



# Genetically Modified Organisms (GMO) Annual Environmental Scan

DECEMBER 2015

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## Glossary

**ADVENTITIOUS PRESENCE** – An event where GM material is unintentionally or inadvertently introduced into the State.

**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.

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

**CONTAINED FACILITIES** – Research and development conducted in a laboratory or other controlled atmosphere environment.

**DEALINGS INVOLVING INTENTIONAL RELEASE** – (DIR) used by the Office of Gene Technology Regulator (OGTR) to describe dealings involving an intentional release into the Australian environment with GMOs which take place outside of containment facilities.

**DEALINGS NOT INVOLVING INTENTIONAL RELEASE** – (DNIR) used by the OGTR to describe dealing with GMOs in a contained facility. They must not involve release into the environment.

**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.

**GENE TECHNOLOGY** – Any technique for the modification of genes or other genetic material, but does not include sexual reproduction or homologous recombination. Recent advances in biotechnology provide ways of introducing very precise changes to genetic material—the sets of instructions in the cells of all living creatures—which can include genes, parts of genes, groups of genes and so on.

**LIMITED AND CONTROLLED RELEASE** – Research and development outside contained facilities. These can range from small scale field trials (i.e. under field conditions. This is also known as open-air research).

**LOW LEVEL PRESENCE** - Low level presence refers to the unintended presence, at low levels, of minute amounts of genetically modified (GM) material that has been approved in at least one country but not in the country that is importing the product.

**NOTIFIABLE LOW RISK DEALING** – (NLRD) used by the OGTR to describe dealing with GMOs that have been assessed as posing low risk to the health and safety of people and the environment provided certain risk management conditions are met.

**SYNTHETIC BIOLOGY** – (also known as synbio) Refers to both:

- the design and fabrication of biological components and systems that do not already exist in the natural world
- the re-design and fabrication of existing biological systems.

**TERMINATOR TECHNOLOGY<sup>i</sup>** - Engineered plants to produce seeds that are sterile so they are unable to reproduce. It is most commonly referred to as “terminator technology” because the plant’s ability to reproduce has been ‘terminated’ at the genetic level (i.e. the plant produces a crop but the seeds of the crop will fail to germinate in the subsequent generation).

**VIABLE PLANT** – one that can live and thrive in the environment.

# Summary

## 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.**

GM crops are still largely grown in the Americas (United States, Brazil, Argentina and Canada). Four commodity crops account for 99 per cent of GM plantings globally – soy, maize, canola and cotton. Soy and maize are around 80 per cent of all plantings<sup>ii</sup>. Most GM crops today end up as animal feed, biofuel feedstock or in highly processed food ingredients that do not need to be labelled<sup>iii</sup>.

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

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

Advances in the use of biotechnology are rapid. This is particularly evident in the health arena. In Australia, the Office of Gene Technology Regulator (OGTR) has issued four Dealings Not Involving Intentional Release (DNIR) for GM retroviruses. The OGTR have also asked for comment on the submission for the commercial supply of attenuated GM influenza (flu) vaccine. This GM vaccine is intended to be a nasal spray and the OGTR will need to consider the potential release into the environment carefully.

For Tasmania's poppy sector, the development of a yeast to make fully synthetic opiates that are non-addictive is one to watch. It is anticipated that the first versions of this fully synthesized morphine are at least 2-3 years away. Scientists suggest that batches of GM yeast could produce the drugs at one tenth of the cost of conventional poppy routes<sup>iv</sup>.

### Consumer sentiment in important current and potential future markets

A snapshot review of Tasmania's ten major trading partners has been conducted. It reveals that for the majority of our significant trading partners, consumer attitude remains sensitive to GE food products. The primary reason that there are no GM crops grown in New Zealand is consumer resistance to GM foods.

Interestingly, here in Australia, sentiment in the dairy processing sector is changing around the potential use of GM pastures with the Australian Dairy Products Federation stressing

caution as their future use due to the potential to provide a non-tariff barrier for Australia's milk products<sup>v</sup>.

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

In the 2013 Departmental review, apart from GM canola, three GM crops (GM pharmaceutical poppies, GM wheat and GM pastures) were identified as the most likely gene technology applications that Tasmania would need to consider for commercial release between the years 2015-2020.

There has been no commercial release of GM wheat in Australia, and the OGTR has not received any licence applications for the commercial release of GM wheat. Licences for trials have been granted, with trials proposed (March 2015 DIR130) to be planted in Murdoch University's Katanning Western Australia facility<sup>vi</sup>.

The Victoria Dairy Futures CRC research project into GM ryegrass has finished. The CRC is now working with the state body responsible for intellectual property, Agriculture Victoria Services, who will work on the commercialisation elements for the use of GM ryegrass crops<sup>vii</sup>.

Zero Tolerance

Tasmania's current policy position on zero tolerance is more stringent to that of other States. Canola growers in Tasmania have advocated for a change to the zero tolerance threshold to the nationally recognized non-GM standard, as it would speed up access to newer non-GM varieties and reduce costs.

