Genetically Modified Organisms (GMO) Annual Environmental Scan

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AgriGrowth Tasmania
Department of Primary Industries, Parks, Water and Environment (DPIPWE)

Tasmanian Government

Contents

Definitions

BIOFORTIFICATION – the development of new crop varieties with increased levels of micronutrients, by either conventional breeding practices or genetic modification[i]

BIOTECHNOLOGY - is a broad term that relates to using living organisms or parts of organisms to carry out biological processes for use in industrial processes or services. There are many examples of biotechnology in agriculture, medicine and waste recycling. It includes using microorganisms to transform materials (such as in fermentation), different methods of propagation (such as plant cloning or grafting), and may involve genetic alteration (through methods such as selective breeding)[ii].

COMMERCIAL PURPOSES – Intentional release of GMOs into the environment which take place outside of containment facilities[iii].

EPIGENEGICS – the study of heritable changes in our genome (the complete set of all of our genes) that occur without altering the DNA or genetic code[iv].

ENVIRONMENTAL SCAN – An environmental scan can help identify the trends most likely to affect a sector or an organisation. It is about gathering information on changing conditions to inform strategy.

GENETICALLY MODIFIED ORGANISM – (GMO or GM or GE) 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[v].

GENE TECHNOLOGY – Any technique for the modification of genes or other genetic material, but does not include sexual reproduction or homologous recombination or any other technique specified in the *Gene Technology Regulations 2001*[vi]

NEW BREEDING TECHNIQUES - A set of New Breeding Techniques (NBTs) can be used to introduce desired characteristics more precisely and in less time. Refer to this document for more detailed information:

http://www.foodstandards.gov.au/publications/Documents/New%20Plant%20Breeding%20Techniques%20Workshop%20Report.pdf

TRANSGENIC – describes an organism containing genes from another organism put into its genome through recombinant DNA techniques. A transgenic organism is one that contains a gene or genes which have been artificially inserted instead of the organism acquiring them through reproduction[vii].

Summary

BACKGROUND

This is the third Environmental Scan completed by AgriGrowth Tasmania since the GMO Moratorium in Tasmania was extended in 2014. It does not seek to reiterate discussion already presented in previous scans but rather to provide an update of changes that have occurred in the last year.

The most significant change since the last Scan, is the commencement of the reviews of the Gene Technology Scheme and the Gene Technology Regulations 2001. It is the third review of the Gene Technology Scheme, with phase two of the consultation process scheduled in November and December 2017. The Legislative and Governance Forum on Gene Technology is conducting this review, independent of the Gene Technology Regulator[viii].

Concurrently, the Office of Gene Technology Regulator (OGTR) is conducting the Technical Review of the Gene Technology Regulations 2001. This review is seeking to provide clarity about whether organisms developed using a range of new technologies (also known as new breeding techniques [NBTs]) are subject to regulation as genetically modified organisms (GMO) and ensure that new technologies are regulated in a manner commensurate with the risks they pose[ix].

The outcomes from these reviews have potential to change how GMOs are developed, reported and released into commercial production but these will be addressed in the 2019 moratorium review.

There are no GM crops or GM animals currently grown commercially in Tasmania.

SUMMARY OF KEY FINDINGS

There is no need to trigger a review of the moratoria on the commercial release of GM into Tasmania's environment at this time.

NBTs offer the opportunity to develop a broad range of novel traits, such as pest and disease resistance, herbicide resistance, drought tolerance, improved nutritional quality, extended shelf-life, and reduced allergenicity. The key advantages of the technology include[x]:

- precise trait development that can achieve both selectable and non-selectable traits;
- faster product development than both conventional breeding and transgenic approaches;
- simultaneous targeting of multiple traits and the capacity to combine multiple traits in a single crop; and
- the promise of a clear regulatory path and acceptance of its products among both farmers and consumers in target markets.

From a human health perspective, NBTs such as CRISPR/Cas9[1] are now revolutionising GM technology use in many areas including human health, drug development, research applications, agriculture and bioenergy. There are also developments with biological insect pest control that has potential application for fruit and vegetable growers. While all of these technologies could offer opportunities in the Tasmanian context, they are at the research stage and still have to work through regulatory approval processes.

From a consumer sentiment perspective, industry and consumer views remain divided as to how commercially released GMOs may impact on markets. The Environmental Scan highlights that NBTs continue to advance rapidly and there remains no common agreement internationally or nationally as to how to regulate them.

Agriculturally, NBTs offer the opportunity to develop a broad range of novel traits. There are already a number of plant varieties developed using NBTs that are approaching field trials, undergoing field trials, or which are already commercialised across the globe. While they could offer opportunities for Tasmanian primary producers, they will need to work through regulatory approval processes before being released into the environment in Australia.

GM Pastures

Ryegrass is naturalised in Tasmania as a pasture plant. There continues to be interest in development of GM perennial ryegrass in Australia. Since the Dairy Futures CRC ended in June 2016, the commercialisation of the GM ryegrass variety has been taken over by

[1] Refer to the Office of Gene Technology Regulator for definition on CRISPR http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/977EF3D4FDD4552ECA2580B10014663C/$File/Discussion%20Paper%20-%20Review%20of%20the%20Gene%20Technology%20Regulations%20.pdf

DairyBio which is a five year joint venture between the Victorian Government and Dairy Australia. Despite the potential benefits for dairy farmers, the commercial success of the variety is not guaranteed. Public acceptance of milk produced from GM pasture is likely to determine whether it is a commercial success and this would be considered carefully by milk processors.

Emerging Issue

There is an emerging issue regarding the organics sector and how it classes new breeding techniques. From an organic standard perspective, there remains a zero tolerance to the presence of GM organisms in organic crops in Australia. The International Federation of Organic Agriculture Movements (IFOAM) European Union (EU) Group has commenced a consultation on new breeding techniques and has released a draft position paper to be voted on at the next General Assembly of the organic movement in late 2017[xi].

Any proposed changes to the Gene Technology Scheme or Gene Technology Regulations in Australia (as a result of NBTs) would need to be considered by the organics industry. The findings of the IFOAM consultation process would have implications for the organics movement in Australia as certifying bodies Australian Certified Organic, Biodynamic Agricultural Association of Australia, National Association for Sustainable Agriculture are members of IFOAM.

Zero tolerance

The Tasmanian canola industry has indicated that there has been no shortage of non-GM canola seed (that meets Tasmania's current GMO threshold levels) for the 2017-18 growing season.

Introduction

BACKGROUND

Tasmania, has since 2001, maintained a moratorium on the commercial release of genetically modified organisms (GMO) into the environment. To this end, Tasmania has applied the Commonwealth laws (also known as the Gene Technology Scheme or 'the Scheme) in the State, first in 2001, with the *Gene Technology (Tasmania Act) 2001,* and then in 2012 when the 2001 was repealed and replaced with the *Gene Technology (Tasmania) Act 2012*.

There is no provision in the Commonwealth legislation for a State or Territory to 'opt-out' of the Scheme on environmental or human and safety grounds. However, on 5 September 2003, the *Gene Technology (Recognition of Designated Areas) Principle 2003 (Cwth)* came into force. That principle states, "*an area is recognised as an area that is designated for the purpose of preserving the identity of GM crops, non-GM crops or both GM and non-GM crops for marketing purposes, if the area is so designated under a State law*".

The then Tasmanian Minister for Primary Industries declared the whole of Tasmania a GMO-free area by the *Genetically Modified Organisms Control (GMO-free Area) Order (Tas)* on 31 October 2005. The aim was to position the State in the global marketplace as a producer of food that is genuinely GMO-free.

In August 2014, the Tasmanian Government extended the moratorium on GMO's until 16 November 2019. As a consequence, a new Tasmanian Gene Technology Policy (2014-2019) and Tasmanian Gene Technology Guidelines were also developed.

TERMS OF REFERENCE

In accordance with the Tasmanian Gene Technology Policy (2014-2019), DPIPWE is responsible for seeking stakeholder views and providing an annual report to the Minister on developments in gene technology and market changes. Specific matters to be reported on include:

1. Development of new generation GMOs that provide health or other benefits;
2. Consumer sentiment in important current and potential future markets; and

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

DPIPWE is to advise the Minister if, based on evidence, there are significant developments in any of these three specific matters that warrant triggering a review of the Policy before the maximum five-year review date. In addition, DPIPWE is to monitor the risks associated with maintaining Tasmania's current GMO threshold levels and any alternative options.

CONSULTATION PROCESS

The most significant change to the GMO environment in Australia (since the last Environmental Scan) is the review of the Gene Technology Scheme and the Gene Technology Regulations. DPIPWE has been in contact with the following industry bodies to alert them that the national reviews are currently underway.

Any observations raised by these bodies to AgriGrowth, at the time of contact, have been captured within this Scan.

- Dairy Australia (through DairyTas)
- Fruit Growers Tasmania
- Poppy Growers Tasmania
- Tasmanian Agricultural Productivity Group
- Tasmanian Beekeepers Association
- Tasmanian Farmers and Graziers Association
- Tasmanian Institute of Agriculture
- Tasmanian Organic-Dynamic Producers Inc
- Tasmanian Salmonid Growers Association
- Wine Tasmania

Findings

EMERGING ISSUE – ORGANICS SECTOR AND NEW BREEDING TECHNIQUES

Organic farms can be found state-wide in Tasmania and are involved in varying enterprises. There are 126 certified operations (79 are producers) in Tasmania representing 3 per cent of the nation's total certified operations[xii]. The producers comprise approximately a dozen large enterprises but the majority of the organic farms are small-scale[xiii].

