# Genetically Modified Organisms (GMO) Environmental Scan

## Final Report - July 2024

Department of
Natural Resources and Environment Tasmania

Tasmanian Government

# Contents

# Executive Summary

The 2024 Genetically Modified Organisms (GMO) Environmental Scan monitors and reports changes in sentiment, markets or gene technology since 2019 when Tasmania's GMO Moratorium was extended for a further 10 years until 2029. It has been prepared by AgriGrowth Tasmania within the Department of Natural Resources and Environment Tasmania (NRE Tas.)

**The Environmental Scan addresses three areas, and makes the following key findings:**

1. **Consumer sentiment in important current and potential future markets**

   Key export markets for Tasmanian premium produce remain sensitive to GMOs. This sentiment is significantly less evident (or absent) in relation to commodity products but remains a market factor across a range of 'high-end' Tasmanian-branded products in key export destinations, for example premium beef sold into the United States and Japan.

2. **New gene technologies that provide positive benefits to primary industry sectors and to Tasmania as a whole**

   New breeding techniques including the SDN-1 gene-editing method (see pages 7-9) are resulting in a growing number of plant varieties with a wide range of desirable traits such as improved nutrition and better drought tolerance. There is a firming consensus internationally regarding the regulation of SDN-1 tools with which Tasmania could align itself while retaining its GMO moratorium for marketing purposes. SDN-1 modified organisms are <u>not</u> considered to be Genetically Modified Organisms under Schedule 1 (Item 4)[1] of the *Gene Technology Regulations 2001*.

3. **Development of new generation GMOs that provide health or other benefits**

   Beyond the traditional view of GMOs being prevalent in plant-based agriculture, work underway in research institutes in Tasmania and internationally seeks to use various gene technologies in biomedical and veterinary research, to fight disease and/or to improve environmental outcomes. The research relates not only to treatment for cancer and neurodegenerative diseases in people but also to the use of genetic tools for vaccines or to supress disease vectors or environmental pests. New generation gene technologies which offer health and other benefits are at risk of being caught up in legislative and policy settings designed originally for agriculture.

# Introduction

## Background

Since 2001, Tasmania has maintained a moratorium on the commercial release of GMOs into the Tasmanian environment. The *Tasmanian Genetically Modified Organisms Control Act 2004* (GMO Control Act) provides the basis for a moratorium and regulates dealings with GMOs for 'marketing purposes'. Under section 5(1), the Minister, by order, may declare the whole or any part of Tasmania to be an area that is free of GMOs if he or she considers that to do so would aid in preserving the identity of non-genetically modified crops and animals for marketing purposes. Under section 36, the GMO Control Act expires 25 years after it commences, inclusive of the day on which it commences – which means November 2029. The Act was last amended in 2019 to legislate a moratorium for a further 10 years until November 2029.

Tasmania's policy exists within the context of a nationally consistent legislative scheme for gene technology: the National Gene Technology Scheme. The National Gene Technology Scheme protects the health and safety of humans and the environment, by identifying and managing risks that gene technology and GMOs might pose. This comprises the Commonwealth's *Gene Technology Act 2000* and *Gene Technology Regulations 2001*, and corresponding State and Territory legislation. The Tasmanian component of the scheme is the *Gene Technology (Tasmania) Act 2012*. This operates to the extent that it does not conflict with an order issued under section 5 of Tasmania's GMO Control Act. This section permits all or part of Tasmania to be declared GMO free if doing so would preserve the identity of non-genetically modified crops or animals for marketing purposes. Thus, it is the GMO Control Act which provides the basis for a Tasmanian marketing-based GMO moratorium allowed for under national arrangements.

The *Tasmanian Gene Technology Policy (2019-2029)*[2] (Gene Technology Policy) and *Tasmanian Gene Technology Guidelines 2019*[3] (Gene Technology Guidelines) describe the dealings that may be authorised under the GMO Control Act. The Gene Technology Guidelines also provide the operational details on how this policy will be implemented by NRE Tas.

Key provisions in the current Gene Technology Policy include:

- The conditional use of GMOs is allowed in pharmaceutical poppies not intended for food or feed, provided all statutory requirements are met and that markets for Tasmania's GMO-free food products can be maintained and appropriate co- existence arrangements developed;
- All other primary industries are prevented by the moratorium from the commercial release of GMOs, and this is defined as the intentional release of GMOs into the environment for commercial rather than research purposes which take place outside of containment facilities;
- The potential for limited exceptions for gene technology used in Physical Containment Facilities for applications such as research for, or production of, human medicines or therapeutics, closed loop industrial processes and animal feeds with non- viable GMO material, and research into other GMOs in Tasmania in Physical Containment Facilities provided all statutory requirements are met; and

- NRE Tas is to report regularly on developments in gene technology, markets and consumer sentiment (this environmental scan) and advise if these are of such significance to warrant an earlier review of the policy before the maximum ten years.

## Terms of Reference

Tasmania's Gene Technology Policy requires that regular reviews are undertaken of developments in gene technology, markets and consumer sentiment which may trigger a review of the State's position earlier than the policy's expiry date in 2029 should developments warrant it. Specific matters to be reported include:

- Consumer sentiment in important current and potential future markets;
- New gene technologies that provide positive benefits to primary industries and Tasmania as a whole; and
- Development of new generation GMOs that provide health or other benefits.

Tasmania's Gene Technology Policy notes that from October 2019, under the National Gene Technology Scheme, the gene-editing technique SDN-1 will not be regulated as a GMO on the basis that that organisms modified using SDN-1 posed the same risk as organisms carrying naturally occurring genetic changes. The policy stipulates that in Tasmania SDN-1 organisms are to be regulated the same as GMOs in the agri-food sector, on the basis that "*there currently is uncertainty around the national decision to not to regulate SDN-1 modified organisms amongst Tasmanian businesses that export to markets that continue to consider SDN-1 modified organisms as GMOs*".

NRE Tas is required to advise the Minister if, based on evidence, there are significant developments in these areas that warrant triggering an earlier review of the policy before the maximum ten years.

## How the Environmental Scan was conducted

This Environmental Scan was conducted from October 2023-May 2024.

Peak and/or sectoral organisations were invited to participate in a structured interview online or via telephone. The interview sought information on:

1: specific emerging gene editing technologies (including SDN-1) or GMOs that may benefit Tasmanian agriculture or the State more broadly;

2: changes (if any) to products they sold into domestic or international markets;

3: the attitudes of customers and/or key markets towards GMO and SDN-1 organisms;

4: market advantages associated with the GMO moratorium; and,

5: the attitude of their sector, members or business to the GMO moratorium generally.

As it is an Environmental Scan only and not a review of the Tasmanian Gene Technology Policy, written submissions were not sought and there was targeted consultation. Interviewees were advised that a fuller and broader consultation would occur in the event that the Environmental Scan prompted a review of any significant aspect of the Tasmanian Gene Technology Policy.

The Department of State Growth assisted in gathering information on the attitudes of key international markets to GMOs and/or gene editing. It did this by seeking responses from its own network of Tasmanian trade agents located in overseas markets and from relevant country specialists in Austrade.

The literature search was conducted online using information leads provided by interviewees, aggregation sites and key word combinations. Reporting in specialist media of GMO or gene editing developments in the public domain (e.g. commercialisation of a new variety) were accepted at face value. However, when available and desirable, peer-reviewed journals and/or regulator web sites were preferred.

# Overview of New Plant Breeding Techniques: Gene editing versus transgenic techniques

New plant breeding techniques encompass a set of diverse methods and concepts that all aim to improve efficiency and/or precision of plant breeding.[4] These techniques did not exist in the early 2000s when legislation to regulate GMOs was first adopted in Tasmania.

## Conventional plant breeding

Up until the 20th Century, spontaneous mutations in plants were the only sources of novel genetic diversity.[5] As a plant germ cell divided, breaks in the DNA would occur which sometimes were imperfectly repaired by the plant and, in some of these cases, a new trait might be noticed in the adult plants which resulted. If the trait was desirable, the seeds of the plants exhibiting this trait were conserved for planting the next generation, and so on. Seeking to breed new varieties using the process of natural mutation was haphazard and lengthy.