The argument to maintain the existing zero-tolerance threshold is that it reduces the likelihood of contamination of seeds by non-authorized GMOs. Recent analysis<sup>viii</sup> shows that the production benefits on-farm in Australia cannot be considered in isolation of consumer perceptions in Asia. Reducing barriers to access to non-GM canola may improve productivity gains, however the potential higher risk of contamination of GM material could 'taint' the brand position of our products in Asian markets.

As the 2013 Departmental Review revealed, there is no collective viewpoint across industry sectors as to whether there is an imperative to change the current policy position on the GMO moratorium for marketing purposes.

# 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 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 (Cth)* 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 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

As part of the Gene Technology Policy 2014-2019, the Minister has asked DPIPWE to report against the following:

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 are to provide the Minister if based on evidence, there are significant developments in these three specific matters that warrant triggering a review of this Policy before the maximum five (5) year review date.

In addition, AgriGrowth Tasmania is to monitor the risks associated with maintaining Tasmania's current GMO threshold levels and any alternative options.

## METHODOLOGY

A desktop study has been undertaken by AgriGrowth over the last 12 months to record developments with GMOs.

The following industry bodies were also consulted for this environmental scan:

- Dairy Australia
- Fruit Growers Tasmania
- Poppy Growers Tasmania (PGT)
- Tasmanian Agricultural Productivity Group (TAPG)
- Tasmanian Beekeepers Association
- Tasmanian Farmers and Graziers Association (TFGA)
- Tasmanian Institute of Agriculture (TIA)
- Tasmanian Organic-Dynamic Producers Inc (TOP)
- Tasmanian Salmonid Growers Association (TSGA)
- Wine Tasmania

AgriGrowth also held meetings with the OGTR and the Australian Biotechnology Council of Australia (ABCA).

# Findings

## OVERVIEW

Moratoria on the commercial release of GM material around the globe, including Australia, have historically been established to allow time for examination and review of the potential market access and trade implications of the introduction of GM crops such as GM canola<sup>ix</sup>.

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

Advances in science and technology have been progressing in recent years with synthetic biology paired with genetic engineering in areas of food additives and food flavours. These projects include where genes from plants are inserted into bacteria or yeast that is then fed sugar to produce a chemical substance to be made in food<sup>x</sup>. Products such as Synbio Vanillin have been released in the United States of America in 2014<sup>xi</sup> however it is unknown as to which food companies are using the technology. The main purpose of these synbio foods is not from a health perspective, rather they are made in a lab and thus not subject to unpredictable variables like weather<sup>xii</sup>.

The Australian Wine Research Institute (AWRI) has been developing wine yeasts that produce wine with less alcohol than those currently available to winemakers. AWRI are approaching their research in several ways with both non-GM and GM technology. In the case of GM technology, yeasts are being genetically modified to divert metabolism away from ethanol production, thus decreasing ethanol concentration by 3.5 per cent<sup>xiii</sup>. These yeasts are not currently commercially available.

New scientific developments include clustered regularly interspaced short palindromic repeats (CRISPR). It is a method for genetic manipulation that is rewriting the way scientists change DNA<sup>xiv</sup>. Scientists say that someday they will be able to use CRISPR to fight cancer, neuter disease carrying insects or even to directly fix genetic defects in humans<sup>xv</sup>. CRISPR has already been used to tweak the genes of human embryos<sup>xvi</sup>.

Other developments that can lead to health benefits but may have an impact on production of poppies in Tasmania include the development of a yeast to make fully synthetic opiates

that are non-addictive; the first versions of this fully synthesized morphine are at least 2-3 years away<sup>xvii</sup>. However, the next step for the researchers is to boost the efficiency of the GM yeast. The yields of yeast-based painkillers need to rise 100,000 times to challenge traditional opium poppy farming.<sup>xviii</sup>

The OGTR continues to have applications for dealings that relate to health and medical related activities.

It has issued four DNIR for GM retroviruses in the last half of 2014. These included:

1. DNIR 550 – Generation of fluorescent lentiviral transduced tumour cell lines
2. DNIR 551 – Human Immunodeficiency Virus anti-viral development
3. DNIR 552 – Use of N1 I murine microglia for drug discovery
4. DNIR 553 Assessing HIV vaccine efficacy.

The OGTR is also in the consultation phase for a DIR for commercial supply of attenuated GM influenza (flu) vaccine.

## SECTION 2: CONSUMER SENTIMENT

From an agricultural producer perspective, consumer concerns regarding GMOs are seen as secondary to the interests of producers, however it remains that most consumers would rather not eat GM foods<sup>xix</sup>. In 2013, the Department's review into the GMO moratorium revealed that GM freedom may serve as a hedge against potential future shifts in consumer sentiment and buying behaviour concerning the attribute<sup>xx</sup>.

It appears that the views on niche market positioning captured by the 2013 Departmental review are still recognised as an important factor in growing Tasmania's economy. The Parliament of Tasmania Legislative Council Select Committee on Growing Tasmania's Economy (2015) noting a combined submission from the NW Chambers of Commerce and Industry that *"maximising our GMO status and a push for organic farming ventures is the right direction the world is taking and Tasmania should be on the leading edge. Look at Cape Grim Beef – taking full advantage of the world's cleanest air and rain to raise premium, grass fed, non-GMO, hormone free beef"*<sup>xxi</sup>.