From an organic standard perspective, there remains a zero tolerance to the presence of GM organisms in organic crops in Australia, with the growing markets for Australia (China, Korea, Japan) having no tolerance for GM in their organic standards[xiv].

While advocates of GM crops point to a number of benefits from the on-farm commercialisation of GM varieties, including enhanced farm productivity, improved weed control, reduced energy and chemical usage, and agronomic improvement of farm systems[xv], the global organic movement officially continues to oppose the release of GMOs into the environment and their use in agriculture.

In a statement issued prior to the European Commission's High Level Conference on Modern Biotechnologies in Agriculture, the Vice President for Policy of the International Federation of Organic Agriculture Movements (IFOAM) European Union (EU) Group was quoted as saying that:

> *All new genetic engineering techniques should be, without question, considered as techniques of genetic modification leading to GMOs and fall within the scope of the existing legislation on GMOs. There are no legal or technical reasons to exclude these techniques from risk assessment, prior authorisation and mandatory traceability and labelling, which apply to current GMOs.*
>
> *Deregulation of new genetic engineering techniques would jeopardise the ability of the organic sector to remain GMO-free and would threaten the freedom of farmers and consumers not to use these new GMOs. The European Commission should guarantee that no product obtained through new genetic engineering techniques will be marketed before detection methods are available, and should fund EU research projects to develop these detection methods.*[xvi]

The statement reaffirmed the IFOAM-EU Group's position on NBTs, which is detailed in a position paper released in December 2015. IFOAM has commenced a consultation on NBTs and has released a draft position paper to be voted on at the next General Assembly of the organic movement in late 2017[xvii]. The draft paper has ten recommendations and advocacy messages. One of them says that NBTs should be considered the same as GMOs. Another one says that, because NBTs will not be detectable, there needs to be an obligatory prerequisite to disclose the breeding technique used to avoid certain strains entering the organic system, and to guarantee freedom of choice for farmers and consumers[xviii].

Any proposed changes to the Gene Technology Scheme or Gene Technology Regulations in Australia (as a result of NBTs) would need to be considered by the organics industry. The findings of the IFOAM consultation process would have implications for the organics movement in Australia as certifying bodies Australian Certified Organic, Biodynamic Agricultural Association of Australia, National Association for Sustainable Agriculture Australia, Organic Federation of Australia are all members of IFOAM[xix].

SECTION UPDATES

This section now discusses in more detail the three areas as specified by the Terms of Reference.

SECTION 1: DEVELOPMENT OF NEW GENERATION GMOS THAT PROVIDE HEALTH OR OTHER BENEFITS

It is worth nothing that on 31 October 2017, it was the 35th anniversary of the approval in the United States of America of the world's first recombinant DNA drug product – GE insulin[xx]. Since then, NBTs such as CRISPR/Cas9[2] are now revolutionising GM technology use in many areas including human health, drug development, research applications, agriculture and bioenergy[xxi].

A new CRISPR trial, which hopes to eliminate the human papillomavirus (HPV), is set to be the first to use the technique inside the human body. In the non-invasive treatment, scientists will apply a gel that carries the necessary DNA coding to the cervixes of 60 women. The aim is to disable the tumour growth mechanism in HPV cells. This method is different to the usual CRISPR method of extracting cells and re-injecting them into the affected area. Twenty further trials are set to begin in late 2017 and early 2018. The research will focus on disabling cancer's PD-1 gene that fools the human immune system into not attacking the cells. Different trials are focusing on different types of cancer including breast, bladder, oesophageal, kidney, and prostate cancers[xxii].

Dengue fever outbreaks occur each year in north Queensland following cases imported from overseas. The Aedes aegypti mosquito is the main vector of dengue and its presence is currently limited to parts of Northern, Central and Southwest Queensland[xxiii]. There is still no cure for dengue. However, Sanofi Pasteur has had its vaccine Dengvaxia approved and endorsed by the World's Health Organization (WHO) on 15 April 2016[xxiv]. As of 11 October 2017, the vaccine is now available in 19 countries including Australia[xxv]. Sanofi-Aventis Australia Pty Ltd is, as of 27 June 2017, the licenced commercial supplier of Dengvaxia in Australia[xxvi].

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[2] Refer to the Office of Gene Technology Regulator for definition on CRISPR http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/977EF3D4FDD4552ECA2580B10014663C/$File/Discussion%20Paper%20-%20Review%20of%20the%20Gene%20Technology%20Regulations%20.pdf

Oxitec, a pioneer in genetic engineering of insect control, developed the self-limiting Aedes aegypti called Friendly™ Aedes: a genetically modified male mosquito that does not bite and does not transmit viruses. Released into nature they mate with wild females. Their offspring inherit the self-limiting gene that causes them to die before they reach functional adulthood. They also inherit a fluorescent marker that enables tracking and monitoring. In addition, the Friendly™ Aedes die along with their offspring, therefore do not persist in the environment or leave any ecological footprint[xxvii].

In five separate trials in Brazil, Panama, and the Cayman Islands, Oxitec's environmentally-friendly solution has reduced the wild Aedes aegypti population by more than 90%[xxviii]. In January 2017, India joined in and launched a Friendly™ Aedes project in Dawalwadi as other available methods have not been effective to date to fight dengue which has had devastating effects on Indian citizens every year[xxix].

Fortunately, Tasmania is not affected by dengue or any other mosquito transmitted diseases. However, the principle method of self-limiting insects is being explored for agricultural pest control by Department of Agriculture and Food, Western Australia[xxx].

Research and development in biofortification seem to be a promising way to prevent nutrition disorders in humans living in poorer countries where supplements and fortified food are unaffordable or difficult to access[xxxi] [xxxii]. World-wide up to 700,000 children die as a result of vitamin A deficiency each year. Researchers in Queensland recently developed a Vitamin A-enriched banana to address the worsening vitamin A deficiency in Africa. Nutrient poor cooking bananas are the main food staple in many rural areas of Africa. In July 2017 the first Vitamin A-enriched crop was produced in Uganda. The target was to deliver 50 per cent of the estimated average requirement of vitamin A in vulnerable populations equal to β-carotene equivalents of 20 μg/g dry weight banana[xxxiii]. Remarkably, they achieved four times the amount of their targeted level.[xxxiv]

Agriculture and Food:

The global population is estimated to reach 9.7 billion by 2050. Nutrient denser crops may be needed to help feed this growing population, particularly if global warming and climate change continue to impact on crops in some regions. Gene-editing technologies such as CRISPR systems as well as epigenetic technologies may help to address these challenges. The precision of gene editing will further improve over time, but most importantly the technology needs to be approved and accepted by regulators, producers and consumers[xxxv] if it is to be freely used to advance quality of human life. More on consumer sentiment is presented in Section 2.

CRISPR/Cas9, one of the NBTs, continues to be explored in the agri-food sector. Self-limiting insect populations are being explored to tackle agricultural pests and they could prove to be the most environmentally friendly and sustainable form of pest control currently available. However, there are concerns about what long-term effects there may be on ecosystems when potentially eradicating entire insect species[xxxvi] although the response may be different in relation to exotic and native species.

In December 2016, Oxitec announced its advancement from contained environment to open field trials with its self-limiting Mediterranean fruit fly (Medfly). One of the trial sites is located in south Perth, Western Australia (WA)[xxxvii]. Fruit fly costs the WA horticulture industry millions of dollars annually in lost production and control costs[xxxviii].

Tasmanian horticulture relies heavily on the State's fruit fly pest free area status for Queensland fruit fly (Qfly) and Medfly. The risk of entry, establishment and spread of Qfly and Medfly is assessed as very low, however the estimated economic consequences will be high. The current technically sound biosecurity arrangements for mitigating risks of fruit fly entry into Tasmania are working. It is also important to recognise that Tasmania's risk profile is changing. Tasmania's *Maintaining Tasmania's Freedom from Fruit Fly: A strategy for the future 2017-2050'*[xxxix] provides an overarching timeframe to assess risk areas in Tasmania's fruit fly management strategy until the year 2050. Biosecurity Tasmania will conduct five yearly tactical reviews and validations of the Strategy. This iterative process will provide effective horizons for forward risk predication, analysis and mitigation measures.

On 5 September 2017, Oxitec announced it was starting field trials of the self-limiting Diamondback Moth. The Diamondback Moth is another highly invasive pest, foraging in brassicas and other vegetables that costs farmers globally over $4 billion per year in crop losses and control management[xl]. The diamondback moth is an important insect pest of Tasmanian agriculture.

The idea of self-limiting insects is not new. In the mid-1980s, there was successful trials of sterile blow flies (irradiation method) to prevent fly strike in sheep on Flinders Island. However, the success was largely due to the geographical isolation. Failed trails on open land and larger islands in addition to high rearing and release costs ceased the funding of the project.[xli]

Tasmania, while relatively pest-free, could benefit from self-limiting insects if proven effective after trials. The technology could increase the State's harvest yields, reduce control management costs and make farming practices more environmentally friendly however these benefits would only be realised if GM insects are not considered the same as GM feed and food from a regulatory and consumer point of view.

