Genetically Modified Organisms (GMO) Annual Environmental Scan

DECEMBER 2016

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

Tasmanian Government

Contents

Definitions

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)[i]

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

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[iii].

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*[iv]

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

Summary

This is the second Environmental Scan completed by AgriGrowth Tasmania since the GMO Moratorium in Tasmania was extended in 2014.

There are no GM crops or GM animals 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.

Development of new generation GMOs that provide health or other benefits

Globally, the major focus of research with GM and NBTs appears to be on reducing the risk of human disease. This is consistent with the Australian situation where the Regulator is dealing with an application for the trials of an attenuated GM Dengue vaccine.

Consumer sentiment in important current and potential future markets

Consumer sentiment in the major export markets for Tasmania has not changed. Research indicates that many consumers in developed countries demonstrate a clear preference for non-GMO crops and that, in general, attitudes and reactions to the topic of GM foods is not positive.

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

Emerging technologies such as NBTs are rapidly advancing. There is no common agreement at an international level about how to regulate around these new technologies. This has the potential to increase challenges from a market and trade perspective and highlights the need for consideration of the legislative definitions of GMOs in Australia.

The Office of Gene Technology Regulator (OGTR) is in the process of completing a technical review of the *Gene Technology Regulations 2001*. The Technical Review aims to focus on new technologies and does not alter the policy settings of the regulatory scheme.

Zero tolerance

Industry has indicated that there has not been an issue relating to supply of non-GM canola seed, that meets Tasmania's current GMO threshold levels, for this growing season.

Introduction

BACKGROUND

Moratoria on the commercial release of GM material around the globe, including in Australia, have historically been established to allow time for examination and review of the potential market access and trade implications of the introduction of GMO crops[v]. Tasmania has maintained a moratorium on the commercial release of genetically modified organisms (GMOs) into the environment since 2001.

Australia has a nationally consistent legislative scheme for regulating gene technology, consisting of the Commonwealth *Gene Technology Act 2000* and *Gene Technology Regulations 2001*, and corresponding State and Territory legislation. The legislation was developed in consultation with all Australian jurisdictions and the scheme is supported by the inter-governmental Gene Technology Agreement between the Australian Government and each State and Territory. In Tasmania, the Commonwealth legislation is applied through the *Gene Technology (Tasmania) Act* 2012, which replaced the *Gene Technology (Tasmania) Act 2001*.

There is no provision in the Commonwealth legislation for a State or Territory to 'opt out' of the national scheme on environmental or health grounds. Gene Technology (Recognition of Designated Areas) Principle 2003[vi] allows a State or Territory to declare an area (free of GMOs) for marketing purposes.

Under section 5(1) of the *Genetically Modified Organisms Control Act 2004 (Tas)*, the Minister for Primary Industries and Water may, by order, declare the whole or any part of Tasmania to be an area that is free of GMOs if he or she considers that to do so would aid in preserving the identity of non-GM crops and animals for marketing purposes. Accordingly, through the *Genetically Modified Organisms Control (CMO-Free Area) Order 2005*, the then Minister declared the whole of Tasmania to be a GMO-free area, effective from 15 November 2005.

In August 2014, the Tasmanian Government published the *Tasmanian Gene Technology Policy (2014-2019)* and *Tasmanian Gene Technology Guidelines*, extending the moratorium until 16 November 2019. The Guidelines specifically prohibit importation, distribution, use and any other dealings that facilitate release of genetically modified (GM) food plants, viable seeds or other propagules intended for use as food or feed to the Tasmanian environment.

The Policy commits DPIPWE to implementing an evidence-based GMO monitoring program to continuously assess developments in gene technology in order to build a better understanding of consumer preference and supply chain dynamics, as well as market and branding implications.

This is the second Environmental Scan completed by the AgriGrowth Tasmania Division of DPIPWE since the Moratorium was extended in 2014. The 2015 Environmental Scan, which was informed by industry consultation, did not reveal any new issues or technologies that warranted a review of the moratorium at that time.