Consumer acceptance of GM ingredients still varies with the product characteristics, geography, and the information that consumers are exposed to<sup>xxii</sup>. Globally, within the

income growing middle class category, consumer’s preferences are changing towards environmentally friendly, sustainable and ethical production<sup>xxiii</sup>.

Of particular relevance to agriculture is the sentiment in Tasmania’s ten major trading partners. As part of the environmental scan, a desktop study was completed to explore whether consumer sentiment had changed with these key trading partners since the 2013 Departmental review into the Moratorium. The table below summarises the most recent information to-hand.

Country	Sentiment
Japan	Japan is one of the world’s largest per capita importers of GE products. However, somewhat contradictory, the most recent in-country survey on food safety indicates 49 per cent of those polled indicated they have high or some concern regarding GE foods.
Hong Kong	Green groups and consumer organisations have been advocating for mandatory labelling of GE foods for many years. Their rationale is not based on food safety or science, but on the consumer ‘right to know’. In 2013, the Hong Kong Consumer Council renewed its call for mandatory labelling for GE foods. Hong Kong retailers have said they would not import any products that carried a GE label as they believe that consumers would not choose GE products when there are other choices available.
United States of America (USA)	GM foods are available in the USA. There is evidence that non-GM labelled foods represent a small share of retail food markets.
Singapore	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.

<p>The United Kingdom (UK)</p>	<p>Products containing soy, corn, glucose or other sugar components of biotech sugar beet or oilseed rape (Canola) must be labelled. There is a vocal minority against GM but most rely heavily on supermarket chains to provide them with safe quality food. All of the retail chains publically declared their private label to be “GM free” in the early 2000s consequently very few biotech derived ingredients/products have made it onto British shelves. However since 2013, Tesco, Marks and Spencer and Sainsbury communicated to their customers that for those who wished to avoid biotech fed livestock, they must now look at organic options. However price is still uppermost in mind for the majority of UK consumers.</p>
<p>China</p>	<p>China is a large importer of biotech soybeans, cotton, corn and soybeans for feed and processing. New regulations are in place around labelling. Foods made of crops where GMO varieties exist (such as Canola) must provide evidence they are GMO-free before they can be advertised as such. China does not import biotech seeds for cultivation. China has a zero tolerance for GMOs that have not been approved and tests for contamination. China’s increasingly slow and unpredictable approval level and lack of a low level presence (LLP) policy has resulted in a large increase in rejected shipments and trade disruptions. China has a lack of consistent approach on detection limits. Import tolerance can range from 0.1 per cent to 0.01 per cent or even less. This can result in cases where an export shipment tests negative for unapproved events but tests positive when it arrives in China. For example, all hay to China has to be certified GMO-free with a 0.2 percent threshold for containing the Roundup Ready Trait<sup>xxiv</sup>.</p>
<p>Korea</p>	<p>There are contradictory views in the market place. The public holds positive views on the use of biotechnology in human and animal research, bio-medicine and the treatment of disease while they tend to be negative towards the use of the technology to produce food. Local retailers are reluctant to carry GM labelled foods since they do not want to put</p>

	<p>product on their shelves that will not sell and would inevitably draw public scrutiny.</p> <p>Korea imports substantial amounts of biotech food ingredients that are currently exempt from the GM food labelling requirements.</p>
Indonesia	<p>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.</p>
Taiwan	<p>Taiwan regulators remain very cautious about domestic cultivation of biotech crops. A series of local food safety scandals including mislabelled rice and adulterated cooking oil created an opportunity for anti-GE activities to push for increased regulations. Taiwan’s consumers and authorities are often sensitive to sensationalistic media claims.</p>
New Zealand	<p>Media articles since 2013 are evenly divided between pro and anti pieces. Some primary sector organisations and farmers remain cautious about the use of biotechnology out of concern that it will tarnish New Zealand’s ‘clean and green’ image and negatively impact on the ability to market products overseas. One of the major supermarket chains “Foodstuffs” has taken a stance on GE whereby it insists on non-GE food ingredients to be used in its private branded products including non-GE feeds being fed to animal products which are sold under their private brand. It has no stance on third party or regular products sold through its stores as long as they are approved and labelled as regulated by FSANZ. Most New Zealand consumers express caution about GE foods.</p>

Sources: Abridged from [www.ers.usda.gov](http://www.ers.usda.gov) and [www.gain.fas.usda.gov](http://www.gain.fas.usda.gov)

In summary, apart from the USA and Singapore, the majority of Tasmania’s major trading partners have consumers that remain sensitive to GE foods. This concern extends to synthetic technologies. Developers of synthetic technologies are having to work with environmental and consumer groups to address concerns about labelling so that

consumers are aware of what they are buying. Consumer groups contend that these products should not be labelled 'natural'<sup>xxv</sup>.

It is worth noting that although China has an inconsistent approach towards importation of GMOs, Chinese President Xi Jinping has backed China's development of GM crops as a means of strengthening food security with agricultural minister Han Changbin following up with measures for promoting GM food to the public<sup>xxvi</sup>.

In March 2015, 17 experts from 11 countries assessed that Glyphosate as "probably carcinogenic to humans<sup>xxvii</sup>", causing Colombia to ban spraying the herbicide glyphosate on illegal plantations of coca, the raw ingredient for cocaine<sup>xxviii</sup>.