Epigenetics (see definitions) is the newest avenue of technology being explored in the agri-food sector. Studies in the field of epigenetics (including information about DNA) has implications for the application of NBTs and potential for crops in the field[xlii]. US company Epicrop found a unique way to improve crop yields and stress tolerance without making any changes to the plant's DNA. Epicrop discovered the MSH1 gene which, when silenced, tricks plants into 'believing' they are growing under stressful conditions such as drought, heat and cold. This causes them to compensate by activating a number of survival mechanisms, resulting in higher yields and more robust growth. More remarkably, the attributes carry through about five generations of offspring. Epicrop believes that this technique could be applied to virtually any plant. To date, there are far fewer regulations for epigenetic crops and therefore, epigenetic seeds may be available soon to help farmers address drought, heat, cold and climate change[xliii].

Traditionally hornless traits in cattle are achieved through selective breeding. In February 2017, United States (US) researchers successfully bred hornless (polled) calves after inserting DNA from hornless breeds into dairy cow embryos that would normally produce horned calves. Although these polled calves are still kept in quarantine researchers are determining whether their offspring will also be polled. The aim is to increase work and public health and safety and reduce global fatalities caused by horned cattle[xliv]. This year, CSIRO scientists discovered a way to make the Australian Poll Gene Marker test more accurate and able to be used across a range of breeds[xlv].

Polled cattle breeds also remove the need of disbudding and dehorning. It would save farmers time and money as well as improve animal welfare and maintenance of social licence. This flows-on to improved meat and leather quality because of reduced stress and bruising. Handling and other aspects of animal management such as feeding and animal health, are critical determinants of meat eating quality[xlvi].

Finding:

While all of these technologies could offer opportunities in the Tasmanian context, they are at the research stage. There will need to be trials and regulatory approvals before these technologies proven in real life farming situations.

SECTION 2: CONSUMER SENTIMENT

Globally, consumer sentiment remains unchanged over the past twelve months with consumers having diverse views over the use of GM in foods. While research over the last year has not indicated any heightened human health or environmental risk from GMOs, European government policy reflects the strong anti-GM public opinion among European consumers[xlvii].

Globally, non-GMO provenance is the fastest growing clean label claim, increasing 49 per cent over the past five years and in the United States alone, sales data of non-GMO products growing by 270 per cent in the past three years[xlviii].

The continued growth in sales for non-GMO provenance products has positive implications for this State. The 2017 Legislative Council Select Committee inquiry into the dairy industry in Tasmania noted that companies such as Fonterra are marketing Tasmania separately so that they can demonstrate attributes (non GMO) with traceability that are preferred in their markets[xlix]. Tasmanian beef brands like Cape Grim Tasmania continue to expand their market share presumably in response to consumers valuing their attributes including GMO freedom. Cape Grim were the first Australian food brand to be certified by the USA based NON-GMO Project protocol[l].

Sentiment within Tasmania's key international trading partners:

According to the 2015-16 Tasmanian Agri-Food Scorecard, beef was the most valuable international food export from the state in 2015-16. Tasmania's pasture-based red meat production system with the ban on Hormone Growth Promotants (HGP) and moratorium on GMOs have been important factors in securing US export contracts for premium grass fed beef[li].

The table below highlights the key export destination for a number of our key commodities.

Commodity	Country	Export destination by value $10 million or over
Meat	Japan	$62 million
	Republic of Korea	$21 million
	United States of America (USA)	$95 million
Dairy	Japan	$21 million
	Malaysia	$10 million
	Sri Lanka	$27 million
	Vietnam	$11 million
Fruit	China	$15 million
	Taiwan	$10 million
	Hong Kong	$12 million

Tasmanian beef is actively promoted as GM free. As an example if Tasmania changed its GM moratorium status, then the value of Tasmanian beef exports that could be affected would be in the vicinity of $178 million (out of total exports of $194 million for 2015-16).

The table below summarises some of the key activities with respect to consumer sentiment, government policy and regulation (with respect to GMOs) in Tasmania's key trading partners over the last twelve months.

Country	Sentiment
Japan	In September 2017, the Consumer Affairs Agency of the Government of Japan held its fifth meeting on labelling of food containing GM food and ingredients. Consumer groups at the meeting expressed their view that all food items should be included for mandatory labelling. However, they also expressed some level of understanding that this might increase food business risks and costs. The expert committee is expected to summarise their review by the end of 2017 and this may contain draft new regulations for mandatory labelling for GE food. Currently there are eight crops and 33 processed food items that require GE labelling in Japan. No analysis has been made on specific crops and whether they are grown in Tasmania.
Hong Kong	Hong Kong has no commercial production of biotechnology crops nor does it conduct field trials. Biotechnological research studies are being conducted in local universities.

	The country has a mandatory pre-market safety assessment to ensure the safety of GM food and has a set of guidelines for voluntary labelling for trade reference. The labelling would assist Hong Kong consumers who have concern regarding GMO foods. The Agriculture, Fisheries and Conservation Department regularly conducts surveys for presence of GMOs in various imported and locally grown crops from local markets and farms in Hong Kong.
United States of America (USA)	GM foods are available in the USA. Food processors are wary of consumer reaction to products containing GM wheat, so no GM wheat is commercially grown in the United States. Depending on the Federal agency, the USA has different terms to describe organisms created through recombinant DNA techniques. The United States Department of Agriculture (U.S.D.A.) Agricultural Marketing Service is currently looking at new rules that will form part of the National Bioengineered Food Disclosure Standard however it has not given a compliance date for labelling GMO ingredients. The U.S.D.A. is also looking at areas of potential overlap relating to recombinant DNA techniques.
Singapore	Singapore recognises the potential of synthetic biology as a future economic driver with wide-reaching applications from agriculture to bio-manufacturing to ground breaking cancer treatments and medicines. The Government aims to position the country as a global biological hub for synthetic biology. There are no vocal consumer groups actively campaigning against the imports of GE products. No barriers exist to imports as long as they are approved as safe for public consumption in their countries of origin before being allowed into Singapore.
The United Kingdom (UK)	From a survey conducted in mid-2016, half of the UK population do not feel well informed about GM crops and a further six per cent have not heard of them. The current license to use glyphosate will expire in the EU in 2017 with member States deciding to extend the product's license for another 10 years. The National Farmers Union has linked glyphosate to the GMO debate and has indicated that if there is a ban on the herbicide use, they will wish access to the use of GMOs instead[lii]. In 2017, the Rothamsted Research Institute in the UK applied for permission for a new trial of GM wheat. Several high profile groups including the Bakers Food and Allied Workers Union submitted a pledge to the Department for Environment, Food and Rural Affairs that was signed by over 350 bakers, millers, farmers and consumers saying they refused to use GM wheat[liii]. Once the UK leaves the European Union, there will be four markets with Scotland, England, Wales and Northern Ireland all delivering different regulatory frameworks and which may cause some issues if the devolved administrations disagree. Northern Ireland and Scotland have indicated they wish to be GM free.
China	China is the world's largest importer of GM crops however is yet to approve any major GM food crops for cultivation. The Chinese Ministry of Agriculture released the Revised Administrative Measures for Safety Assessment of Agricultural Genetically

	Modified Organisms in 2016. The 13th Five-year plan for Science and Technology Innovation aims to push forward the commercialisation of new domestic types of Bt corn, Bt cotton and herbicide resistant soybean by 2020. At the same time, delays in import approvals continue to increase, causing unpredictability for traders. GE crop cultivation is approved on a province-by-province basis. China has not approved any GE food or feed crops by foreign biotechnology firms for domestic commercial production. As an example, it reported that when foreign companies have asked to submit an application for domestic cultivation, the Ministry of Agriculture informs them that China's foreign direct investment restrictions prohibit them from doing so. China does not have a co-existence policy. China's Food Safety Law incorporates existing regulations on biotechnology labelling. China has zero tolerance for the presence of unapproved biotechnology traits in imported products. Although PCR testing is voluntary, it is believed that PCR testing is de-facto mandatory and imports to China are strictly held to import thresholds.
Republic of Korea	On 9 June 2017, Korea's Ministry of Food and Drug Safety (MFDS) made changes to labelling laws relating to GMOs and decided to exempt U.S. organic processed products from the mandatory biotech labelling requirements. For products that do not have biotech counterparts (such as non-GM banana) the use of non-GMO or GMO free claims are prohibited on product labels. Foods subject to GM food labelling requirements have been expanded from top-five ingredients to all ingredients. Non-detectable products are exempt from mandatory biotech labelling. The MFDS allows up to three per cent of unintended presence of approved biotech components in unprocessed non-biotech products.
Indonesia	In the past, GM maize, GM soybean, and GM sugarcane have received food safety approval. The majority of consumers prefer fresh foodstuffs which are readily available in their neighbourhood at affordable prices with 'healthy eating' becoming more popular among educated consumers. There is broad support for the technology from farmer organisations. Due to a lack of information and general knowledge about biotechnology, consumers are more hesitant if they know their food contains GE products. Indonesians have widely consumed GE soybean derived tempeh and tofu for the last three decades. GMO derived ingredients are required to be labelled.
Taiwan	Taiwanese regulators continue to remain very cautious about domestic cultivation of biotech crops however GM canola, GM Cotton, GM Maize, GM Soybean and GM Sugar Beet have been approved.
New Zealand (NZ)	The New Zealand Government announced in late 2016 that it would review the appropriateness of councils being involved in regulating GMOs. This was prompted after a high court decision in September that ruled councils with a GMO prohibition in their resource management plan have jurisdiction under the Resource Management Act to regulate their use.