Since the 1930s, chemicals or irradiation have been used to encourage breaks in DNA. This now is referred to as conventional mutation breeding. Propagules or parts of the organism (e.g. seeds) are exposed to mutagenic chemicals (e.g. ethyl methanesulfonate) or to radiation (e.g. x-rays, gamma rays or fast neutrons). Under conventional mutation breeding, the occurrence of mutations can be dramatically increased. Conventional mutation breeding has produced more than 3,000 new varieties, some of which have become major commercial varieties of food crops which now feed much of the world's population. Drawbacks include the large number of propagules which require treatment with mutagens to produce an effective population from which to select useful breeding lines that occur with relatively low frequency. It may take many years to develop a commercial cultivar. These conventional breeding techniques are generally untargeted and can result in undesirable traits as well as good ones.

## New plant breeding techniques

The new breeding techniques developed over the past 20 years are targeted. They can be used to generate DNA sequence variants at defined positions in a genome. Depending on the target gene, such variants may result in improved or new traits; for example, disease resistance, stress tolerance or increased yield.[6]

One of the most promising of the new techniques is genome editing with the help of a programmable nuclease. These are commonly referred to as SDN (site-directed nuclease) techniques or sometimes as SSN (sequence-specific nuclease) techniques. SDN techniques are being used in an increasingly wider array of applications, especially following introduction of the CRISPR-Cas9 system.[7]

The difference between gene editing and classical genetic engineering is explained by Ahmad and others in Frontiers in Plant Science (October 2023)[8] as follows:

> *"It is noteworthy that among different gene editing tools, CRISPR-Cas9 gained rapid popularity in crop improvement programs because of its simple design, less time consumption, cost-effectiveness, good reproducibility, high efficiency, precise targeting, and diverse applications…CRISPR-Cas9 simply introduces [Double strand breaks] DSBs at the target site in the genome. DSBs in the genome provoke* **natural** *DNA repair systems such as non-homologous end joining (NHEJ), or homology-directed repair (HRD) in the cell…"*

> *"Desired traits in crops can be achieved through CRISPR-Cas by utilizing nature generated genetic variations present in the genomes of non-modified plants. For example, SDN-1 and SDN-2 genome edited plants which can be generated through targeted modifications of the plant's own genes without permanently integrating DNA in the plant genome may arise from spontaneous mutations or can be achieved through classical breeding. So, CRISPR edited SDN-1 and SDN-2 plants are generally characterized as non-GM, because they are not based on introducing new genes in the host plant to obtain desirable traits, thus making them more acceptable as compared to the plants generated through conventional genetic engineering (Abdallah et al., 2015; Jones et al., 2022). Compared to GM crops, non-GM crops have certain benefits associated with those such as faster development, precise modifications in the genome, absence of transgenes, predictable outcomes, and reduced regulatory challenges. In contrast, SDN-3 crops are produced by providing a donor template containing large DNA fragment such as transgene or cis-gene and are regulated under strict GMO regulations (Georges and Ray, 2017)."*

In the years since 2019 when Tasmania's GM policy was last reviewed, a widespread general shift has become evident towards the use of new breeding techniques such as SDN-1. The shift is evident in agronomy through a multitude of research and development programs using SDN techniques, the outcomes of which now are being adopted commercially in the farmed landscape elsewhere in the world. The shift is also evident in regulatory regimes where countries have either introduced regulations to enable their use or are currently reviewing their position with a view to doing so.

An overview of new breeding techniques and their regulation is provided by Bucholzer and Frommer (New Phytologist, 2022):

> *"Genome editing provides the means for targeted DNA changes in precise locations in a plant genome. Large parts of the world have already introduced regulations or guidelines for crops that were subjected to genome editing. Over the past 2 years, many more countries have introduced guidelines that enable the use of such edited lines in agriculture in a similar way as conventionally bred lines, provided they do not contain a transgene….*

> *Genome editing (sometimes called gene editing) is a widely used technology that generates DNA sequence variants at defined positions in a genome…Depending on the target gene, such variants may improve or produce new traits; for example, disease resistance, stress tolerance, or increased yield potential. The best-known system in the genome editing toolbox is CRISPR/Cas9, for which Emmanuelle Charpentier and Jennifer Doudna, the inventors of the genetic scissors, received the Nobel Prize (Ledford & Callaway, 2020). Other excellent systems are transcription activator-like effector nucleases (TALENs) or Zinc-finger nucleases (ZFNs), which can also be used for editing (Shukla et al., 2009; Li et al., 2012). All three editing tools target a specific sequence in the genome and induce*

*chromosomal breaks at or in the vicinity of the target site that are repaired imperfectly by the cell, thereby generating sequence variants at the target site (Wada et al., 2020). Regulatory systems distinguish three types of genome editing by site-directed nucleases (SDNs). SDN-1 introduces small changes at the target site. SDN-2 uses template-guided repair by homologous recombination to introduce a specific DNA sequence replacement in the genome. SDN-3 inserts larger genetic elements (e.g. full genes) in a similar manner as SDN-2 (Friedrichs et al., 2019)."*

Discussion of regulation of gene editing techniques which utilise site directed nucleases usually distinguishes three sub-categories of gene editing: SDN-1, SDN-2 and SDN-3.

### SDN-1

Gene editing in which there is a spontaneous repair of a double-strand DNA break (DSB) whose repair does not introduce external DNA, is usually referred to as SDN-1. In addition to CRISPR-Cas9, other effective techniques are transcription activator-like effector nucleases (TALENs) or Zinc-finger nucleases (ZFNs) which can also be used for gene editing. All of these editing tools target a specific sequence in the genome and induce chromosomal breaks which are repaired imperfectly by the cell, thereby generating sequence variants at the target site.

### SDN-2[11]

This system uses template-guided repair by homologous recombination to introduce a specific DNA sequence replacement in the genome.

### SDN-3[12]

SDN-3 inserts larger genetic elements (e.g. full genes, transgenes) using techniques similar to SDN-2.

# Global overview of SDN regulations

University of Tokyo public policy researchers recently reported on their survey of regulations for organisms and products derived from genome editing.[13] Their analysis of jurisdictional approaches to regulating gene editing focussed on SDN-1 and SDN-2 techniques. This is because SDN-3 techniques introduce foreign genes and are generally subject to GMO regulation. Differences in jurisdictional approaches to gene-edited organisms relate to SDN-1 and SDN-2 techniques. They described the overall regulatory environment relating to genetics as *"a patchwork of international regulations that are difficult to harmonize. However, if the approaches are arranged in chronological order and the overall trend is examined, the regulation of genome-edited organisms and GM food products has recently been trending towards a middle ground…"*

Four separate approaches to regulation of gene-edited organisms were summarised which, from the most restrictive to the least restrictive, were:

1. GMO regulations are applied 'as is' to genome-edited products. As a result, prior safety assessment and approval by the government are required.
2. Simplified GMO regulations will be applied to genome-edited products. As a result, simplified safety review and approval procedures will be applied.
3. Genome-edited products are exempt from GMO regulations. However, confirmation by the government is required before placing on the market.
4. Genome-edited products are exempt from GMO regulations. Prior confirmation is not required by the government.

The first two approaches embody the underlying position of subjecting gene-edited organisms to GMO regulations:

- the first approach **(#1)** under this position applies the GMO regulations as-is and the second approach **(#2)** under this position adopts a somewhat simpler application of the GMO regulations to gene-edited organisms/produce.
- The third and fourth approaches embody the underlying position of excluding gene-edited organisms from the scope of the GMO regulations.
- One of these approaches **(#3)** requires prior confirmation from a regulatory body while the other approach **(#4)** does not.

Tasmania has adopted the most restrictive regulatory regime (approach **#1**). Table 1 maps various jurisdictions against these four approaches to SDN techniques together with the year their approach was adopted. If a particular jurisdiction's approach varies between SDN-1 and SDN-2, the SDN-1 approach is indicated.

Table 1. Based on Tachikawa and Matsuo (2023). Modified by NRE Tas (March 2024).

| Approach | 2014 | 2015 | 2017 | 2018 | 2019 | 2020 | 2021 | 2022 | 2023 |
|---|---|---|---|---|---|---|---|---|---|
| #1 | NZ* | | | EU* | Tasmania | | | | |
| #2 | | | | | | | FSANZ* | China | |
| #3 | | Argentina | Chile<br>Israel | Brazil | Japan | | | Canada<br>India<br>Philippines | |
| #4 | | | | | Australia (not Tas.) | US | | | UK (England) |

Notes:

Asterisk (*) indicates under review with a view to liberalisation.