Countries are still looking to a point of difference regarding their markets and branding and GMO free can be one of these attributes. In August 2015, Scotland announced that it is looking to prohibit GMO crops as the Government is worried that GMO crops could damage the country's "clean and green" brand. The country is utilising new European Union rules that allow countries to opt out of EU-approved GM crops<sup>xxix</sup>.

Domestically, many Australian consumers still believe that labelling associated with GM does not allow them to make well-informed purchasing choices<sup>xxx</sup>. Uncertainty about the GM policy in some jurisdictions of Australia continues. Approximately 12 months ago, the Western Australian (WA) Premier indicated that the WA State Cabinet had flagged considerations for a review of their Act which could be repealed in light of party policy to cut excess red tape. Premier Colin Barnett and Minister for Agriculture and Food Ken Baston are now being lobbied by WA growers to repeal State legislation that could be used to cut-off their future access to GM crop technologies, however in the lead-up to the WA election (March 2017) it is widely held by the industry that if Labor wins the next State election, its GM-free policy would make growing GM canola illegal the following year<sup>xxxi</sup>.

### SECTION 3: NEW GENE TECHNOLOGIES IN PRIMARY INDUSTRIES

Industry consultation did not reveal any new issues or technologies that would trigger a review of the existing moratorium.

During 1 January to 31 March 2015, the OGTR<sup>xxxii</sup> completed the following:

- 2 licenses issued for Dealings involving the Intentional Release (DIR) of GMOs into the environment
- 1 licence issued for Dealings Not involving the Intentional Release (DNIR) of GMOs into the environment.
- 17 physical containment facilities were certified
- 24 instruments surrendered
- 49 certificates, four DIR licences and 10 DNIR licenses were varied.

The OGTR in 2013 gave Nuseed a licence to conduct field trials of a GM canola, currently under development, which contains healthy long-chain omega-3 oils. The licence for the trials is for five years and their pre-commercialisation work continues<sup>xxxiii</sup>. If commercially released, this GM canola would have major benefits to the dietary supplements and pharmaceuticals industries as well as and DHA-rich aquafeed markets (of interest to Tasmanian salmon growers).

The GM safflower has been modified to alter the oil profile in the seed, specifically to increase the level of oleic acid and decrease the levels of other fatty acids. The OGTR anticipate that with the trials commercial release is likely to be 4-5 years away.

GM apples that have enzymes removed to reduce browning have been approved for commercial release in the United States and JR Simplot have developed the GM potatoes, which will be marketed under the name Innate and have been modified in a similar way—except with the addition of reducing acrylamide (said to increase rate of cancer)<sup>xxxiv</sup>. As yet, there has been no application to the OGTR to introduce these particular GM plants in Australia.

There are those that are suggesting that GM is running out of steam with the growth in plantings of corn, cotton and oilseed flattening<sup>xxxv</sup> however more promising for broad acre agriculture is the technology used to introduce nitrogen-fixing abilities into plants. Although early days, this approach could have the potential to reduce applications of nitrogen fertilisers, however it is in early stages of development<sup>xxxvi</sup>.

It remains that separate industry sectors can have differing views to use of GM technology. Globally, GM Lucerne is available to be planted commercially. The dairy industry is watching the developments of this fodder crop with interest. The Australian lucerne seed industry has a moratorium on GM so that producers are unable to grow GM lucerne in Australia. One of the biggest concerns that the Lucerne industry has is the potential

impact on the industry's export markets, the biggest of which is Saudi Arabia, a country that does not accept GM seed<sup>xxxvii</sup>.

Synthetic biology is not just genetically engineering compounds like algae and yeasts to produce useful compounds, it can also be designing and printing genes from scratch<sup>xxxviii</sup>. Synthetic biology has been used to develop algae oil that is replacing palm kernel oil. The environmental benefits of this are considered significant as palm oil production has significant implications for the rainforest where it is sourced<sup>xxxix</sup>.

The use of GM animals has so far been mainly used for biomedical research or for the production of human proteins with GM cattle, sheep, pigs and chickens now being produced experimentally<sup>xl</sup>. Through gene editing applications, researchers have engineered pigs that are immune to African swine fever virus, as well as gene editing to develop double-musclcd pigs<sup>xli</sup>. Although researchers hope that the double-musclcd pigs could become the first GM animals to be approved for human consumption, other examples (such as GM salmon) highlight the ongoing lengthy time frame for regulatory approvals. The transgenic salmon produced in the United States of America, has remained in regulatory approval processes since 2013 and is yet to be commercially released<sup>xlii</sup>.

The development of a GM chicken in the United Kingdom could solve avian flu crisis as the bird does not pass the avian flu virus onto other birds. The researchers do not foresee the GM chicken being introduced into the United Kingdom any time soon but rather in countries which have more pragmatic views of GM such as China<sup>xliii</sup>.