Sources: Abridged from www.ers.usda.gov and http://gain.fas.usda.gov, and www.pir.sa.gov.au and www.cfs.gov.hk and www.ams.usda.gov and www.royalsociety.org

Labelling and public concern

Public pressure can shape regulations relating to the adoption of technology. Examples include public controversies over GMOs, which have had major influences on regulation and approval of new Crops in Europe[liv]. At a forum in New York in October 2017, leaders of companies developing GMOs indicated that agriculture needs to do a better job at explaining gene editing technologies to consumers[lv]. Governments also will need to anticipate public concerns around the most recent biotechnological advances, especially gene editing[lvi]. Increasingly, more voices are asserting that new technologies should be regulated not only on their benefit-risk profiles but also on their societal context and need[lvii].

Gluten-free, non-GMO and convenient/easy to prepare attributes have led product innovation plans of speciality food manufacturers for 2017[lviii]. At an international level, GMO labelling is applicable for pre-packaged food, packaged food and for food additives. Many countries are now considering trade regulations for GMO foods through labelling[lix]. In regions such as Asia Pacific, there is a lack of standardisation with labelling, however there is also a view that mandatory food labelling would burden the food industry with unwieldy and costly requirements[lx].

Labelling can lead to varied results. While some labels provide useful information that is not readily detectable by consumers, labels can also contain misleading claims that exploit a knowledge gap, for example labelling a bottle of water "gluten free' and 'non-GMO'[lxi].

In a recent study by the University of Florida Institute of Food and Agricultural Sciences, consumers were not able to distinguish between the terms 'organic' and 'non-GMO' on food labels, mistaking them as synonymous.[lxii] According to the research, consumers paid more for a 'Non-GMO Project' verified label products with the 'USDA Organic' label not holding as much weight[lxiii]. This research finding could influence manufacturers as to how they invest in non-GMO or consider organic certification (within organic standards across the globe, the use of GMOs in foods is prohibited).

Globally, different approaches continue to be taken in rolling out GM foods to consumers. Cargill has been working with the NON-GMO Project to verify several of its non-GMO ingredients because of demand for non-GMO foods[lxiv]. The rollout of the first GM food animal (4.5 tonnes of GM salmon) has been released into the Canadian food market, however the Canadian Government does not require GM foods to be labelled.

Consequently some consumers are concerned that they do not have choice in being able to avoid purchasing the product[lxv].

In contrast, the GM 'Arctic' Apple (non-browning apple) is being sold in retail stores with distinctive packaging that highlights how the apples are produced and where the fruit is sold[lxvi]. The company is promoting its product with key messages such as reducing waste and tackling obesity by increasing consumption[lxvii].

Growers in Australia feel they are being left behind in the global rollout of the GM non-browning apples and GM potato that offer industry gains in reducing wastage, consequently Horticulture Innovation Australia has commissioned a major study investigating the likely acceptance of these new breeding technologies in the local industry[lxviii]. The major grower concern is consumer acceptance followed by the cost of applying new breeding techniques to the relatively small vegetable market in Australia[lxix].

Consumer sentiment within Australia:

Food Standards Australia New Zealand consider the importation of GM food and over time has approved sixty foods derived from GM crops imported into Australia[lxx]. Research on consumer attitudes over the last decade indicates that views have shifted from a lack of knowledge of gene technologies that drive negative attitudes, to confirming that attitudes are driven more by personal risk-benefit perceptions and values[lxxi].

Recent research into perceptions of harm versus safety noted that even the highly science-literate women who worked in health science saw GM food as being in conflict with their core food values with all the women surveyed preferring food that was 'natural' (as in unprocessed), locally produced, healthy and nutritious and free from additives[lxxii].

Former Deputy Prime Minister John Anderson has reflected on the debate about new technology and the need for calm, reasoned discussion as discussion driven by emotions can hinder access to GM technologies,[lxxiii] while others emphasise the need for clear communication and consultation with the public through appropriate channels[lxxiv].

A recent inquiry by the Parliament of Tasmania Legislative Council Select Committee into the Tasmanian Dairy Industry reported that there remains diverse views from the dairy sector on the benefits (or otherwise) of GMOs[lxxv]. As part of the submissions, two agricultural consultants stated the potential to improve farmer profits by adoption of dual systems (GMO and non GMO) in Tasmania, with the Chair of the TFGA Dairy Council stating that Tasmania had not yet realised any measurable benefit from remaining GMO free[lxxvi]. However dairy processor Fonterra, urged caution with any decision to change Tasmania's GMO free status[lxxvii].

In October 2017, the OGTR released a Report into community attitudes to gene technology[lxxviii]. The findings of this Report indicate that attitudes to GMOs in Australia have settled and do not show any degree of change, with about 13 per cent of the population strongly opposed to GMO[lxxix]. There are wide differences in support of GMOs in medical (63 per cent), industrial (55 per cent), environmental (54 per cent) and food and crops (38 per cent)[lxxx]. Of those who supported GM foods, almost half the respondents were open to the production of GM food as long as regulations were in place to make sure it was safe, however knowledge about what foods in Australia were GM foods is generally poor[lxxxi].

Non-GM Canola

GM canola and GM cotton are the only two commercially grown GM crops in Australia. With non-GM canola, the only canola crop that can be grown in Tasmania, it is worth noting the following trends.

There has been expansion in the area of GM canola grown in three mainland States[lxxxii]. In 2015-16 there was 983 hectares of non-GM canola planted in Tasmania, producing 1,983 tonnes from 33 agricultural enterprises[lxxxiii]. This represents less than one per cent of the national total production for 2015-16. Irrigation expansion in Tasmania creates further opportunity to increase the area planted given appropriate market signals.

More than 80 per cent of Australia's canola oil is likely to end up in the fuel tanks of European cars and trucks this year, rather than as human food as EU buyers are largely interested in buying non-GM canola due to the negative consumer sentiment towards GM products[lxxxiv]. The demand for certified non-GM canola outside Australia is high, with some non-GM canola attracting a higher premium[lxxxv]. This creates further opportunities for Tasmanian growers.

Other domestic matters

Like Tasmania, South Australia will continue the moratorium on all GM crops as a point of difference that allows South Australia to represent its produce to the world as being grown in a GM-free State[lxxxvi]. A Bill tabled in the South Australian Parliament seeking to extend the moratorium in that State until 2025 (the current moratorium expires in September 2019) passed in mid-November 2017[lxxxvii lxxxviii].

In Western Australia, the Environment and Public Affairs Committee of the Western Australian Legislative Council has commenced in December 2017, an inquiry into compensation mechanisms for farmers who lose money because of contamination from GM material. The public submission period opened on 7 December 2017 and will close on 16 February 2018[lxxxix].

Finding:

In respect to consumer sentiment, government policy and regulation in Tasmania's key trading partners, opinion remains divided as to how commercially released GMOs may impact on markets. The Environmental Scan shows that NBTs continue to advance rapidly and there remains no common agreement internationally or nationally as to how to regulate them.

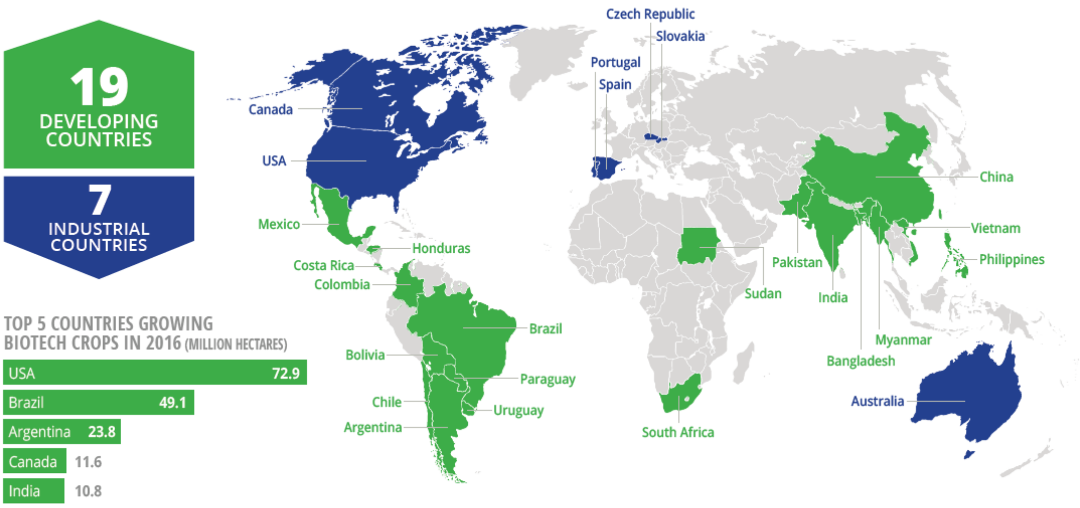
SECTION 3: NEW GENE TECHNOLOGIES THAT POTENTIALLY PROVIDE POSITIVE BENEFITS TO PRIMARY INDUSTRY SECTORS AND TASMANIA AS A WHOLE

As with many of the technologies that underpin agricultural advancement, the basic scientific understanding and practical applications of gene technologies are moving rapidly. The 2016 Environmental Scan served as an introduction to the technologies and their application to agriculture, and in particular Tasmanian agriculture. This section builds on that introduction to provide a more in-depth commentary.

Despite the rapid uptake of several GM crops and numerous GM varieties in some countries, the development and commercialisation of new GM crop varieties and traits has tended to be slow[xc]. The average time to market for a new GM crop variety, 13 years, includes over five years for regulatory and registration activities[xci]. This compares to 7-12 years to produce a new variety through conventional plant breeding, which is more laborious and time-consuming but less burdened by regulation[xcii].