FSANZ approves food products in Australia and New Zealand.

2016 is absent because no national regime surveyed determined its approach that year.

The regulatory environments of these and other countries are further outlined below. Unless otherwise noted, the information in the section below is sourced from the non-profit Genetic Literacy Project.[14]

# Oceania

## Australia (excluding Tasmania)

### Lightly regulated. Regulatory restrictions have been relaxed to focus on the product and not the process.

Australia established a regulatory system *the Gene Technology Act 2000* (*Cwth*) came into effect in June 2001 to oversee the use of gene technologies.[15] Gene-edited plants are regulated by the Gene Technology Regulator while Food Standards Australia New Zealand (FSANZ) regulates food (pre-market regulations, labelling etc).

In 2018, Australia joined 12 other countries (including Argentina, Canada, Brazil and the US) in issuing a joint statement to the World Trade Organisation supporting relaxed regulations for gene editing.[16] It stated that government should "avoid arbitrary and unjustifiable distinctions" between crops developed through gene editing and crops developed through conventional breeding. In 2019, the Australian Government decided not to regulate SDN-1 techniques under the National Gene Technology Scheme on the basis that the process presents the same risk as a naturally occurring genetic change, given that no foreign DNA is present in such plants.[17] The OGTR maintains a list of organisms which are GMO and organisms which are not GMO. These are provided in Appendix 2-3.

This change brought Australia in line with evolving regulation in the US, Brazil, Argentina, India, China and the UK where, if no foreign DNA is present, gene-edited plants are exempt from the regulatory oversight applied to transgenic crops.

### New Zealand

**Highly regulated with all gene editing techniques considered as GM. However, significantly relaxed regulations are foreshadowed.**

New Zealand has announced it will abandon its current position on gene technology which is so restrictive that field trials have rarely been approved.

In March 2024, the New Zealand Government announced it would pass new gene technology legislation by the end of 2025, citing the fact that Australia, Japan and the United Kingdom (England) had safely embraced new technologies and that the European Union was working to liberalise its rules.[18]

While the detail of New Zealand's proposed new rules is still to be developed, the Government has indicated that the new rules would cover GMOs as well as gene editing, and will be based on managing risk rather than focussing solely on the methods of genetic modification.

## Asia

### Japan

**Lightly regulated. Gene-edited crops do not require safety or environmental testing but must be registered. Labelling is voluntary.**

Japan is one of the world's largest per capita importers of food and feed produced using modern biotechnologies. Gene-edited (GE) crops are identified through three types of labelling: GE; non-GE; and non-segregated, where a product for which approved GE varieties exist is distributed without identity preservation.[19] For varieties grown by inducing mutations using conventional methods such as irradiation, no special safety checks are required.[20] To date Japan has introduced three gene-edited products: a GABA-enriched tomato, fleshier red sea bream, and high-growth tiger puffer fish.

The Ministry of the Environment in Japan determined that Living Modified Organisms are not subject to regulation if they do not contain foreign DNA or RNA or if the introduced DNA or RNA is no longer present in the final organism.[21] This current regulatory framework in Japan allows for SDN-1 organisms to remain regulation free, whereas SDN-2 and SDN-3 organisms are subject to regulation. This is due to the SDN-2 technique using a template at the target site and SDN-3 introducing genes to the target site. No safety or environmental assessment is required of SDN-1 edited crops as there is no foreign DNA integrated into the genome.[22]

Historically, Japanese markets have been sceptical of GMO foods.[23] A 2017 survey found that the public was inclined to a zero-risk policy, which limited the growing of GM crops.[24] To date, the introduction of the gene-edited products has not led to similar public concern.

### China

**Regulations not fully developed. Limited approval case-by-case, no commercialised products.**

On 24 January 2022, the Ministry of Agriculture and Rural Affairs (MARA) issued *Guidelines for Safety Evaluation of Gene-Edited Plants for Agricultural Use (Trial)*, establishing for the first time an application procedure and requirements for gene-edited plants.

Applications may fall under one of four categories:

1. target traits that do not increase risk of environmental and food safety;
2. target traits that may increase environmental safety risk;
3. target traits that may increase food safety risk;
4. target traits that may increase environmental and food safety risk.

These new guidelines are expected to reduce the process for approval of gene-edited crops to 1-2 years compared to up to 6 years for GMO crops.[25]

In 2023 gene-edited soybean with high oleic acid was approved by MARA, which recently also approved the safety of gene-edited corn and wheat for commercial production. Uptake of these has been slow due to concerns about perceived health and safety impacts.[26]

### India

**Lightly regulated. Gene-edited crops without 'foreign genes' are exempt from restrictive regulations in place for transgenic (GMO) crops.**

Approximately 85 plant species are under development in the private and public sectors using gene editing technologies for a variety of traits, such as pest and disease resistance and increasing nutritional composition.[27]

In March 2022, the Ministry of Environment, Forest and Climate Change revised regulations[28] to allow open field trials of crops developed "free of exogenous introduced DNA" (derived by either SDN-1 and SDN-2 processes) leading to commercial release. Products derived through SDN-3, which involves the introduction of foreign genes, are still considered GMOs.[29]

## Americas

### USA

**No unique regulations. Most gene-edited crops are regulated as conventional plants so they do not face the heavier restrictions of GMOs.**

In 2018, the U.S. Secretary of Agriculture issued a statement, clarifying that the U.S. Department of Agriculture (USDA) "does not regulate or have any plans to regulate plants that could otherwise have been developed through traditional breeding techniques as long as they are not plant pests or developed using plant pests."[30]

Food produced using gene editing techniques is held to similar standards as conventional foods. The USDA does not require agency approval if researchers produce a trait in a crop that could otherwise occur naturally.

Conversely, transgenic plants containing foreign genes (GMOs) face far tighter restrictions and must continue to be labelled.

# Europe

## United Kingdom

**England has no unique regulations for gene-edited crops, but restrictions remain in rest of UK based on the EU model.**

On March 2023, the Genetic Technology (Precision Breeding) Bill was passed into law into England. The Act applies to precision bred plants, (gene-edited crops), removing them from the regulatory system for GMOs.[31] The objective of the legislation was to ensure the crops produced using gene editing were regulated proportionally to risk.[32]

The UK government maintains it is committed to making it easier and less expensive to develop and market gene-edited plants and animals but will continue to restrict those derived from transgenic techniques.

Under the new regulations, gene-edited foods would not be labelled if the changes could occur naturally. The new legislation does not apply to Scotland, Wales and Northern Ireland, which currently have stricter regulations based on the existing EU model.[33]

## European Union (excluding UK)

**Mostly prohibited but relaxation of legislation has begun.**

Some organisms produced by New Genomic Techniques (NGT: the EU terminology for new breeding techniques) will be classified differently from GMOs in Europe under planned changes to its current rules which are based on a 2001 directive.[34]

A public consultation on the European Commission's planned regulatory environment for NGTs has concluded with the European Parliament's Environment Committee approving a *Proposal on New Genomic Techniques*.[35] The proposal will have significant impacts on Europe's seed companies, farmers, and vegetable growers. Plants resulting from targeted mutagenesis and cisgenesis (i.e. transfer of genes between organisms that could otherwise be conventionally bred) will be categorised separately from GMOs.

Currently, plants produced using new gene editing techniques in the European Union are subject to the same rules as GMOs. Under the proposed legislation, plants produced using new techniques that could also occur naturally or by conventional breeding will be subject to a verification procedure, based on set criteria. The plants that meet these criteria are treated like conventional plants and therefore exempted from the requirements of the GMO legislation. These plants will not require risk assessment.

For all other gene-edited plants, the requirements of the current GMO legislation would apply. This means that they are subject to risk assessments, and they can only be put on the market following an authorisation procedure. Detection methods and tailored monitoring requirements will be applied to these plants. The new proposal only concerns plants produced by targeted mutagenesis and cisgenesis and their food and feed products. It does not include plants obtained by transgenesis, as such techniques remain subject to the existing GMO legislation.

The European Parliament vote on 7 February 2024 means that MEPs have adopted this position for negotiation with member states.