In January 2014, a patent application as lodged in the United States where genes of Holstein dairy cattle are edited to remove their horns by the use of the genetic sequence that naturally causes Angus cattle to lack horns. Although conventional breeding can achieve the same results, GM techniques are being used to save time in cross breeding<sup>xliv</sup>. There are synthetic biology developments into animal-free dairy products. The start-up company Muufri is producing animal-free milk through adding cow DNA sequences into yeast cells. After they grow the cultures, the resulting milk proteins are ready for harvest<sup>xlv</sup>. This synthetic modified food is only in early development phase and yet to be released. Other research continues into 'lab-grown meat' (also known as 'cultured meat') however funding of the research has become a major issue as it sits between the medical and food related areas<sup>xlvi</sup>.

In August, 2015, Australian Government Senators backed a motion supporting GM crops for being an environmentally friendly farming technology supported by scientific rigor. The

federal Senate motion was raised by influential crossbench Senators David Leyonhjelm, Bob Day and Dio Wang. Despite the Greens having a long-held anti-GM policy position, the motion was passed without needing a division or debate over the potentially controversial topic<sup>xlvii</sup>.

## SECTION 4: ZERO TOLERANCE THRESHOLD FOR GM CANOLA

### Adventitious presence

Around the globe, a GM crop can be grown only after it has been extensively tested and approved as safe for humans, animals and the environment under rigorous approval processes<sup>xlviii</sup>.

Adventitious presence – or technically unavoidable presence – may occur in all arable farming, and at any step in the production of seed or grain, or in processing of harvested product in the food/feed chain<sup>xlix</sup>. Adventitious presence of GM material is not a crop safety issue but relates solely to the production and marketing of crops approved for use<sup>l</sup>.

Globally, countries have recognised that adventitious presence of unauthorised GM material has the potential to cause significant economic impacts<sup>li</sup>. In an ideal world, unwanted mixing with GM canola would be avoidable simply through separation of GM and non-GM material across all stages in the supply chain, however almost nobody expects that 100 per cent separation would be practical<sup>lii</sup>. Consequently, regulators and/or markets have set thresholds or tolerance levels at maximum allowable level of adventitious (unintended) presence of GM material<sup>liii</sup>. Many countries, like Australia, enforce a zero tolerance threshold policy for unapproved GM crops, including those that have been deemed to be safe through a comprehensive safety assessment in another country<sup>liv</sup>.

### ZERO TOLERANCE

The setting of tolerance levels came after the introduction of GMOs. As the introduction of GMOs to the environment is almost impossible to reverse, thresholds are instruments introduced to manage market implications and are an attempt to deal with primary production systems already contaminated and to bring clarity to industry about how to deal with adventitious presence.

Tolerance levels in grain are different to tolerance in seed for sowing due to the end-point use. Markets may accept grain tolerance due to the process/extraction end point. For example, GM presence at any level should not be an issue if products like oil are being extracted through a process to make them non-viable. Tolerance in seed for planting means that viable GMO will persist in the environment at low levels and be capable of reproducing, unless it carries terminator technology.

In Australia, industry believes that establishment of adventitious presence thresholds are critical for delivery of market choice<sup>iv</sup>. GM labelling is triggered by GM levels above 0.9 per cent. Industry accepts low levels of impurity with seed of plants of a different variety or seeds of other crops<sup>vi</sup>. However, new technology such as GM presents a new challenge in controlling conventional seeds for adventitious presence of GM seeds.

### International legislation and threshold levels

The European Union (EU) has a zero-tolerance policy on the marketing of food containing GMOs or ingredients produced from GMOs if they are not approved for food use in the EU<sup>vii</sup> (although the EU sets out that technical zero is at the level of 0.1%<sup>viii</sup>). For trade purposes, the Member States of the EU has established different thresholds for adventitious and technically unavoidable presence of approved GMOs in non-GM harvests, taking into account the demands of consumers and their markets<sup>ix</sup>. For example, EU regulation 2010/c200/01 recognises that the market demand for particular food crops may result in economic damage to operators who would wish to market them as not containing GMOs even if GMO traces are present at a level below 0.9 per cent<sup>lx</sup>.

Directive 2001/18/EC and 1829/2003 provide the legislative basis in the EU on GM food and feed and ensure strict control of placing on the market GMOs in the EU<sup>xi</sup>. The current EU legislation requires the labelling of products that contain GM higher than a 0.9 per cent threshold<sup>lxii</sup>. Products containing GM material in proportions higher than this have to be labelled. Products derived from livestock (i.e. milk, meat or eggs) are not subject to labelling<sup>lxiii</sup>. The European Commission formulated a policy that coexistence measures should not go beyond what is necessary in order to ensure that adventitious traces of GMOs stay below the labelling threshold in order to avoid unnecessary burden for the operators concerned<sup>lxiv</sup>.

The International Seed Testing Association (ISTA) and the International Organization for Standardization (ISO) aim to achieve uniform application of procedures for evaluation of seed and grain moving in international trade. These agencies are non-government

standard-setting bodies that have developed guidance documents, rules and/or standards on sampling for seeds and grains (ISO and ISTA), testing for foodstuffs (ISO), and testing for seeds (ISTA). Test methods for specific GM events are not provided in these standards; the focus is on defining principles, describing general methods, and specifying definitions and performance requirements<sup>lxv</sup>.