As is apparent in Section 2 of this Environmental Scan, GM crops face significant consumer resistance and opposition from non-government enterprises in many Organisation for Economic Cooperation and Development (OECD) countries. This opposition has slowed the commercialisation and adoption of GM crops by lessening the incentives for biotechnology companies to invest in developing new GM crops and varieties, and for farmers to adopt the varieties.

In spite of the time to market, a record 185.1 million hectares of GM crops were grown globally in 2016 in twenty six countries involved in the production of biotech crops in 2016 (see below).



Source: www.isaaa.org Note that with the above graphic, the ISAAA have incorporated Tasmania and South Australia in the country where crops are grown, however both these States have a moratorium on the commercial release of GMO's into the environment.

Around 88 per cent of crops are grown in the Americas and 10 percent in Asia[xciii]. More than half (54 per cent) was grown in developing countries, with three countries (Brazil, Argentina and India) accounting for around 84 per cent of developing country production[xciv].

Of the 18 countries that grew at least 50,000 hectares of GM crops in 2016, 4 were high income OECD countries, including the USA, Canada, Australia and Spain. The USA and Canada accounted for almost 99 per cent of GM crop production by area in these countries. The USA alone accounted for around 85 per cent, equivalent to 39 per cent of world GM crop production by area[xcv].

Australia's GM crop production increased from 0.7 million hectares in 2015 to 0.9 million hectares in 2016, an increase of 29 per cent - the largest percentage increase of any country and the fifth largest increase in absolute terms after Brazil, the US, Canada and South Africa[xcvi].

A Report by GP Economics into the global economic benefits of GM crops, has found that over the last 20 years, crop biotechnology has significantly reduced agriculture's environmental impact and stimulated economic growth in the 26 countries where the technology is used[xcvii].

Since 1996, the development and commercialisation of GM crops has proceeded from first generation varieties with single traits, such as herbicide tolerance or pest/disease resistance, to second generation varieties with two or more 'stacked' herbicide tolerance and/or insect resistance traits, or tolerance of abiotic stress such as drought[xcviii]. In 2016 stacked 'GM events' (specific genetic modifications in a specific species) made up 82.6 per cent of all approved GM events globally[xcix].

The focus of so-called 'third generation' GM crops is on the development of output traits, such as modified starch or oils (e.g. high omega-3 fatty acids, oleic acid or stearic acid), non-browning or bruising flesh, reduced woodiness (low lignin), and increased micronutrients (e.g. beta-carotene, ferritin and vitamin E) [c].

With some recent exceptions, the GM crops in cultivation around the world are transgenic GMOs produced using gene technologies originally developed in the 1980s. These technologies have enabled not only the genetic modification of crop varieties but also the acceleration of conventional breeding programs through a process known as marker-assisted selection (MAS) that uses genetic markers linked to agronomic traits[ci].

Advances in DNA sequencing and the mapping and characterisation of genes and their functions have resulted in a substantial increase in the number of genetic markers being available to crop and livestock breeders. Genomic selection is a technique related to MAS that uses large sets of genome-wide genetic markers (up to hundreds of thousands of individual markers) to predict the breeding value of an animal or plant[cii]. It enables plant and animal breeders to target complex traits controlled by large numbers of genes, whereas MAS is limited to use with less complex traits controlled by one or a few genes.

In 2010, two United States companies (Cargill USA and Branhaven LLC) filed a patent describing a method for identifying genetic traits in cattle using 2,510 genetic markers known as Single Nucleotide Polymorphisms[ciii]. In June of this year, the Federal Court finished hearing an appeal (launched by Meat and Livestock Australia) against the patent, which claims that the patent could restrict access to genomic testing and research into cattle genetics by giving the companies the right to licence service providers or charge licence fees for genomic testing[civ]. The outcome of the appeal could have important implications for the use of genomic selection in Australian livestock breeding programs.

Genetic manipulation in all its forms is a technically complex area of science hence any meaningful discussion must contain a degree of scientific complexity including use of standard scientific terminology. Complexity has therefore been minimised in the following discussion, particularly in respect to the practical agricultural applications of science.

New Breeding Techniques (NBTs)

NBTs offer the opportunity to develop a broad range of novel traits, such as pest and disease resistance, herbicide resistance, drought tolerance, improved nutritional quality, extended shelf-life, and reduced allergenicity. The key advantages of the technology include[cv]:

- precise trait development that can achieve both selectable and non-selectable traits;
- faster product development than both conventional breeding and transgenic approaches;
- simultaneous targeting of multiple traits and the capacity to combine multiple traits in a single crop; and
- the promise of a clear regulatory path and acceptance of its products among both farmers and consumers in target markets.

Scientific understanding

Over the past two decades a range of new gene technologies have been developed that are commonly referred to as 'New Plant Breeding Techniques' or simply 'New Breeding Techniques' (NBTs). The term encompasses diverse technologies[3], including:

- Site-directed nuclease (SDN) techniques;
- Oligo-directed mutagenesis (ODM);

[3] Refer to the Office of Gene Technology Regulator for definitions on new breeding techniques http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/977EF3D4FDD4552ECA2580B10014663C/$File/Discussion%20Paper%20-%20Review%20of%20the%20Gene%20Technology%20Regulations%20.pdf

- Cisgenesis (transferring a gene from the same or closely related species) and intragenesis (inserting a reorganised regulatory coding region of a gene from the same species)[cvi]
- RNA-dependant DNA methylation (RdDM) – a technique that uses RNA interference (RNAi) to interrupt or suppress gene expression, also known as 'gene silencing';
- Grafting of non-GMO scion on to GMO rootstock;
- Reverse breeding; and
- Agro-infiltration.

NBTs have significantly increased the range of options available in breeding programs, beyond conventional breeding techniques and the genetic modification techniques used since the 1980s. While several NBTs are restricted to use in plants or are not currently used in farm animals or microorganisms (including grafting, agro-infiltration, RdDM and reverse breeding)[cvii], SDN and ODM can be used in plants, animals and microorganisms[cviii].

The application of NBTs is resulting in the emergence of novel products that raise fundamental questions about the definition of a GMO and how best to regulate gene technology to protect the health and safety of people and the environment, without unduly stifling innovation. SDN and ODM techniques are so precise that they can be used to produce organisms that are (in practice) indistinguishable from the products of conventional breeding or spontaneous mutations[cix]. It is likely to be almost impossible to detect these organisms, unless they are deliberately genetically 'barcoded' to facilitate detection.

In the case of agro-infiltration, reverse breeding and RdDM, transgenes are only present during an intermediate step in the technique and not in the final product[cx]. The techniques may also result only in changes to the *expression* of target genes through the spread of small RNA molecules, instead of changes to the DNA sequence of the plant's genome[cxi]. The resulting organism is therefore indistinguishable from conventionally bred crop lines using DNA-based analytical methods including Polymerase Chain Reaction (PCR) and DNA sequencing.

Increasingly, research is turning to the use of sprays containing chemically synthesized short RNA molecules to induce gene silencing in plant pathogens or the host plant as a method of controlling pests and diseases[cxii].

Genome editing

Crop improvement requires the continuous production of new biological diversity from which desirable variants can be selected[cxiii]. In conventional breeding programs, genetic variation is produced through crossing existing plants, which results in new combinations of existing variation, or through the generation of new genetic variations using chemical- or radiation-induced mutagenesis[cxiv cxv].

Chemical or radiation-induced mutagenesis, results in random changes to the genome (and the process of growing and crossing plant populations and selecting desirable variants) is laborious and time-consuming[cxvi]. It can also be difficult to separate desirable genes from closely linked genes that may have neutral or negative effects[cxvii].

ODM and SDN, which are commonly referred to as 'genome editing', offer significant advantages over other breeding methods, including speed, precision, versatility and cost[cxviii]. Genome editing enables targeted modification of the genome of an organism at precise locations by either producing random point mutations or directed changes to the DNA sequence. Depending on the technique used, the directed changes can range from the deletion, addition or substitution of one or several nucleotides in the DNA sequence through to the insertion of large DNA fragments that can include genes, regulatory elements and selectable markers[cxix]. Such precision is virtually impossible with the more established genetic modification techniques[cxx].

SDN techniques use a cutting enzyme (nuclease) to produce a double-stranded break in the DNA at a specific location in the genome and utilises the cell's DNA repair machinery to produce changes at the target site. A variety of enzymes can be used to achieve the targeted DNA breaks, including meganucleases (MNs), zinc finger nucleases (ZFNs), transcriptional activator-like effector nucleases (TALENs), and clustered regularly-interspaced short palindromic repeats (CRISPR)-associated proteins such as CRISPR-Cas9[cxxi,]. The techniques can be used to produce changes ranging from random mutations (SDN-1), predefined mutations (SDN-2), to the addition of large DNA sequences that can include genes and regulatory elements (SDN-3)[cxxii]. Whereas SDN-1 results in random insertions, deletions and substitutions, often of only a few nucleotides, SDN-2 and SDN-3 work on the principle of using a supplied template to guide the cell's repair machinery[cxxiii].

Among the genome editing techniques in use, CRISPR-Cas9 has become the most widely used because of its relatively low cost, versatility and ease of use[cxxiv].