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 following organisations were contacted for input into this Scan:

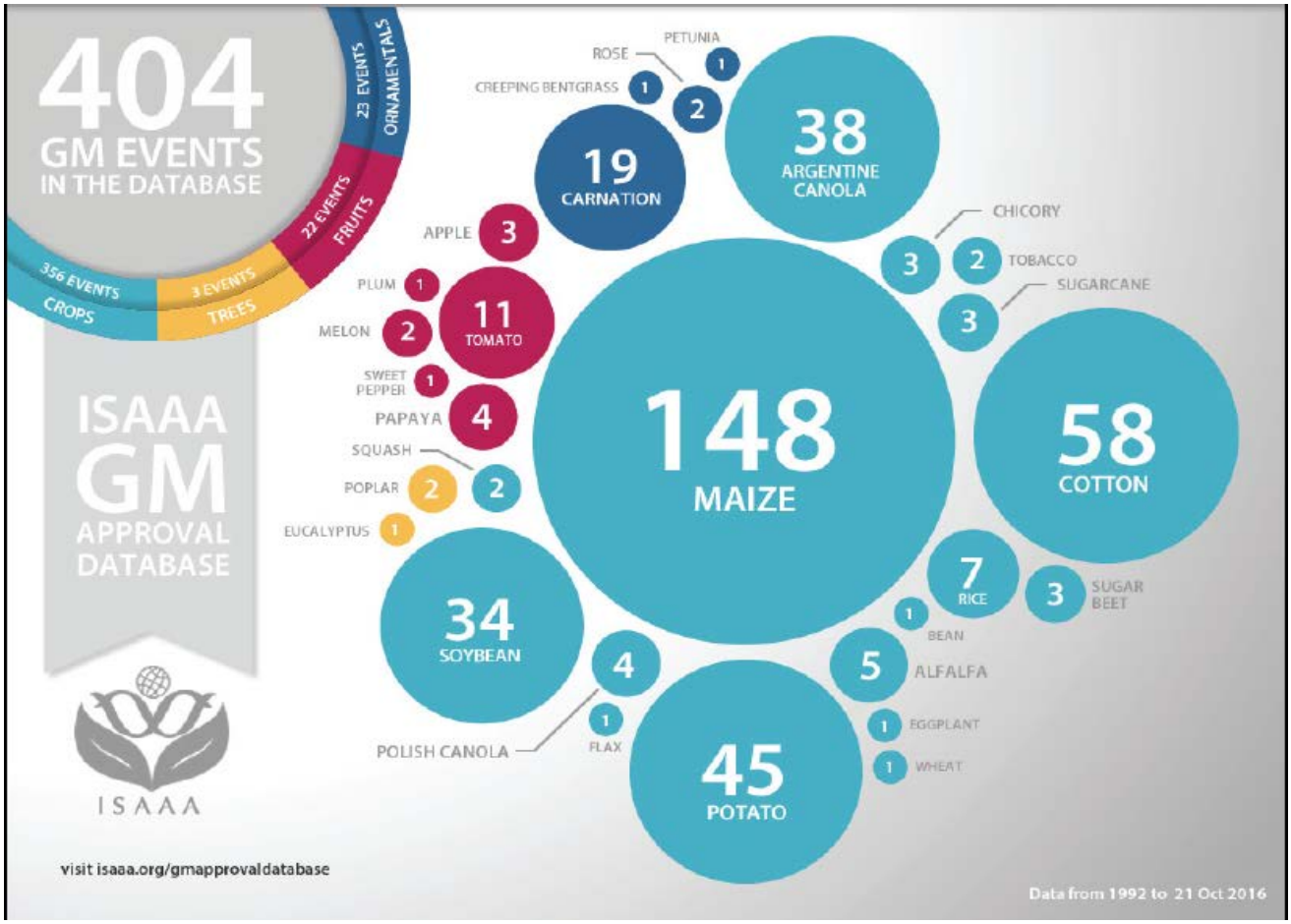
- Dairy Australia (through DairyTas)
- Fruit Growers Tasmania
- Poppy Growers Tasmania
- Tasmanian Agricultural Productivity Group
- Tasmanian Beekeepers Association