Table 2. Country table of gene editing regulations

| Country | SDN-1 | SDN-2 | SDN-3 |
|---|---|---|---|
| USA | Deregulated | Deregulated | Case-by-case |
| Argentina | Deregulated | Deregulated | Deregulated (if not transgenic) |
| Australia (excl. Tas) | Deregulated | Regulated | Regulated |
| New Zealand | Regulated (under review) | Regulated (under review) | Regulated (under review) |
| Japan | Deregulated | Deregulated | Regulated |
| Brazil | Deregulated | Deregulated | Deregulated (if not transgenic) |
| Canada | Case-by-case | Case-by-case | Case-by-case |
| EU | Regulated (under review) | Regulated (under review) | Regulated |
| Israel | Deregulated | Deregulated | Deregulated (if cisgenic) Regulated (if transgenic) |
| Colombia | Case-by-case | Case-by-case | Deregulated (if not transgenic) |
| Honduras | Case-by-case | Case-by-case | Deregulated (if not transgenic) |
| Chile | Deregulated | Deregulated | Deregulated (if not transgenic) |
| China | Under development | Under development | Under development |
| India | Under development | Under development | Under development |
| Pakistan | Under development | Under development | Under development |

*Table derived from Aftab et al, Frontiers in Plant Science October 2023*[36]

# Consumer sentiment in important current and potential future markets

## China

The Department of State Growth's trade advocate in the People's Republic of China reported that Tasmania has maintained its reputation as a source of premium produce. However, the extent to which Tasmania's GMO moratorium contributed to this reputation varied between importers and the general consumer. Awareness of Tasmania's position on SDN-1 produce appeared to be entirely absent from all elements of the supply-chain from distributors to consumers.

The trade advocate contacted a small sample of businesses in Shanghai, Beijing and Hong Kong. She reported that Tasmanian products are always well regarded as premium Australian-sourced products due to the State's pure, clean and natural environment. There was awareness of the State's GMO-free status among importers and distributors associated with those companies which did not want, or did not have authorisation, to import GM produce. However, beyond this small sub-group there was little awareness of Tasmania's GMO-free status:

> *"There is limited awareness of Tasmania's GMO moratorium among consumers and it is not used as a selling point for Tasmanian products sold in greater China because most Chinese consumers treat Australia as the GMO-free country as they seldom heard [that] … any food products in Australia are GMO."* (Sept.2023)

It was reported that consumers paid more attention to GMO or non-GMO when it came to cooking oils or to foods made from soybeans. Anxiety related to whether genetically modified foods were safe for consumption.

The State Growth trade advocate reported that there are no market access restrictions for either GMO food or SDN-1 produce. She stated that there was low awareness of GM in non-food, fodder or pharmaceutical products in China generally, and even less for SDN-1 in either food or non-food products.

## South Korea

Tasmanian produce continues to be well regarded in Korea by the food and beverage industry. State Growth's trade advocate in Korea said that people outside the industry might not realise the high quality of Tasmanian goods but those in the industry with experience of Australian products are likely to be familiar with Tasmanian products' premium quality.

The perceptions by Korean food industry insiders of Tasmanian produce being of higher quality were due to several factors which were stated as:

- Tasmania's cool climate is ideal for growing produce, its pristine environment and strict food safety regulations;

- Tasmanian products are perceived to be more natural/less processed, a strong focus on organic farming and sustainable agriculture;
- Tasmanian food products are perceived as more expensive (because the cost of production was seen as higher in Tasmania compared to other Australian regions); and
- Tasmanian food products are seen as being more unique: a diverse range of produce and products not available from other parts of Australia.

There was uncertainty about the extent of knowledge of the State's GMO moratorium. Specific examples of quality food products popular in South Korea were cited as apples, honey, seafood (especially salmon), trout, oysters, wine and dairy products. Research by the Tasmanian Government in 2022 into the market viability of Tasmanian food and beverage items in South Korea found that strong interest from buyers of the State's produce was accompanied by concerns about cost and accessibility. However, the research suggested that these consumers were more likely to buy Tasmanian food and drink products if they have organic or GMO-free labels.

It was reported that South Koreans are more open to accepting GMOs for medical or veterinary uses than they are for food for human consumption.

On SDN-1 technology, the State Growth trade agent noted that the Korean Government has approved applications for SDN-1 use. The prevailing sentiment is that if SDN-1 technology is determined to be safe, it has the potential to enhance food security as well as offer functional applications.

The South Korean Government allows both GMO produce and produce derived from SDN-1 breeding techniques to be sold on the market. It requires that GMO products are labelled as such.

## United States of America

As a small exporter to a very large market, awareness of Tasmania and its produce among the general USA population is minimal.

In reference to the general population, feedback included the comment: *"Noone really knows where Tasmania is…or is aware of our GMO moratorium. If they knew about it, they would say that it is good to hear."*

In reference to food and beverage industry professionals, Austrade noted: *"Buyers have said… that Australia should put GMO status on their packaging. Americans don't know about it because they are not aware. It would be a selling point. At the very least tell the buyers."* Where there was some awareness of Tasmania, the view was that Tasmania's climate, cleanliness and non-pollution were great. These attributes coupled with avoidance of over-farming meant that Tasmanian products were *"also great"*.

The feedback suggested that at least a significant minority of American consumers choose 'clean food' when shopping. The State Growth trade advocate commented: *"There is a large body of people who are particularly driven to buy clean food. 'Wholefoods' for example does not allow any GMO-based products."* She noted that this was despite 'clean food' being known by consumers as being more expensive.

Neither source was aware of differences in consumer attitude or market reaction between GM produce on one hand and SDN-1 produce on the other, regardless of whether the products were food for human consumption, fodder for animals or pharmaceutical products.

## Japan

Sentiment towards GMOs remains mixed in Japan, with consumer behaviour exhibiting apparent contradictions. The large Japanese Consumers' Co-operative Union (a national organisation) continues to promote non-GMO products. This position contrasts with the Ministry of Agriculture, Forestry and Fisheries (MAFF), politics and industry.

Advice from the country-based trade specialists is that, generally speaking, most Japanese consumers prefer non-GMO products but that the market remains price-driven. Most of the vegetable oils sold in the Japanese market are from GM crops.

In the years since Tasmania extended its GMO ban to include all gene-edited organisms (including SDN-1), Japanese regulators have moved further in the opposite direction. In April 2021, MAFF relaxed procedures relating to feed and feed additives derived from cross-breeding genome edited varieties previously notified to MAFF with other previously notified genome edited varieties, conventional varieties or genetically engineered products for which MAFF has granted feed safety approval. These products now are exempt from MAFF's consultation process for genome-edited products.

The Japanese food and beverage sector appears alert to both GM food and gene-edited food. A case in point was the approval by FSANZ (6 May 2022) to import into Australia for human consumption flour or other wheat products derived from genetically engineered HB4 wheat originating in South America. The approval related to wheat products only, and not approval to grow the wheat in Australia. Japanese flour millers were concerned that Australia might accidentally export the GM wheat and had to be reassured that Australia is not planning to grow it. These millers also said they would not want gene-edited wheat either.

Another recent FSANZ[37] decision related to the approval of genetically modified bananas (resistant to Panama disease) to be grown for human consumption. Rather than grow the bananas commercially now, the plan is to hold the variety in reserve in case a Panama disease outbreak decimates the banana industry here. When notified, Japan's Ministry of Health Labour and Welfare questioned whether Australia intended to export planting material to countries that Japan imports from. It seemed satisfied that there were no plans in Australia to commercialise the variety.

# Trends in sentiment in relation to GMOs and gene editing

## Global sentiment towards GMOs and gene editing

World-wide trends show a difference in sentiment towards gene-edited produce as opposed to GMOs. In a large-scale review of the content of both mainstream and social media over 5 years to 31 December 2022, Lynas et al[38] reviewed 200 'top tier' media and 75,000 online media with social media to analyse trends globally.

They report that: *"in the context specific to agricultural biotechnology, gene editing achieves consistently higher favourability ratings than GMOs in both social and traditional English-language media. Our sentiment analysis shows that favourability is especially positive in social media…"*

For the purposes of the study, traditional media comprised print, online news outlets, blogs and broadcast content. Social media posts were from Twitter (now X) and Facebook. For gene editing, they analysed 48,500 traditional media articles and 138,200 social media posts. These were categorised for the purposes of sentiment analysis as 'pro', 'anti', 'neutral' or 'mixed'. The favourability percentage combined 'pro' and 'neutral' because the neutral designation for factual content was considered likely to improve awareness, to educate and to persuade readers of the value of the technology.