Unintended effects

Chemical or radiation-induced mutagenesis, induces random mutations at a rate several hundred times higher than the spontaneous mutation rate in plants[cxxv]. In comparison, ODM and SDN result in one or a few predefined mutations and possibly some 'off-target' mutations[cxxvi]. End products containing a desired mutation can be produced much more quickly and precisely through gene editing than through conventional breeding, and through the use of whole genome sequencing it is possible to check that these products contain only the desired mutation(s)[cxxvii].

Unlike cisgenesis, intragenesis[4] and the more established genetic modification techniques, most genome editing techniques (including ODM, SDN-1 and SDN-2) do not result in end products containing exogenous DNA[cxxviii] and the predefined mutations generally bring about very limited modifications to one or more pre-existing genes[cxxix]. Conversely, SDN-3 results in the introduction of one or more new genes and/or regulatory elements. Whereas the more established genetic modification techniques lead to the uncontrolled insertion of transgenes into the plant genome, which can lead to undesired effects on the expression of non-target genes or the gene itself (so-called 'position effects'), SDN-3 enables the targeted insertion of the gene to a specific location in the genome, thereby minimising the potential for unintended effects[cxxx]. Nonetheless, when a new gene is introduced into an organism through either SDN-3 or the more established genetic modification techniques, its interactions with the endogenous genes of the recipient organism cannot always be predicted[cxxxi].

Although genome editing techniques result in a much lower number of unintended effects, the frequency of these 'off-target' mutations and the risks they pose continues to be debated. A 2015 Norwegian study into the current status of scientific knowledge concerning SDN and ODM concluded that the techniques "are not fully scientifically understood and thus pose many uncertainties connected to mode of action as well as potential unintended effects"[cxxxii]. In theory, with the rapid development of synthetic 'designer' nucleases and the ability to use DNA sequencing to confirm the presence or absence of off-target mutations, it should become increasingly possible to minimise the occurrence of off-target effects.

[4] Refer to the 2016 Environmental Scan Appendix Two for explanation
http://dpipwe.tas.gov.au/Documents/GMO%20Annual%20Environmental%20Scan%202016.pdf

Australia's peak life sciences organisation, AusBiotech Ltd, asserts that ODM, SDN-1 and SDN-2 introduce changes to the organism's own DNA and are essentially chemical mutagenesis techniques and therefore should be regulated in the same way as chemical mutagenesis"[cxxxiii]. Opponents of this position argue that unlike chemical or radiation-induced mutagenesis, which results in random mutations, genome editing techniques can be used sequentially to make profound, targeted changes to the genome, and could be deliberately misused to create entirely new diseases and poisons[cxxxiv].

The Gene Technology Technical Advisory Committee (GTTAC) established under the *Gene Technology Act 2000* (Cwth) to provide scientific and technical advice to the Gene Technology Regulator and Ministers, has resolved that the risks posed by organisms altered by SDN-1 are unlikely to be different to naturally mutated organisms, and that SDN-2 and ODM are unlikely to pose risks that are different to natural mutations, conventional breeding or mutagenesis[cxxxv]. However, the Committee also resolved that successive rounds of modifications using SDN-2 and ODM may pose risks similar to inserting new genes or SDN-3, and that off-target effects do pose risks different to the intended effects[cxxxvi].

Regulatory uncertainty

There continues to be no global uniformity in the regulation of NBTs. Most countries, including Australia, have process-based regulatory schemes which regulate novel organisms based on the biotechnology process used to develop them. Canada and the USA are unusual in having regulatory schemes that focus on the properties of the product, although process frequently comes into consideration for regulatory assessments of GM crops in the USA[cxxxvii]. Canada's strong adherence to a product-based regulatory scheme means that the products of conventional breeding, mutagenesis, transgenesis or genome editing are all subject to a similar regulatory approval process[cxxxviii].

Despite being process-based, the regulatory systems in Australia, Argentina and Brazil have delivered regulatory approvals in a manner relatively consistent with that seen in North America[cxxxix]. In comparison, the European Union's (EU) process-based regulatory system has had the effect of stifling the commercialisation and adoption of GM crops. This has led to the current situation in which only one GM crop (a variety of maize) is able to be commercially grown in the EU, despite its member states being among the world's largest importers of GM crops for use in food, animal feed or other products.

The USA and Canadian regulators have already approved or exempted from regulation, several genome edited crops and this has led to the rapid commercialisation of these varieties in North America. However, there continues to be uncertainty surrounding the regulation of the products of genome editing and other NBTs in countries with process-based regulatory schemes.

The EU has been considering whether to regulate the products of NBTs as GMOs for over a decade with no clear outcome as yet. Along with regulation, consumer sentiment will also have a major impact on the incentives to develop, commercialise and adopt GM crops and livestock developed using NBTs.

In October 2016, Australia's Gene Technology Regulator initiated a Technical Review of Australia's *Gene Technology Regulations 2001* (Cwth) to clarify whether organisms developed using a range of new technologies are subject to regulation as GMOs and ensure that new technologies are regulated in a manner commensurate with the risks they pose[cxl]. The focus of the review is on genome editing techniques, but it also considered other NBTs.

In October 2017, the Gene Technology Regulator put forward a draft proposal under which organisms modified using site-directed nucleases without templates to guide genome repair (i.e. SDN-1) would not be regulated as GMOs. However, if a template is used (i.e. SDN-2, SDN-3 or ODM), the resulting organism will continue to be regulated as a GMO[cxli]. Under a separate proposal, the use of RNA molecules to induce gene silencing (e.g. in a spray) would not constitute gene technology provided the RNA cannot give rise to changes to genomic sequence and cannot be translated into proteins. On the other hand, gene silencing techniques that involve inserting DNA sequences into the genome or the use of viruses would continue to result in GMOs subject to regulation. The Regulator is consulting on these draft proposals until late January 2018.

In parallel with the Technical Review, the Commonwealth, State and Territory Ministers with portfolio responsibility for gene technology (known as the Legislative and Governance Forum on Gene Technology) have initiated a review of the policy settings of Australia's Gene Technology Scheme. The Review is considering (among other things) whether Australia should adopt a product-based regulatory scheme or a hybrid scheme.

Applications of new gene technologies

There are already a number of plant varieties developed using NBTs that are approaching field trials, undergoing field trials, or which are already commercialised across the globe[cxlii], including herbicide resistant canola developed using ODM, a soybean with modified oil composition developed using SDN-2 that is intended to be commercialised in 2018, disease-resistant potatoes developed through cisgenesis, and scab-resistant apples modified to contain the vf gene of the Japanese flowering crab apple (*Malus floribunda*)[cxliii]. The development of genome edited farm animals is also a rapidly emerging field.

In microorganisms SDN-3 has been successfully used in bacteria, yeast and fungi[cxliv]. Microorganisms edited with CRISPR-Cas technique are already commercially used for food and feed applications, for example in starter cultures for dairy fermentation (yoghurt and cheese)[cxlv].

Innate Potatoes

In July and August 2017, the J. R. Simplot Company (known as Simplot) received the necessary approvals from Canadian regulatory authorities for three new Innate genetically modified varieties of Russet Burbank, Ranger Russet and Atlantic potatoes to be imported, planted and sold in Canada for both human and animal consumption[cxlvi]. The varieties, which were developed in the United Kingdom and approved by USA regulators in February 2017, are the second generation of Innate potato varieties developed by Simplot. The newest varieties have been developed to be resistant to the disease Late Blight (also known as Irish Blight) through the insertion of a gene from an Argentine variety of potato into commercial varieties using cisgenesis. Late Blight is a major disease of Tasmanian potato crops grown in wetter conditions, and both Russet Burbank and Ranger Russet are varieties grown to supply Simplot's Tasmanian potato processing operations.

Simplot claims that the Innate Generation 2 potatoes reduce the use of fungicide by half, have reduced bruising and black spots and enhanced cold storage capacity, produce less acrylamide (a carcinogen) when cooked at high temperatures, but still have the same taste, texture and nutritional qualities as conventional potatoes. Production of the first generation of Innate potatoes began in the USA in 2015 and since then, the area planted has increased to approximately 2,428 hectares in 2017[cxlvii]. However, McDonald's decision in 2014 not to use the genetically modified potatoes in its French fries, is likely to have limited the adoption of the varieties. This has particular relevance for Tasmania as the fast food market is a significant customer for Tasmanian-grown potatoes.

SU Canola

The first NBT derived product to be commercialised was a variety of herbicide-resistant canola, SU Canola, developed by Cibus Global using ODM to induce a single base mutation, which occurs naturally in related species[cxlviii]. SU canola gained market approval in the USA and Canada in 2014 with commercial cultivation commencing in the USA in 2015[cxlix] and in Canada in 2017[cl]. Canada accounts for around 90 per cent of North America's canola production.

Cibus Global is reportedly looking to introduce SU Canola introduce into China, Europe, and Australia while also working to add more specialized traits to canola and expand its product line by introducing other crops with improved characteristics[cli]. While several regulatory bodies in EU member states have concluded that ODM is a form of mutagenesis that can be excluded from GMO legislation[clii], the final decision on the matter may rest with the European Court of Justice.

Other genome edited crops

There have been a number of genome edited plant varieties developed using the ZFN, TALEN and CRISPR-Cas9 SDN techniques[cliii]. The first genome edited crop produced using CRISPR-Cas9 was a corn variety developed by DuPont Pioneer through the inactivation of a single gene leading to corn with a high concentration of amylopectin starch, an ingredient in processed foods and adhesives.