For seed and grain, the following table highlights some examples of current international tolerance levels:

**Table I = Labelling and country tolerance levels for adventitious presence of unauthorised GM material (ingredient)<sup>lxvi</sup>**

Country	Threshold level
Canada	Not more than 1.0% for grain <sup>lxvii</sup>
European Union /United Kingdom	EU approved GMOs in non-GM seed and grain for use in food and feed is 0.9 per cent. This is also the threshold for labelling. The threshold level for GMO content in seed has not yet been determined. The EU has suggested thresholds from 0.3 to 0.7 per cent depending on the crop. For the interim period, threshold was set up to 0.5 per cent.
Australia/New Zealand	Up to 1 per cent of unintended contamination is permitted (some exemptions).
Japan	If an ingredient is at least 5 per cent of the total weight of the product
Korea	3 per cent or higher

All thresholds set for adventitious presence of GM in seed and grain in Australia’s canola export markets are equal to or higher than the thresholds set in Australia for adventitious presence in non-GM canola<sup>lxviii</sup>. Some countries have adopted a marked-based approach (Canada and the United States) where co-existence measures are described in industry best

practice guidelines or equivalent<sup>lxxix</sup>. In Canada for example, the technology use moved so quickly that by the time thresholds were looked at, zero tolerance was just not possible.

Organic certification is based on certifying the production method rather than giving an end product guarantee as to the product's freedom from GMOs or excluded products<sup>lxxx</sup>. The United States of America National Organic Program does not have regulations established for GMO tolerance thresholds, with no federal agency establishing tolerance levels for the inadvertent presence of organic products of excluded methods (GMOs).<sup>lxxxi</sup> Against a backdrop of no organic sector-specific legal threshold existing for the presence of GMOs in organic product in both North America and the EU, the EU 0.9 per cent labelling threshold applicable to GM presence in any product applies equally to organic produce<sup>lxxxii</sup>.

In Australia, the Organic Industry Standards and Certification Council (OISCC) is assessing an application from the Australian Organic Ltd<sup>lxxxiii</sup> to develop a procedure for dealing with adventitious or accidental GM contamination. This appears to have arisen from the Marsh versus Baxter ruling in 2014. As yet, OISCC has not released its decision, although in December 2014 OISCC rejected a submission by the Western Australian Department of Agriculture and Food to increase the allowable threshold of GM material in certified organic food<sup>lxxxiv</sup>. China has indicated that if Australia waters down the GMO tolerance laws in any way then it could have impacts on the importation of Australian organic products<sup>lxxxv</sup>.

In the case of honey exports to the EU, in September 2012, pollen was re-classified as a natural constituent of honey. Pollen from GM plants is only permitted if the plants are authorised for food use in the EU. Pollen must be mentioned as an ingredient on honey labels if the amount of GM pollen is higher than 0.9 per cent (labelling threshold) of the total pollen in the honey<sup>lxxxvi</sup>.

### Commonwealth Legislation

The legislative framework in Australia is made up of the Commonwealth *Gene Technology Act 2000* (the Act), the *Gene Technology Regulations 2001* and corresponding State and Territory legislation. All Australian jurisdictions contributed to developing the scheme and legislation. The scheme is supported by the Intergovernmental Gene Technology Agreement 2001 between the Australian Government and each State and Territory.

The Act started on 21 June 2001. The object of the Act is to protect the health and safety of people, and the environment, by identifying risks posed by or as a result of gene

technology, and by managing those risks through regulating certain dealings with genetically modified organisms (GMOs)<sup>lxxxvii</sup>.

In 2005, the Primary Industries Ministerial Council (PIMC) noted that trace levels of GM canola had been detected in Australia's non-GM canola production systems. PIMC agreed to a nationally consistent definition of threshold levels in canola grain and seed for traces of those GM events approved by the OGTR. PIMC agreed to adopt a threshold level set at:

**Box 1:**

- 0.9 per cent for canola crop, (noting this threshold is applicable to the EU)
- seed (for commercial seed for sale) should be 0.5 per cent for 2006 and 2007 seasons and therefore after the intention was to set a limit of 0.1 per cent<sup>lxxxviii</sup>

The above thresholds for canola seed and grain were adopted in 2005 by all Australian States and territories except Queensland and the Northern Territory (which did not have moratoria in place on the commercial cultivation of GMOs) and Tasmania, which differed from the mainland States in that it adopted a GM-free stance on GM canola, an option available under the PIMC agreement<sup>lxxxix</sup>.

In Australia, the standards for thresholds are set by industry for adventitious presence of approved GM canola in conventional canola. They are put in place for marketing purposes for co-existence. Grain standards are set by Grain Trade Australia, with oil seeds by the Australian Oilseed Federation (AOF) and pulses (Pulse Australia), utilising consultative processes<sup>lxxx</sup>. In the case of canola, the following standards have been set by the AOF<sup>lxxxi</sup>.

**Box 2:**

- The adventitious presence of up to 0.9% of GM events (approved by the Australian Government Office of the Gene Technology Regulator) is allowed in non-GM canola. Canola is rejectable over this limit.
- The adventitious presence of up to 5% of GM events (approved by the Australian Government Office of the Gene Technology Regulator) is allowed in non-GM canola meal. Canola meal is rejectable over this limit.

