdf](http://gazette.tas.gov.au/editions/2008/april_2008/20831_-_Gazette_09_April_2008.pdf).

**Effective date of these Guidelines: September 2019**