The authors noted that the consistent difference between the favourability of gene editing as compared with GMOs was observed in all media over virtually the entire 5-year period of the study, with gene editing enjoying substantially higher favourability ratings than GMOs.

## Tasmanian producer sentiment towards GMOs and gene editing

Sentiment among Tasmanian producers towards GMOs remains mixed, ranging from those who do not support the current GMO moratorium to those who strongly support it. However, even the latter group included some who:

- Expressed openness to considering the use of GMOs if necessary to combat pests or diseases, especially in the context of an effective emergency response to an exotic pest/disease incursion; and,
- When prompted on SDN-1, expressed significantly softer attitudes towards this technique than they did to GMOs.

A general trend was the view that niche or speciality producers whose products were marketed as premium or natural products were gaining a benefit to the extent that the Statewide GMO moratorium contributed to the State's clean and green image. It was not seen as an advantage by those who produced commodities.

## Pharmaceutical agriculture

Tasmania's Gene Technology Policy allows for the use of GMOs in pharmaceuticals poppies with qualifications.

The industry's principal output - opiate alkaloid - is a specialised commodity subject both to global demand pressures and international competition. The Tasmanian product has earned its own reputation for quality and alkaloid content but otherwise the commodity does not gain a Tasmanian place-of-origin benefit. The efficient production of biomass in Tasmania is fundamental to the sector's viability.

Advances in agronomy and improved genetic lines through traditional breeding have resulted in yields increasing from 5 kg/ha to 100 kg/ha over the course of half a century. However, the industry reports that these gains have plateaued. The rate of improvement seen historically can no longer be maintained using traditional means.

To remain competitive in the global environment, the opiate industry needs certainty of access in Tasmania to new tools and techniques as and when they become available. These innovations might include both GMO poppies and non-GMO poppies bred through SDN-1 techniques. Desired traits include improved alkaloid yield per plant, greater disease resistance to reduce pesticide usage, improved ability for the plant to utilise nutrients and drought tolerance, among others.

Australian agriculture necessarily has a first-world cost structure. Industry leaders stressed the need for a relentless focus on competitiveness through significant productivity improvements per plant if broadacre poppy production in Tasmania is to remain competitive in a world where others are looking at alternative methods of alkaloid production (see the Case Study below).

The Gene Technology Policy, and associated Gene Technology Guidelines, already allows for the use of GMOs in pharmaceutical poppies not intended to be used for food or feed, provided all statutory requirements are met and the markets for Tasmania's GMO-free food products can be maintained and appropriate coexistence arrangements developed. By direct inference this provision already extends to pharmaceutical poppy plants produced using SDN-1 techniques because current policy is to treat SDN-1 plants as though they are GMOs for marketing purposes.

In addition to pharmaceuticals, the poppy sector also supplies poppy seed for use as a culinary product. These are seen by the market as a quality Tasmanian product and benefit from Tasmanian place-of-origin brand reputation with however, little reference to the GMO status being a specific market benefit or limitation to access alternative markets.

The sector is seeking clarity on the process and conditions for the adoption of gene technology. If the industry is to invest in GMOs or new genomic techniques to maintain competitiveness within Tasmania, it needs a high degree of certainty that it can commercialise all forms of the potential end product.

## Case Study:
## Competition to Growing Poppies from Synthetic Biology

Many important opioid medications used in pain management such as morphine and codeine are derived exclusively from the cultivation and processing of poppy plants. Poppies have been commercially grown in Tasmania for this purpose since the 1960s, with the industry valued at between $31 million and $52 million at the farm gate in recent years.

Internationally, there have been technical advances in synthetic biology that have enabled the creation of genetically modified yeast and bacteria strains, engineered to convert sugar to opioids and opioid precursors in closed fermentation vessels. This new approach potentially represents a feasible alternative to poppy-based production that could reduce pharmaceutical reliance on agriculture.

For example, the US-based company Antheia Inc. has been scaling up its yeast-based biomanufacturing of pharmaceutical compounds such as thebaine, a key ingredient in medications such as oxycodone and naloxone, with the aim of delivering commercial quantities in 2024. Thebaine is also the main opiate produced by the Tasmanian poppy industry.

As microbial methods of opioid production are scaled up, they are likely to compete with poppy-based production. Proponents of these new technologies are actively promoting their advantages in terms of reliability, efficiency and cost-effectiveness.

Continuous research and innovation will be essential for the Tasmanian poppy industry to continue to compete against new methods of opioid production. This includes access to biotechnologies which offer the potential to achieve greater plant productivity and efficiencies.

### Food agriculture

Other Tasmanian agriculture stakeholders indicated overall support for SDN-1 adoption in Tasmania, recognising the benefits of new breeding techniques and wanting Tasmania to benefit when the new varieties were ready for adoption.

Well-progressed work in Victoria on behalf of the dairy sector using new breeding techniques to produce an easily digestible high-energy ryegrass for pasture was cited as a particularly beneficial development. It will soon undergo field trials ahead of expected commercialisation within three to five years.[39] In consultation, the dairy sector made a clear distinction between GMO and SDN-1 organisms. From a dairy perspective, continuation of the GM moratorium was non-contentious. However, gene-editing was seen as different and wanted. The sector cited the greenhouse trials underway in Victoria on an SDN-1 ryegrass with increased nutritional value and drought tolerance (see page 23).

Openness to SDN-1 products was also voiced by specific sectors and/or their representative organisations involved in premium produce, the marketing of which aligned with Tasmanian brand values. In this regard they shared the generalist view that good genetics is prized, and they did not want a situation where new varieties could be grown in mainland states but not in Tasmania.

A clear differentiation on GMOs is evident within the food sector between those who produce premium products and those who produce commodities. Specialised products which gained either market access and/or higher prices from clean and green place-of-origin Tasmanian branding benefited from the GMO moratorium to the extent that the moratorium contributed to the brand image. This produce range included cherries, wine, grass-fed meat, premium meat, seafood, honey and the entire organics sector, among others.

One meat producer which markets its premium brand as Tasmanian, GM-free, HGP[i]-free, natural and grass-fed said that the backing of the Tasmanian Government's moratorium was a 'massive advantage', especially in its most important international market, the USA. Another meat producer said that the sensitivity of its large Japanese market to GMOs was such that any decision to abandon the moratorium would present an existential risk to its business. They stated significantly softer attitudes to SDN-1 produce when prompted on the technique.

Wine producers in Tasmania operate in line with the viticulture sector's national policy of being GMO free in all aspects from the wine grapes themselves to wine additives. Using the current FSANZ definition (as opposed to the OTGR's), the sector's policy is presumed to encompass some of the new genomic techniques. The sector generally seeks to align its policies to the International Organisation of Vine and Wine (OIV) to avoid international trade barriers. However, it notes that trading nations are currently reviewing their position [of whether some new breeding techniques are GMO or not] as is FSANZ.[ii] The conclusions of these reviews may trigger revision of the viticulture sector's national position.

Among even strong supporters of the GMO moratorium some voiced support for the use of GM technology if required to fight diseases or pests, or to mount an effective response against incursion of an exotic disease or other threat. The sentiment was that if the genetic modification impacted only the pest and not the plant or animal producing the premium product itself, then such an intervention might be worthwhile if circumstances warranted it.

The canola industry is unique in the context of Tasmania's GM policy in that a commercialised GMO variety is already approved and in use on mainland Australia but cannot be grown here. The local industry generally views the moratorium negatively. As commodity producers, the GMO moratorium offers them no advantages. It denies them the GM variety's benefits of greater yield per hectare, reduced chemical inputs and higher oil content (per tonne of seed.) It imposes costs and restrictions in importing canola seed to Tasmania which must be tested to ensure it is non-GM. Tasmania's low tolerance level for GM presence (0.1% or less) compares with the 0.9% tolerance level used in GM-free districts on the mainland. Tasmania's climatic conditions are excellent for canola which produces seeds here that are 47% oil, exceeding the oil content produced on the mainland even by the GM variety. Nevertheless, the industry reports difficulty in attracting sufficient growers in Tasmania due to competition from other crops, some of which offer a higher return. The sector says it needs to be able to offer every advantage, including GMO canola, if it is to attract sufficient growers to meet the demand.

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[i] Hormone Growth Promotant (HGP)

[ii] FSANZ is considering amending the definitions for 'food produced using gene technology' and 'gene technology'. These *definitions determine* what foods are classed as *Genetically Modified under the ANZ Food Standards* Code. Its proposed approach was to include specific product-based criteria for excluding certain foods from pre-market safety assessment and approval as GM food. At the time of writing, the FSANZ review remained underway.