- Where required, genetic modified seed or meal is to be expressed as the percentage by weight of the clean seed or meal and reported to the nearest 0.1%.

A summary of each State’s position in growing GM canola is as follows:

**Table 2: Jurisdictions ability to grow Canola**

	Other Australian States	Tasmania
Ability to grow GM Canola	√	×
Ability to grow non-GM canola that meet national accepted standard thresholds.	√ <b>Note includes South Australia who have Moratorium</b>	×
Ability to grow lowest possible detection (0.0001 per cent) non-GM canola	×	√

Although South Australia, like Tasmania has a moratorium on GMO commercial cultivation, it allows GM canola field trials in the State’s mainland regions. Kangaroo Island (KI) promotes being GMO-free. Its branding includes KI Pure Grain and KI Pure Honey. In the case of KI Pure Grain, they have up to 70 growers producing grain and legumes on a total of 40,000 ha. They promote that farmers on KI grow non-GM food quality grains, oilseeds, pulses and honey. KI Pure Honey promote that “the bees are assisting the canola farmers by pollinating their crops, while the increasing canola crop is helping to produce non-GM canola honey to meet demand in the order of 60 tonnes for this specialised premium market”. However the threshold for KI and South Australia more broadly is not zero, they rely on the national recognised standards for non-GM<sup>lxxxii</sup>.

In Australia, adventitious presence is only allowed for GM foods that are approved by the FSANZ standard. Zero tolerance is applied for GM presence that is not approved for human consumption<sup>lxxxiii</sup>.

### Tasmanian Legislation

In 2009, the Tasmanian Government policy noted that it would accept as evidence of zero contamination a negative result from a test capable of detecting one GM canola seed in 10,000 non-GM canola seeds with 95 per cent confidence or an alternative import proposal which activities are an equivalent level of assurance that GMOs are absent. This is also known as testing to the limits of detection.

In Tasmania, imports of GMOs into Tasmania are regulated through import requirements contained in the Plant Biosecurity Manual Tasmania, issued under section 68 of the *Plant Quarantine Act 1997 (Tas)*. Import Requirement 32: Canola Seed and Grain – Freedom from Genetically Modified (GM) Brassicaceae Seed, requires all imported canola seed and grain to be accompanied by a certificate or statement of analysis demonstrating freedom from GM contamination.

Import Requirement 36: Seed for Sowing is also relevant in that it prohibits importation of viable genetically modified seed unless authorised under the *Genetically Modified Organisms Control Act 2004 (Tas)*. Imported products that do not comply with these import requirements are held and dealt with by Biosecurity Tasmania.

Biosecurity Officers enforce a zero tolerance policy on GMOs at the State barrier for imported products. If imported products are suspected of posing a risk to Tasmania's GMO-free status, the importer will be asked to produce evidence the product contains no GMOs before being released by Biosecurity Tasmania. The exception to the zero tolerance level is GMOs imported for use in scientific research under permit with risk mitigation conditions imposed.

### Sampling

A recent survey by the Food and Agricultural Organisation of the United Nations (FAO) has been conducted to evaluate the issue of adventitious presence to examine the impact on trade flows. Of the countries that responded to the survey that produce GM crops, only 47 per cent indicated that they have the technical capacity to detect GMOs in imports<sup>lxxxiv</sup>. The survey concluded that most countries do not have a threshold level for adventitious for food<sup>lxxxv</sup>.

The ISTA has developed and published rules for the sampling and testing of seeds, with the aim of achieving uniform application of procedures for evaluation of seeds moving in international trade<sup>lxxxvi</sup>. The sampling and testing needs of the Australian seed and grain

industry for GM events in non-GM seed and grain depends on the market demand for differentiated products<sup>lxxxvii</sup>.

Real-time PCR is used widely for GM threshold testing scenarios – it is a quantitative test giving quantifiable results. Most literature references for seed lot testing are using Real-time PCR.

The Tasmanian testing procedure requirements are very similar to New Zealand Ministry of Agriculture and Forestry (MAF) test protocols but with detection requirements of 1 in 10 000 seeds rather than 1 in 1000 seeds as required by MAF. The current testing provides DPIPWV with the highest level of confidence (95%) that the inadvertent presence of 1 GM seed in 10,000 seeds will be detected and is of greater sensitivity than the Australian Seed Federation tests that are considered a minimum standard for industry.

### Canola Industry profile in Tasmania

Canola (*Brassica napus*) is an oilseed crop that has been grown in Tasmania since the early 1990s for oil and seed. The State's comparatively mild finishing conditions allow for a longer flowering period, better seed set and higher oil content relative to mainland growing areas. Markets for locally grown seed include crushing for oil and whole grain for stockfeed.

Most growers are using canola as a rotation crop in cereal cropping systems. Canola is seen by growers in the new irrigation regions of Tasmania as an excellent break crop opportunity because of its weed reduction potential. With the benefit of bio fumigation from canola the rotation before poppies is more relevant than ever with the systemic downy mildew issue.

The three non-GM cultivars grown in Tasmania are Conventional, Triazine Tolerant (TT) and Clearfield canola cultivars. Most growers are using TT and Clearfield due to their weed control. Industry anecdotally reports that the inferior varieties being sourced (as a result of our strict testing threshold) is in the region of a 30 per cent yield penalty compared to mainland growers and their access to new conventional varieties.