- Tasmanian Farmers and Graziers Association
- Tasmanian Institute of Agriculture
- Tasmanian Organic-Dynamic Producers Inc
- Tasmanian Salmonid Growers Association
- Wine Tasmania

Findings

OVERVIEW OF GMOS GLOBALLY

The infographic from the International Service for the Acquisition of Agri-Biotech Applications (ISAAA) below highlights the number of transgenic GM plants on the GM approval database from 1992 to October 2016[vii].



The global plantings of GM or biotech crops has increased from 1.7 million hectares in 1996 to 179.7 million hectares planted in 2015 by up to 18 million farmers, making biotech crops the fastest adopted crop technology in recent times[viii]. In a landmark decision in November 2015, the Federal Department of Agriculture in the United States approved the first GM animal for commercial food production and human consumption (GM Salmon), which is anticipated to enter the food chain in the United States before 2018[ix].

Source[x]

FIGURE S-1 Type and location of commercially grown genetically engineered (GE) crops in 2015.[1] NOTE: In 2015, almost 180 million hectares of GE crops were planted globally. Over 70 million hectares were planted in the United States. GE crops produced in Brazil, Argentina, India, and Canada accounted for over 90 million hectares. The remaining hectares of GE crops were spread among 23 countries.

As the diagram on page ten highlights, there are 12 (twelve) GM crops under commercial production throughout the world, representing 180 million hectares. The ISAAA notes a range of new GM crops that were approved in 2015 and planned for commercialisation in 2016 and beyond in countries other than the United States[xi]. These include:

Argentina – drought tolerant soybean and a virus resistant potato

Brazil – 20 per cent higher yielding home-grown eucalyptus and commercialisation of a virus resistant bean and a herbicide tolerant soybean.

Myanmar – Bt cotton

Canada – non-browning apple

Golden Rice has been bred into mega varieties and confined field tests are in progress in the Philippines and a field trial has been approved in Bangladesh. Around 100 to 150 grams per day of the Golden Rice is said to provide more than half the needs of people suffering from vitamin A deficiency[xii].

Interestingly, the ISAAA note that the high rates of adoption of current major biotech crops leaves little room for expansion into mature markets in principle crop countries however the pipeline of new biotech crop products (approximately 85 potential GM crops) that could be available during the next five years or so (subject to regulatory approval for planting and import) creates future prospects[xiii].

EMERGING ISSUE – NEW BREEDING TECHNIQUES

Molecular biology has made significant advances since GE crops were first introduced over 20 years ago. Gene technology is a rapidly developing field of science. Emerging technologies or NBTs are blurring the distinction between genetic engineering and conventional plant breeding[xiv]. The Tasmanian Institute of Agriculture (TIA) has provided input into this section of the Scan. Refer to Appendix 1 for a summary of techniques and organisms not currently classed as GMO in Australia and to Appendix 2 for an outline of the science relating to some of these NBTs.

NBTs are being considered by various countries. Regulators in some countries such as Germany, Sweden and Argentina, have made a distinction between GMOs and gene editing with tools such as clustered regularly interspaced short palindronomic repeats (CRISPR) and there are signs that the U.S. Food and Drug Administration might follow suit[xv]. Members of the ethics advisory councils of Germany, France and the UK, met on 21 October 2016 in Berlin to discuss genome editing and its potential uses in a range of applications in plants, animals and humans[xvi].

Although many of the countries below may not be key trading partners, it is worth noting how NBTs are being considered in those jurisdictions. See Table 1 below and Appendix 3.