# New gene technologies that potentially provide positive benefits to primary industry sectors and Tasmania as a whole

The wider use of new breeding techniques has resulted in an expanding number of new gene-edited organisms at either trial or fully commercialised stages.

## Australia – gene-edited plant traits

More nutrition and improved sustainability of dairy production in the face of climate change are outcomes being delivered by an SDN-1 ryegrass[40] being trialled in Victoria by DairyBio (a joint initiative of Dairy Australia, the Gardiner Foundation and the Victorian Government.) Tasmania's dairy sector wants this new variety to be available to Tasmanian farmers once trials are completed and the seed is released for use. Research leader Dr Dan Isenegger reported that results to date are very encouraging:[41] herbage quality has been improved and future project work will validate the changes seen, such as increased digestibility, and selecting the first batch of seed to be made available for commercial breeding programs. The SDN-1 ryegrass variety has reduced lignin in cell walls which makes it more digestible, translating directly into greater energy for the animal. There is an intention to expand the work to cover a wider range of temperate species such as cocksfoot and lucerne, and also some warm season forages. Dr Isenegger said: *"This is to provide more options for pasture that may be better suited to future climates…Part of the thought is to safeguard the industry…Other hardy forages like cocksfoot, which are expected to be better suited to future environments may have less digestibility now, so it sort of makes sense for us to improve the herbage quality of these species too to provide our farmers with more options for their farming systems."* The improved ryegrass is expected to be ready for release in three to five years.

## United Kingdom (England) – gene-edited plant traits

In 2022, Rothamsted Research confirmed that field trials were underway for oleic rich *Camelina sativa*: a brassica with high levels of oleic oil.[42] Earlier that year, the UK eased regulations for research to make a clear distinction between GM and gene-edited crops. The same institute a year earlier announced that field trials were underway for wheat with a reduced cancer risk. It had been gene edited to have lower levels of the amino acid asparagine, which could help reduce the risk of cancer-linked acrylamide forming from asparagine when cooked to high temperatures.[43]

The John Innes Centre announced in 2022 it was researching tomatoes with boosted levels of provitamin D3.[44] The Centre believes the new crop could help millions of people with vitamin D insufficiency which it says is a growing issue linked to higher risk of cancer and dementia among other pathologies. In 2021, the Centre was undertaking field trials into healthier wild brassicas (broccoli, cabbage, sprouts, kale) with increased levels of glucosinolates which may promote improved blood glucose control thus reducing risk of cardiovascular disease.[45]

In the same year, researchers at the John Innes Centre used gene editing techniques to identify a key gene in wheat responsible for maintaining 50% of the yield of this worldwide staple, potentially giving wheat varieties yield resilience in the face of climate change.[46]

The company British Sugar is investigating gene-edited sugar beet seed to produce plants resistant to the Virus Yellows group of viruses which devastated crops across eastern England during the 2020-21 season.[47] Successful trials promise a long-term solution to the disease. It aims to have that country's farmers growing sugar beet crops resistant to Virus Yellows within three to five years.

## European Union – gene-edited plant traits

Researchers in Netherlands in 2020 used CRISPR techniques to develop a tomato with improved resistance to powdery mildew which is a worldwide disease that threatens the production of greenhouse- and field-grown tomatoes.[48] The result was plants with a reduced, but not complete loss of, susceptibility to the powdery mildew pathogen. They concluded that the research demonstrated the efficiency and versatility of the CRISPR-Cas9 system as a powerful tool to study and characterise susceptibility genes.

In Spain, field trials (2022-2025) are underway on salinity and drought tolerance in broccoli gene-edited using CRSIPR-Cas9.[49] Earlier, researchers there and in France used the same new breeding technique to develop a tomato resistant to black speck disease.[50] Significantly, the bacterium responsible for this disease in tomatoes, *Pseudomonas syringae*, is widespread and a causes disease on a broad range of economically important plant species.

Researchers in Germany, France and elsewhere have used CRSIPR-Cas9 to develop rice with broad spectrum resistance to bacterial blight.[51] The disease is most severe in southeast Asia but is increasingly damaging in west African countries, and results in substantial yield loss.

## USA – gene-edited plant traits

In the USA, the agricultural company, GreenVenus LLC, specialises in new genomic techniques. It recently announced (2023) new gene-edited grape varieties with natural preservation properties which diminish or negate need to use sulphites to prevent oxidation/ browning of grape juice during processing.[52] It said the new grape cultivars exhibit intrinsic antioxidant capabilities to safeguard wine from oxidation, thereby protecting its authentic colour and flavours. It regarded these as significant progress in the development of new grape varieties that require fewer chemical inputs while still ensuring production of premium quality wines. The same company also announced last year that a new non-browning lettuce it developed had achieved commercialisation.[53] The romaine lettuce has improved shelf-life of up to two weeks and a potential for higher marketable yield with no tip burn. It was estimated in 2019 that about $3.3 billion worth of lettuce is lost due to waste annually, half of which is the romaine type.

In March 2023, Japan added a waxy corn developed in the US by Corteva Agriscience to its list of gene-edited products not subject to GMO regulations.[54] It was the fourth type of gene-edited product added to the list by Japan's Ministry of Health, Labour and Welfare (MHLW) and MAFF and the first developed by a non-Japanese company. Corteva Agriscience used CRISPR-Cas9 technology to increase amylopectin in the corn starch from 75% to nearly 100%. In addition to the food industry, amylopectin is used in the textile and paper sectors.

## Japan – gene-edited plant traits

In December 2020, Japan approved the first genome-edited product to be exempt from regulatory provisions which apply to GMOs. This was a gene-edited tomato where CRISPR-Cas9 technology was used to increase the gamma-aminobutyric acid (GABA) content of the tomato.[55] GABA is effective in lowering blood pressure. The gene-edited GABA tomato was developed jointly between the University of Tsukuba and Sanatech Seed. Japanese research institutes have since used gene editing to develop fleshier sea bream and high growth puffer fish (see page 12).

# Development of new generation GMOs that provide health or other benefits

> *"Diet-related health problems are on a steep increase and non-communicable diseases are now the leading cause of death worldwide… Interconnected areas are agriculture, nutrition, climate, circularity and innovation… Linking food, health and socio-economic development is important."* [56]

Society is moving away from an era where matters were considered sector-by-sector and discipline-by-discipline. The interconnected influences of environmental changes, technology and social practices are shaping the reality in which our food systems operate. The term 'food systems' refers to all the elements and activities relating to producing and consuming food, and their effects including economic, health and environmental outcomes.[57] The CSIRO highlights changing climates, supply chain and workforce disruptions, rising input costs and nutrition-related public health concerns as drivers of change in food systems.[58]

Thinking from a food system perspective means consideration of the potential contribution of both GMOs and new genomic techniques to human health and well-being outcomes; to sustainability of our food system; to combatting destructive pests; and, to conservation of an environment which is increasingly impinged by human activity.

The gene-edited organisms (principally SDN-1) identified in the previous section offer health benefits including higher vitamin content, a reduction in precursors to harmful compounds produced when cooking, reduced wastage through extended shelf life and a reduced need for non-food additives during post-harvest processing. In all these cases it is the plant or animal itself which has been modified through gene editing. However, there is a growing range of other innovations where the subject of the gene editing or, in some cases, genetic engineering is not the plant or animal itself but rather an aspect of its environment. The subject of the genetic technique may be a farmed animal's forage crop, or a vaccine against a disease, or a pest attacking the plant or animal. In these instances, genetic innovations may deliver very significant benefits to animal or plant health and to the sustainability of food systems without any genetic change to the plant or animal concerned.

## Case study:
## Gene technology in human health and medicines

Since the introduction of Australia's Gene Technology Scheme in 2001, there has been increasing use of genetically modified organisms (GMOs) in human health and medicines worldwide.

According to the Office of the Gene Technology Regulator (OGTR), the use of gene technology in human health in Australia is now almost as common as GMOs in agriculture[i], and in 2019-20 approvals for medical dealings involving intentional release (DIR) licences exceeded those for GM crops[ii].

Some of the uses of GMOs in human health include:

- producing vaccines for diseases such as influenza, Japanese encephalitis, dengue fever, COVID-19 and cholera;
- making medicines such as insulin; and
- developing diagnostic tests.