According to market based research in 2012<sup>lxxxviii</sup>, non-GM canola seed (spring sown) has a gross margin similar to that of poppies (\$2,000 to \$2,500/ha) which is well above gross margins for standard cereal or canola crops. Non-GM canola seed (autumn sown) is largely aimed at the Japanese buyer cooperatives. Tasmania is supplying this market along with producers in South Australia (Kangaroo Island) and Western Australia<sup>lxxxix</sup>. It has additional benefits in a rotation in terms of weed and disease control.

In 2012-13, the Australian Bureau of Statistics (ABS)<sup>xc</sup> indicated that the area grown was 555 hectares with 850.6 tonnes of production from 17 agricultural enterprises. At a 2012-13 stable price of \$563/tonne<sup>xci</sup> this equates to an estimated gross value of \$478,550.

Demand for growing canola has increased in Tasmania and is mainly driven by irrigation expansion.

### Restriction and Impacts

The current zero tolerance level is restricting national seed companies to supply the State with non-GM canola seed. This is because of the cost and high risk of failure at the test repetition levels required to meet the lowest possible detection levels.

Growers at a 2014 meeting facilitated by TFGA indicated that they are losing the potential for productivity gains because of the reduced ability to access new seed lines.

### SUMMARY ON ZERO TOLERANCE THRESHOLD

Tasmania's current policy position on zero tolerance is more stringent to that of other States. Canola growers in Tasmania have advocated for a change to the zero tolerance threshold to the nationally recognized non-GM standard, as it would reduce costs. South Australia's position of maintaining their non-GM status with the national threshold standard presents as the case for lifting the threshold as they are able to sell their non-GM canola into similar markets to Tasmania, such as Japan.

At present, Tasmanian farmers are able to purchase non-GM canola seed if it clears the testing threshold requirements. The issue is the testing. Maintaining the existing zero tolerance level for contamination of GM material will require maintaining the same testing regime at present (testing to limits of detection). The risk with maintaining the status-quo is that it may incur an increase in testing costs to industry if more varieties of GM seed and grain crops are grown commercially interstate.

The argument to maintain the existing zero-tolerance threshold is that it reduces the likelihood of contamination of seeds by non-authorized GMOs. In addition, the 2013 Departmental Review into the GMO Moratorium revealed that the State's GM-free status provides a platform for the organic and biodynamic systems. Compliance costs to this

sector would increase if there were any changes to the threshold because of the current zero tolerance to GM material required by Australian organic certifiers.

Recent analysis<sup>xcii</sup> also shows that the production benefits on-farm in Australia cannot be considered in isolation of consumer perceptions in Asia. Reducing barriers to access to non-GM canola may improve productivity gains, however the potential higher risk of contamination of GM material could ‘taint’ the brand position of our products in Asian markets.

As the 2013 Departmental Review revealed, there is no collective viewpoint across industry sectors as to whether there is an imperative to change the current policy position on the GMO moratorium for marketing purposes.

## Appendix I: Comparison of other State Canola Regulations

Jurisdiction	Legislation	Scheme
NSW	<i>Gene Technology Act (Cth) and via the Gene Technology Act 2003 (NSW)</i>	<p>Minister can declare an order for approval of a licensed GM food plant for commercial cultivation in NSW.</p> <p>GM canola has been grown commercially in NSW since 2008.</p> <p>The State is a signatory to the thresholds set by PIMC 2005 regarding non-GM canola thresholds.</p>
Victoria	<i>Gene Technology Act (Cth) and via the Gene Technology Act (2001) Vic</i>	<p>Minister may grant an exemption to cultivate under section 6 of the <i>Control of Genetically Modified Crops Act 2004</i>.</p> <p>GM canola has been commercially grown in Victoria in 2008.</p> <p>The State agreed to the thresholds set by PIMC in 2005. The Victorian Government also allows the market to determine whether segregation of non-GM canola from GM canola in the grain supply chain is required, acknowledging that the tolerance level agreed by PIMC provides a sound basis for the co-existence in the supply chain.</p>
South Australia	<i>Gene Technology Act (Cth) and Gene Technology Act 2001 (SA)</i>	<p>Minister may confer an exemption from GM Moratorium under section 6 of the <i>Genetically Modified Crops Management Act 2004</i>.</p> <p>GM crops are not commercially grown in South Australia.</p> <p>The State agreed to the thresholds set by PIMC in 2005.</p>

<p>Western Australia</p>	<p><i>Gene Technology Act (Cth) and the Gene Technology Act 2006 (WA)</i></p>	<p>Minister may grant an exemption from GM moratorium under section 6 of the <i>Genetically Modified Crops Free Areas Act 2003</i>.</p> <p>GM canola has been grown since 2008 and 2010 respectively.</p> <p>The State agreed to the thresholds set by PIMC in 2005.</p>
<p>Queensland</p>	<p><i>Gene Technology Act (Cth)</i></p>	<p>Not implemented any other legislation.</p> <p>GM canola has been grown since 2008.</p> <p>The State did not sign the agreement set by PIMC in 2005 as it does not have any specific State based legislation.</p>

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