In April 2016, the U.S.D.A. decided to forego regulation of the corn and a variety of button mushroom (*Agaricus bisporus*) genome edited to resist browning on the basis that the organisms do not contain foreign DNA[cliv]. In the case of the mushroom, CRISPR-Cas9 was used to delete a handful of base pairs in the mushroom's genome, inactivating one of six genes involved in the expression of an enzyme responsible for browning[clv].

Arctic Apples

In November 2017, the world's first genetically modified non-browning apple, Arctic Golden (a variety of Golden Delicious), was due to go on sale in the United States[clvi]. Arctic Golden is one of three varieties known collectively by the trade name Arctic Apples (Arctic Golden, Arctic Fuji and Arctic Granny). The varieties were developed using a double-stranded RNA gene silencing technique to suppress the activity of an enzyme, polyphenol oxidase, responsible for the browning in apple flesh when the fruit is cut or bruised[clvii].

Arctic Golden apples will initially be available exclusively as 10-ounce bags of pre-cut apple slices to highlight the apple's non-browning trait and convenience to consumers. The marketing of Arctic Apples is being seen as an important test of consumer acceptance of GM foods in that the varieties have been intentionally developed to primarily benefit consumers and the food service industry rather than producers, as has been the case with most GM crops.

Livestock breeding

Genome editing is an important new tool in livestock breeding. By December 2015, it had already been used to produce more than 300 differently edited pigs, cattle, sheep and goats worldwide[clviii]. Some well-publicised recent applications include hornless dairy cows; 'double-muscled' pigs, sheep and cattle (obtained through changes to the myostatin gene that controls muscle growth[clix]) and increased resistance to diseases, including African swine fever virus, Porcine Reproductive and Respiratory Syndrome (PRRS) virus[clx] and tuberculosis in cattle[clxi]. PRRS is one of the most significant diseases in intensively reared pigs in Europe, North America and Asia. Although Australia currently remains free of PRRS, its introduction could devastate Australia's commercial pig industry[clxii].

In October, Chinese scientists reported creating 12 healthy pigs with about 24 per cent less body fat than normal pigs using the CRISPR-Cas9 technique[clxiii]. Reducing dietary animal fat could make a significant contribution to addressing the world obesity epidemic, however there is doubt that products from the genome edited pigs would be allowed to enter the food chain in the United States where GM salmon has met with intense opposition from environmental and food safety groups[clxiv].

Notwithstanding rapid advances in the application of the technology, the commercialisation of genome edited farm animals for food is in its infancy and none have reached the market, although gene edited animals are being used to produce pharmaceutical proteins in milk and eggs[clxv]. The use of genome editing in animals also raises significant animal welfare considerations. For example, genome edited double-muscled pigs produced using an SDN-1 technique reportedly experienced birthing difficulties, and only one of 32 cloned piglets survived and developed into a healthy animal[clxvi]. There remains considerable uncertainty globally around the regulation of genome edited animal products and whether they will achieve public acceptance.

As with plant breeding, the potential applications of genome editing in livestock are only limited by knowledge of the genomes of farm animals. While genome editing in animals has initially focused mainly on disease resistance and a small number of other traits through the creation of gene variants that exist in the same or similar species, other changes to animal physiology have been suggested[clxvii]. Examples include the production of offspring of a single sex, improved welfare by avoiding castration, and the prevention of the production of allergens or disease-causing prion proteins[clxviii], such as those implicated in bovine spongiform encephalopathy, commonly known as 'mad cow disease'.

Genome editing promises the possibility of producing commercial livestock with precise genetic changes that would be difficult or impossible to achieve with conventional selective breeding[clxix]. Although early genome editing in animals has tended to focus on inducing a mutation in a single gene, there is considerable scope for innovation. Compared to more established genetic modification techniques, SDN-3 offers a simpler, more precise and efficient way of introducing DNA fragments containing genes and/or regulatory elements into the genome of animals and the simultaneous induction of multiple genetic modifications is possible[clxx].

Transgenic Atlantic salmon

2017 marked the first commercial sale of a genetically modified animal for food. The AquAdvantage Atlantic salmon produced by AquaBounty Technologies has been engineered to grow faster on less feed and reach a marketable size in 16-18 months (instead of three years) through the introduction of a growth-hormone gene from Chinook salmon and genetic regulatory elements from a third fish species. Despite being first demonstrated in 1989, the salmon was only approved for human consumption by the United States Food and Drug Administration (FDA) in November 2015, and by Health Canada in 2016[clxxi]. While the first Canadian sale of the salmon was announced on 4 August 2017, sales of the product are currently prohibited in the US until the FDA institutes labelling guidelines and a program to disclose to consumers whether a fish has been genetically altered[clxxii].

Globally, aquaculture is increasingly important as a source of protein. Marine biotechnology is seen as an important enabling technology at different steps in the value chain as it can significantly enhance breeding and can be used for vaccine development and the development of fish feed[clxxiii].

Australian research and development

Australia's Office of Gene Technology Regulator (OGTR) is responsible for administering the *Gene Technology Act 2000* (Cwth) and corresponding state and territory laws, including the licensing system under which a person can apply to the Regulator for a licence authorising certain dealings with GMOs. Dealings with GMOs that take place outside of containment facilities are known as Dealings involving an Intentional Release (DIR) of GMOs into the Australian environment.

Most DIR licences issued by the Regulator are for experimental field trials (limited and controlled releases) or general/commercial releases of GM plants. The Regulator maintains a record of DIR licence applications and authorisations, and consultations on licence applications, through which it is possible to monitor the pipeline of new applications of gene technology relevant to Tasmanian agriculture[clxxiv].

During the twelve months to the end of October 2017, the OGTR issued nine licences for dealings involving the intentional release into the environment of several GM crop varieties including cotton, banana, Indian mustard (Juncea canola), potato, wheat, barley and sorghum. The following licences are broadly relevant to Tasmanian agriculture:

- Licence DIR 149 issued to Nuseed Pty Ltd in February 2017 authorised field trials of Indian mustard genetically modified to produce long chain omega-3 oils at various sites in New South Wales, Victoria and Queensland between April 2017 and 2022. Mustard can be grown in Tasmania.
- Licence DIR 150 issued to the Queensland University of Technology in February 2017 authorised a two-year field trial in Queensland to assess the agronomic characteristics and disease response of a potato variety genetically modified to be resistant to potato virus X, which is currently not found in Tasmania.
- Licence DIR 151 issued to the CSIRO in May 2017 authorised a five-year field trial of wheat genetically modified for disease resistance, drought tolerance, altered oil content and altered grain composition at two sites in the Australian Capital Territory and New South Wales.
- Licence DIR 152 issued to the University of Adelaide in July 2017 authorised field trials of wheat and barley varieties genetically modified for frost tolerance and enhanced yield at up to five sites in South Australia, Western Australia and New South Wales between July 2017 and January 2021.

Each of the GM wheat lines to be used in the CSIRO trials will contain up to three introduced genes derived from wheat, barley, maize or rice. Of the 37 introduced genes to be used in the trial, 22 are intended to give the GM wheat tolerance to rust disease or drought while 15 are intended to alter the starch, oil or dietary fibre content of the grain and/or leaves. The field trial will assess the agronomic characteristics of the wheat lines, as well as the nutritional characteristics of flour derived from the wheat.

Some of the GM wheat lines in the University of Adelaide field trials of GM wheat and barley varieties will contain up to three introduced genes for yield enhancement, derived from rice and thale cress, while other lines will contain one of seven frost tolerance genes. The GM barley lines will contain one of two frost tolerance genes.

None of the GM crops produced through any of the field trials will be permitted to enter the commercial human food or animal feed supply chains, however some GM material from the Nuseed and CSIRO trials may be used for small-scale experimental animal nutritional studies. Some GM material from the CSIRO trials may also be used for human nutrition trials.

Conventional wheat and barley varieties are currently grown extensively in Tasmania with the gross margin largely being driven by yield and quality.

The OGTR is also currently consulting on licence applications for the commercial release of GMOs into the environment relating to canola (DIR 155), cotton (DIR 157), safflower (158) and perennial ryegrass (DIR160).

DIR 155 concerns an application from Nuseed Pty Ltd for the commercial release of a GM canola line, DHA canola, which has been modified to produce long chain omega-3 polyunsaturated fatty acids (predominantly docosahexaenoic acid, DHA) in the seed oil through the introduction of seven yeast and marine algae genes involved in fatty acid biosynthesis. If the application is approved, the GM canola and its products would enter general commerce, including use in human food and animal feed. The GM canola oil has the potential to be used in place of fish and algal oils, including in animal feed, aquaculture feed, food additives, pharmaceuticals and nutraceuticals.

Application DIR 155 follows field trials conducted in New South Wales, Victoria and Western Australia from 2014 to 2016 under licence DIR 123. DHA canola has also been released for field trials in Canada from 2016.

DIR 158 concerns an application by GO Resources Pty Ltd for the Australia-wide commercial release of two safflower (*Carthamus tinctorius* L.) lines genetically modified for high oleic acid composition through the insertion of two gene fragments derived from safflower that work to lower the expression of two fatty acid biosynthesis genes. The GM safflower lines also contain an antibiotic resistance gene used in the development of the lines.

Safflower is cultivated commercially as a minor oilseed crop, primarily in NSW and Victoria and to a lesser extent South Australia and Queensland. The aim of the proposal is to introduce the GM safflower into the Australian cropping system. If a licence is issued, the GM safflower and its derived products would enter general commerce, with the oil derived from the GM safflower intended for commercial industrial oil production. Products derived from the GM safflower are not intended for use in human food.