Australian and Tasmanian research is exploring gene therapies to potentially treat genetic diseases, cancer, infectious diseases, motor neurone disease, dementia, and other neurodegenerative diseases. Gene therapy works in individual patients by replacing a disease-causing gene with a healthy copy of the gene. Any changes made to a person's cells will not be passed on or inherited. Using gene therapy, scientists have developed a single-dose treatment for spinal muscular atrophy in infants that is now available through the Pharmaceutical Benefits Scheme[iii], and introduced new genes into leukaemia sufferers that make it easier to target and destroy cancerous cells[iv].

The use of gene technology in human health and medicines in Australia is regulated by the OGTR and the Therapeutic Goods Administration. In Tasmania, a permit is currently required to use GM medicines and therapeutics under the *Genetically Modified Organisms Control Act 2004*. As the use of gene technology in human health and medicines becomes more common in mainstream clinical practice, Tasmania's policy settings may need to be clarified to ensure that Tasmania's GMO moratorium continues to be appropriately targeted to GM crops and animals for marketing purposes.

[i] Of the licences granted for dealings involving intentional release (DIR) over the five years to 30 June 2023, 43% were agricultural, 40% were human therapeutics, 10% were veterinary therapeutics and 7% were for other licences. OGTR Annual Report 2022-23 https://www.ogtr.gov.au/sites/default/files/2023-10/operations_of_the_gene_technology_regulator_annual_report_2022_23.pdf

[ii] OGTR Retrospective Report 2 - Changing research landscape - June 2021 https://www.ogtr.gov.au/about-ogtr/twenty-years-ogtr

[iii] Therapeutic Goods Administration https://www.tga.gov.au/resources/auspmd/zolgensma

[iv] Australian Government Department of Health National Gene Technology Scheme https://www.genetechnology.gov.au/using-gene-technology/human-health

## Meeting environmental challenges: climate change, greenhouse gases and pasture sustainability

A GMO clover trial is underway in Victoria to produce a forage crop designed to reduce production of methane gas in grazing livestock. The trial is based on a variety where insertion of a gene from the closely related hare's-foot clover turned on an existing pathway in the plant so that condensed tannin was produced in the leaves rather than in the flowers alone. *"The goal was to deliver farmers a clover with lower bloat risk and – equally important to industry – a clover option that results in lower methane emissions when eaten by livestock"*.[59] The report stated that researchers are confident that the clover's yield will be comparable to existing clover crops used by farmers while methane emissions will be down by as much as 20% and bloat risk possibly eliminated. The trial is part of a joint venture between Grasslanz (the commercial arm of the New Zealand Government's research institute AgResearch) and PGG Wrightson Seeds. This research is backed by one of NZ's Crown research institutes, but it had to move out of NZ where it originated ten years ago because that country's gene technology rules were considered by the researchers to be too restrictive. NZ recently announced that these rules will be replaced.

## The health of wild animals: a vaccine to fight against Devil Facial Tumour Disease?

On 14 June 2023, the Office of the Gene Technology Regulator issued a licence to the University of Tasmania (UTAS) for a limited and controlled trial outside the laboratory of a GM vaccine for the prevention and/or treatment of devil facial tumour disease (DFTD) in Tasmanian devils.[60] The licence provides for the vaccine (an attenuated version of the human adenovirus) to be administered to Tasmanian devils kept in enclosures within trial sites in Tasmania. The trial is planned to run for five years.

The researchers at the Menzies Institute for Medical Research at UTAS also will require a permit issued under Tasmania's GMO Control Act, and a permit from the Australian Pesticide and Veterinary Medicines Authority (APVMA). Any application from UTAS will be considered on its merits when it is received.

Tasmania's Gene Technology Guidelines currently allow for approval, subject to conditions, of live GM animal vaccines or microbes intended for 'bioremediation or biological control of pests or diseases.'

## A resurrected thylacine (Tasmanian tiger) would be a GMO

Colossal Biosciences Inc. is a US bioscience and genetic technology company founded in 2021 and based in Dallas, Texas. Describing itself as a 'de-extinction company', Colossal Biosciences states that it is working to de-extinct the woolly mammoth, the dodo and the Tasmanian tiger.[61]

The thylacine project lead is University of Melbourne Genetics and Developmental Biology Professor Andrew Pask. ABC News reported that, if de-extincted, the returned species would be classified as a GMO which presents a challenge because of the Tasmanian moratorium on the commercial release of GMOs into the Tasmanian environment.[62]

ABC News quoted Professor Pask as saying that a discussion was developing about 'how or if' the government would differentiate de-extincted species from other GMOs: *"Globally all governments around the world are starting to develop policies of how we work with these things."* The same article quoted Colossal Biosciences Inc. co-founder Benn Lamm: *"A lot of governments are looking at exceptions because GMO is too broad a category. The broad catch-all definition worked 15 years ago, but it just doesn't work for all these cases today."*

## Gene drives: protecting crops from insect pests

Biosciences are developing new non-chemical tools to tackle threats such a Queensland fruit fly, Medfly and other highly damaging pests. An extensive release (36 million individuals) of sterile but non-GM pest fruit flies occurred in February and March 2024 in South Australia as a preventative measure.[63] The sterile insects would interrupt the breeding cycle of any wild populations by vastly outnumbering them and reducing the chance of wild fruit flies being able to mate with a fertile one. The South Australian release is preventative but Sterile Insect Technique (SIT) also can be used as one of the tools to combat a new incursion.

While the flies used in South Australia were rendered infertile by irradiation, various genetic techniques also may be used to confer not only sterility but some other trait in the pest which would cause rapid population decline. The use of genetic techniques to encourage a particular trait to be propagated in a population is known as a gene drive. It introduces a bias which increases the relative chance of the desired trait being inherited even if it is disadvantageous to the organism.[64]

No country was identified during this Environmental Scan which had determined its regulations for gene drives, although some are moving towards it. The Australian Government earlier this year released the consultation draft of a policy guide on the nature of the information and assessment process which might be used in response to a gene drive application.

In 2021, the OGTR issued a licence to the University of Melbourne authorising contained research to explore gene drive designs using a non-harmful fruit fly species *Drosophila melanogaster*, and it has released hypothetical case studies on two potential gene drives.[65]

Most recently in the United States, experts from North Carolina State University developed a CRISPR-based gene drive that supressed populations of vinegar flies (*Drosophila suzukii*) that affect soft skinned fruits such as raspberries in Europe and the Americas.[66] The technique led to female sterility characterised by females that do not lay eggs. The researchers used mathematical models to predict that releasing just one modified fly for every four wild flies could suppress the population in eight to 10 generations.[67]

In the United States, Cornell University researchers developed a genetically engineered diamondback moth with a self-limiting gene that prevents female caterpillars from surviving, which could help control moth populations that damage crops. They completed a controlled open-field trial in 2019.[68]

Researchers at University of California San Diego and University of California, Berkeley used CRISPR to determine insect sex and fertility. Using fruit fly as a test case, they used the CRISR-based technique called precision-guided SIT (pgSIT) to generate eggs from which 100% of progeny surviving to adulthood were sterile males. The target genes used in this case are common in a wide cross-section of insects, suggesting the technique could feasibly be applied to many different insect pests.[69]

## Gene drives: protecting human health from diseases and their vectors

Researchers based at Imperial College, London, used CRISPR-Cas9 to target a sex-related gene in the malaria-carrying mosquito *Anopheles gambiae* which resulted in the complete suppression of a caged population of the insect.[70] They designed a gene drive which altered a region of the *doublesex* gene that is responsible for female development. Males carrying the modified gene showed no changes, and neither did females with only one copy of the modified gene. Females with two copies of the modified gene showed both male and female characteristics, failed to bite and did not lay eggs. The experiments showed that the gene drive transmitted the genetic modification nearly 100% of the time. After eight generations no females were produced, and the population crashed because of lack of offspring.[71]

## Gene drives: countering antibiotic resistance in bacteria

Researchers at the University of California San Diego used CRISPR in 2019 in a gene drive to combat antibiotic resistance in *Escherichia coli (E. coli)*.[72] Widespread prescriptions of antibiotics and their use in animal food production have led to rising prevalence of antimicrobial resistance in the environment. Evidence indicates that these environmental sources of antibiotic resistance are transmitted to humans and contribute to the current health crisis associated with the dramatic rise in drug-resistant microbes. While further significant research work remains to be done, there may be the potential to combine the gene drive mechanism with a human delivery system to address such conditions as cystic fibrosis, chronic urinary tract infections and infection associated with resistant biofilms that pose difficult challenges in hospital settings. When combined with other delivery mechanisms, the technology might also be effective in removing, or 'scrubbing', antibiotic resistant strains from the environment in various settings such a feedlots and fishponds.