GM safflower lines have previously been approved for field trials in Australia under licences DIR 121 and DIR 131 and there have been field trials of cotton genetically modified for the same trait (increased levels of oleic acid composition) under licence DIR 039/2003 and DIR 085/2008. Field trials of GM safflower with different traits have also been approved in the USA and Canada.

Agronomically, safflower could be grown in Tasmania with the decision to grow driven by relative gross margins. While it is not a commercial crop in Tasmania, the GM safflower lines are notable in that they contain 'gene silencing' constructs that suppress the expression of two endogenous safflower fatty acid biosynthesis genes involved in the conversion of oleic acid to linoleic acid or palmitic acid. As a result, the GM safflower produces seeds that accumulate a high proportion of oleic acid (approximately 92 per cent) and very low linoleic acid (less than 2 per cent).

GM ryegrass

DIR 160 concerns an application by the Victorian Government to conduct field trials of a perennial ryegrass (*Lolium perenne*) line genetically modified to contain two introduced genes from perennial ryegrass involved in the biosynthesis of fructan (a type of sugar found in cool-season grasses), in order to assess its agronomic characteristics and multiply seed for future trials. The GM perennial ryegrass line also contains a bacterial gene encoding antibiotic resistance used in the development of the line, and short regulatory sequences derived from perennial ryegrass, rice and the Cauliflower Mosaic virus that control expression of the genes. If approved, the trials would be conducted in Southern Grampians Shire in south-west Victoria over two growing seasons from May 2018 to June 2020. The GM perennial ryegrass line proposed for release has been previously approved for limited and controlled release into the Australian environment under licence DIR 082. Ryegrass is naturalised in Tasmania as a pasture plant.

The perennial ryegrass line that is the subject of DIR 160 is a variety of transgenic GM 'high-energy' perennial ryegrass developed in Victoria in 2003 through the Centre for AgriBioscience (AgriBio), and later the Dairy Futures Cooperative Research Centre (CRC). The variety is continuing to undergo field trials in Victoria and Argentina in preparation for an application to the Gene Technology Regulator for a licence to commercially release the variety in 2020[clxxv]. Meanwhile, New Zealand researchers are reportedly beginning trials in the US of a different ryegrass variety genetically modified to contain an increased fat and oil content.

In 2015 it was predicted that the high-energy ryegrass variety could increase productivity in the dairy industry by 10-15 per cent per hectare[clxxvi]. The final 2016 report of the Dairy Futures CRC notes that the variety is able to produce an extra megajoule of metabolisable energy per kilogram of dry matter, with modelling indicating that it could boost dairy annual productivity in northern Tasmania by $750 a hectare[clxxvii clxxviii]. According to the report, the impact of this change has been confirmed as the largest generator of value from all current innovations that are under development.

Since the Dairy Futures CRC ended in June 2016, the commercialisation of the GM ryegrass variety has been taken over by DairyBio, a five year joint venture between the Victorian Government and Dairy Australia. Despite the potential benefits for dairy farmers, the commercial success of the variety is not guaranteed. Any application to commercially release the variety is likely to attract opposition from some agricultural producers, agri-businesses and community groups, including organic dairy farmers concerned about the potential impact on their organic certification. If the variety is approved for commercial release, public acceptance of milk produced from GM pasture is likely to determine whether it is a commercial success.

Among the major dairy processors, Murray Goulburn has a long-held position of not accepting milk containing GM material[clxxix], however the likely buyer of Murray Goulburn, Canadian dairy giant Saputo, does not have a policy on the issue. Fonterra's policy is nuanced, recognising both the possibilities offered by new and emerging technologies such as genome editing, and the value of New Zealand's global reputation for its GM status[clxxx]. While the co-operative is not anti-GM, its products do not contain GMOs and nor has it released or commercialised any GMOs. The policies of the other major milk processors in Tasmania, Lion and Mondelez (Cadbury), are unclear.

DairyBio is reportedly continuing to fast-track the development of other new perennial ryegrass varieties at Hamilton, Victoria, through the world's largest precision-planted perennial ryegrass field trial looking at conventionally bred cultivars and F1 hybrid grasses[clxxxi]. The trial includes the use of sensors to identify elite plants and genomic selection to make DNA-based decisions. In addition to conventional breeding, research is being conducted at AgriBio's Melbourne laboratories using genome editing techniques to reduce lignin production and increase pasture digestibility[clxxxii]. DairyBio's work on ryegrass involves a joint investment by Agriculture Victoria, Dairy Australia, DairyNZ and Heritage Seeds.

If the SDN-1 genome editing technique is deregulated, as proposed by the Gene Technology Regulator, genome edited perennial ryegrass varieties developed using the technique would avoid regulation as GMOs. Given the relative speed of genome editing techniques and the potential opposition to transgenic GM ryegrass, it is conceivable that a genome edited perennial ryegrass could be successfully commercialised before a transgenic variety.

One final note, the 2017 Legislative Council Select Committee Final Report on the Tasmanian Dairy Industry reported that "…they now have a GMO rye grass…what this means that because they have got access and we don't it halves our profit"[clxxxiii]. This statement could be construed by some that GMO ryegrass is available now for release into the environment. This is not the case. GMO ryegrass remains in trial with no license issued by the OGTR for its commercial release into the environment.

Other Australian developments

In April 2017, an international team involving researchers from Australia announced that it had sequenced the entire barley genome, thus providing researchers with a map to work out which genes control specific traits[clxxxiv]. The map will facilitate the development of new barley varieties using both conventional breeding and modern biotechnologies. It is hoped that this development will ultimately lead to more stable and sustainable yields and improved malting, resulting in reduced farmer risk and increased profitability. Given the importance of barley as a cereal crop in Tasmania, and the recent growth in Tasmania's brewing and distilling industries, it has the potential to deliver significant long-term benefits and opportunities for Tasmanian agriculture and the broader agri-food sector.

In July 2017, Queensland University of Technology researchers announced that they have worked on a 'proof of concept' technology required to produce a vitamin A bio-fortified Cavendish dessert banana, with field trials conducted in the Northern Territory[clxxxv]. The realisation of this concept could have significant nutritional benefits for Australians and people in developing countries for whom bananas form a significant component of their diet.

In October 2017, researchers at the University of Adelaide reported that they had identified a naturally occurring wheat gene that when turned off eliminates self-pollination but still allows cross-pollination, thereby opening the way for streamlined breeding of high-yielding hybrid wheats[clxxxvi]. Traditional hybridisation has been recognised as an effective plant breeding technology for the past half century and delivered quantum improvements in maize varieties. Adoption of this technology in Australia could have significant benefits for wheat production.

Zero Tolerance

As noted in the introduction, the *Tasmanian Gene Technology Policy (2014-19)* also commits DPIPWE to "monitor the risks associated with maintaining Tasmania's current GMO threshold levels and any alternative options".

Thresholds or tolerance levels specify the maximum allowable level of adventitious (unintended) presence of GM material permitted by regulators and/or markets. Different countries apply different adventitious presence threshold depending on their production conditions for agricultural products[clxxxvii]:

Europe = 0.9 per cent
Japan = 5 per cent
Taiwan and **Korea** = 3 per cent
Australia and **New Zealand** = 1 per cent
United States of America – Not-defined

The *Tasmanian Gene Technology Guidelines* maintain a 'zero tolerance' threshold for viable GMO contamination in imported canola seed and state that the Tasmanian Government will accept as evidence of zero contamination (i) a negative result from a test capable of detecting one GM canola seed in 10 000 non-GM canola seeds (i.e. 0.01% contamination) with 95% confidence, also known as testing to the limits of detection, or (ii) an alternative import proposal which achieves an equivalent level of assurance that GMOs are absent.

The importation of GMOs into Tasmania is regulated in accordance with import requirements specified in the Plant Quarantine Manual Tasmania issued pursuant to section 68 of the *Plant Quarantine Act 1997 (Tas)*. Import Requirement 32 requires all imported canola seed and grain to be accompanied by a certificate or statement of analysis demonstrating freedom from GM contamination. Imported products that do not comply with these import requirements are held and dealt with by Biosecurity Tasmania.

Tasmania's zero tolerance threshold is more stringent than the threshold of 0.9% (canola crop and 0.5% seed for commercial sale) adopted by all other States that have specified a threshold (Victoria, South Australia, New South Wales and Western Australia). Testing to the limits of detection (0.01%) is more costly than testing to the standard employed by other States and, for importers of canola seed, there is a risk that consignments will be rejected if they do not comply with the Tasmanian threshold.

Industry bodies connected with the growing of canola in Tasmania have confirmed that there has been no shortage of suitable canola seed for sowing this growing season. AgriGrowth Tasmania will continue to monitor the situation.

Appendix I[clxxxviii]:

Schedule 1A—Techniques that are not gene technology

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.

Schedule 1—Organisms that are not genetically modified organisms

Item	Description of organism
1	A mutant organism in which the mutational event did not involve the introduction of any foreign nucleic acid (that is, non-homologous DNA, usually from another species).
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.
6	An organism that results from an exchange of DNA if: (a) the donor species is also the host species; and (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: (a) such exchange can occur by naturally occurring processes; and (b) the donor species and the host species are micro-organisms that:

Item	Description of organism
	1. (i) satisfy the criteria in AS/NZS 2243.3:2010 for classification as Risk Group 1; and 2. (ii) are known to exchange nucleic acid by a natural physiological process; and (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.

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