# Conclusion

This Environmental Scan finds that key markets for premium Tasmanian produce including Japan, China and the United States remain sensitive to GMOs.

Peak Tasmanian primary industry groups and many agricultural sectoral groups voice general support for continuation of a GMO mortarium which does not apply to pharmaceutical poppies if satisfactory co-existence arrangements are implemented.

While acknowledging that commodities such as canola are particularly disadvantaged by the GMO moratorium in non-pharmaceutical agriculture, this Environmental Scan concludes that ending the GMO moratorium at this time is unlikely to enjoy widespread support among primary producers due to fear of negative market reaction.

The continuing treatment in Tasmania of SDN-1 organisms as though they were GMOs runs counter to national and most international arrangements. New Zealand and the European Union are the only two significant jurisdictions identified which have a similar regulatory stance to Tasmania, and both of these jurisdictions have started processes with the express aim of liberalising their regulatory regimes. Softer attitudes to gene editing (especially using SDN-1 techniques) compared to GMOs have been discerned among populations globally and this difference in attitude is also evident among Tasmanian primary industry peak and sectoral groups. Alignment with national and firming international consensus on treatment of gene-editing is possible without abandoning the GMO moratorium.

Tasmania's market-based GMO moratorium was conceived and implemented to protect the identity of the State's non-GM agricultural produce. In the years leading up to and including the early 2000s when Tasmania's GMO moratorium was instigated, the focus of applied commercial genetic technologies was plant-based primary industry. Declaring Tasmania to be a GMO-free area achieved the desired outcome of excluding genetically modified produce from Tasmanian agriculture without greatly impacting non-farm sectors. Since then, the scope of gene technologies including genetic modification has expanded enormously. Research into, or the application of, gene technologies now includes gene therapies to treat human conditions, vaccines for people and animals, bioremediation, control of environmental pests, control of disease vectors and the re-creation of extinct species for which DNA remains available.

Given the above, a more precise demarcation of which activities are prescribed as gene technologies may be warranted.

# Appendices

## Appendix 1: *Gene Technology Regulations 2001*, Schedule 1A – Techniques that are not gene technology

(regulation 4)

| Item | Description of technique |
|---|---|
| 1 | Somatic cell nuclear transfer, if the transfer does not involve genetically modified material. |
| 2 | Electromagnetic radiation induced mutagenesis. |
| 3 | Particle radiation induced mutagenesis. |
| 4 | Chemical induced mutagenesis. |
| 5 | Fusion of animal cells, or human cells, if the fused cells are unable to form a viable whole animal or human. |
| 6 | Protoplast fusion, including fusion of plant protoplasts. |
| 7 | Embryo rescue. |
| 8 | *In vitro* fertilisation. |
| 9 | Zygote implantation. |
| 10 | A natural process, if the process does not involve genetically modified material. Examples: Examples of natural processes include conjugation, transduction, transformation and transposon mutagenesis. |
| 11 | Introduction of RNA into an organism, if:<br>(a) the RNA cannot be translated into a polypeptide; and<br>(b) the introduction of the RNA cannot result in an alteration of the organism's genome sequence; and<br>(c) the introduction of the RNA cannot give rise to an infectious agent. |

# Appendix 2: *Gene Technology Regulations 2001*, Schedule 1B – Organisms that are genetically modified organisms

Note: See regulation 4A.

### 1.1 Genetically modified organisms

For the purposes of regulation 4A, an organism is a genetically modified organism if an item in the following table applies to the organism.

**Organisms that are genetically modified organisms**

| Item | Description of organism |
| --- | --- |
| 1 | An organism that has had its genome modified by oligonucleotide directed mutagenesis. |
| 2 | An organism modified by repair of single strand or double strand breaks of genomic DNA induced by a site directed nuclease, if a nucleic acid template was added to guide homology directed repair. |

# Appendix 3: *Gene Technology Regulations 2001*, Schedule 1 – Organisms that are not genetically modified organisms

(regulation 5)

| Item | Description of organism |
|---|---|
| 2 | A whole animal, or a human being, modified by the introduction of naked recombinant nucleic acid (such as a DNA vaccine) into its somatic cells, if the introduced nucleic acid is incapable of giving rise to infectious agents. |
| 3 | Naked plasmid DNA that is incapable of giving rise to infectious agents when introduced into a host cell. |
| 4 | An organism modified by repair of single strand or double strand breaks of genomic DNA induced by a site directed nuclease, if a nucleic acid template was not added to guide homology directed repair. |
| 6 | An organism that results from an exchange of DNA if:<br>(a) the donor species is also the host species; and<br>(b) the vector DNA does not contain any heterologous DNA. |
| 7 | An organism that results from an exchange of DNA between the donor species and the host species if:<br>(a) such exchange can occur by naturally occurring processes; and<br>(b) the donor species and the host species are micro organisms that:<br>(i) satisfy the criteria in AS/NZS 2243.3:2010 for classification as Risk Group 1; and<br>(ii) are known to exchange nucleic acid by a natural physiological process; and<br>(c) the vector used in the exchange does not contain heterologous DNA from any organism other than an organism that is involved in the exchange. |
| 8 | An organism that is descended from a genetically modified organism (the **initial organism**), if none of the traits it has inherited from the initial organism are traits that occurred in the initial organism because of gene technology. |
| 9 | 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, if:<br>(a) the initial organism was not a genetically modified organism (because of the application of regulation 5); or<br>(b) all such inherited traits are traits that occurred in the initial organism as a result of a modification described in an item in this Schedule. |
| 10 | An organism that was modified by gene technology but in which the modification, and any traits that occurred because of gene technology, are no longer present. |
| 11 | *Agrobacterium radiobacter* strain K1026. |
| 12 | *Pasteurella multocida* strain PMP1. |

## Appendix 4: Organisations/businesses contacted for this Environmental Scan

- TasFarmers (formerly Tasmanian Farmers and Graziers Association)
- Tasmanian Agriculture Productivity Group
- Tasmanian Seafood Industry Council
- SunPharma (ANZ)
- Tasmanian Poppy Growers Association
- Tasmanian Beekeepers Association
- Macquarie Oil
- H.W. Greenham & Sons
- Tasmania Feedlot
- Extractas Bioscience
- Reid Fruits
- DairyTas
- WineTas
- Fruit Growers Tasmania

# Glossary

**Genetically Modified Organism** (GMO) – 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 Drive** – genetic elements that are favoured for inheritance, and which can therefore spread through populations at a greater rate than genes with standard Mendelian inheritance. Gene drives can only spread from sexually reproducing parents to their offspring. If gene technology is used to introduce or create a gene drive in an organism, the resulting organism will be a GMO and subject to regulation under the *Gene Technology Act 2000*.

**Gene Editing** (also genome editing) – the process of making highly specific changes to the genome of an organism using enzymes designed to target specific DNA sequences. SDN-1 techniques are an example of gene editing. In this document, the term is used to distinguish from genetic modification using transgenic methods.

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

**New Breeding Techniques** – also New Plant Breeding Techniques – are gene editing methods to accelerate the development of new desirable traits in plant breeding.

**Site-Directed Nuclease-1 (SDN-1) Techniques** – a gene editing technique which uses an enzyme (nuclease) to cut DNA at a predetermined location, after which the cell's own DNA repair mechanism makes an unguided repair which may result in a sequence variant at the repair site. Examples of SDN-1 technologies include CRISPR-Cas9, ZFNs and TALENs. It is distinct from other SDN gene editing techniques such as SDN-2 and SDN-3 which involve the introduction of a foreign DNA template to guide the repair process.

**Synthetic Biology** – A broad term describing the design, manipulation and creation of biological systems for useful purposes.

**Transgenic Modification** – the process of introducing foreign DNA into a host organism's genome.

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AgriGrowth Tasmania

Department of Natural Resources
and Environment Tasmania

P: 1300 292 292

E: farmpoint@nre.tas.gov.au

W: www.nre.tas.gov.au

Tasmanian Government

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