Table 1 – Overview of expected regulatory status of NBTs in selected countries:

Country	Detail
United States of America	In the process of review. The regulation of GMOs in USA is defined by the verifiable characteristics of a product.
Japan	NBT's considered on case-by-case basis. Japan has a distinct product-based approach in that any product that does not contain a transgene is not considered to be a GMO. Products derived through the use of biotechnologies are not by default treated as a GMO unless proven otherwise.
China	Unknown
European Union	The term "GMO" is defined by the process used to create it and not by verifiable characteristics of a product. The EU has not finalised its assessment. However the EU Member State 'New Techniques' expert working group (Podevin et al., 2012) clarified and documented where new breeding techniques fall outside the scope of the current GMO legislation, concluding that the legal

	definition of a genetically modified organism did not apply to most of the new breeding techniques.
Germany	The responsible authorities have already declared that certain genome-edited varieties are in principle the same as products of conventional breeding.
New Zealand	The definition of a GMO as maintained in New Zealand addresses both product and process. Regulation is considered on a case-by-case basis. The existing legislation and regulatory framework is considered adequately cover regulation of (products derived from) plants through the use of NBTs.

Source: Abridged from http://www.nbtplatform.org/background-documents/rep-regulatory-status-of-nbts-oustide-the-eu-june-2015.pdf and http://www.interacademies.net/File.aspx?id=28130 and http://gain.fas.usda.gov/Recent%20GAIN%20Publications/Govt%20Agencies%20argue%20about%20classification%20of%20CRISPR%20and%20other%20NBT%E2%80%99s_Berlin_Germany_11-30-2015.pdf and https://tuebingen.mpg.de/en/homepage/detail/proposal-for-the-assessment-of-new-methods-in-plant-breeding.html and http://ensia.com/voices/crispr-is-coming-to-agriculture-with-big-implications-for-food-farmers-consumers-and-nature/ and https://www.nap.edu/download/23395# and www.gain.fas.usda.gov

What is evident from Table 1 and Appendix 3 is that there is no consensus across jurisdictions at an international level about how to regulate around emerging technologies. This has the potential to increase challenges from a market and trade perspective.

There is a view in the scientific community that genome editing offers a timely and powerful unique set of significant advantages over conventional and GM crops in four domains (precision, speed, cost and regulation)[xvii]. The industry body representing the Australian plant science industry (CropLife Australia) position is that in many cases, NBTs result in products which are similar to or indistinguishable at the genome level from products developed through traditional breeding methods and as such, should be regulated in the same way as conventionally bred plants[xviii]. Alternatively, Gene Ethics Australia has lobbied the Australian Government to amend and extend existing laws and regulations under a COAG agreement between relevant national and state regulators responsible for the assessment, licensing and monitoring of all new genetic manipulation techniques technologies and their products, including those badged as genome editing[xix].

Similarly to the European Union, the term "GMO" in Australia is defined not by verifiable characteristics of a product but by the process used to create it. The Office of Gene Technology Regulator (OGTR) is aware of differences of opinion among regulated stakeholders as to whether organisms modified using some new technologies are subject to regulation as GMOs. In October 2016 the OGTR called for a technical review of the *Gene Technology Regulations 2001* to provide clarity around these new technologies and organisms and whether they are subject to regulation[xx].

This Environmental Scan makes no analysis as to how NBTs such as CRISPR[xxi] would be regulated (or otherwise). This will be dealt with by the review to be undertaken by the OGTR.

SECTION UPDATES

Tasmanian industry stakeholders were contacted to seek an update on the three key areas that the Tasmanian Government has asked AgriGrowth Tasmania to monitor. The broad view reported by these industry bodies is that their position has not changed since the moratorium was extended in 2014. Many expressed appreciation that the Department is monitoring the position relating to GMOs.

The Tasmanian industry stakeholders consulted in undertaking this Scan were notified that the Regulator is conducting a review into options for regulating new technologies with the public submission closing date of 16 December 2016.

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

The major focus of research with GM or NBTs appears to be on reducing the risk of disease to humans, although there is no doubt that these techniques are being explored for crop genetic improvements. NBTs are seen as a promising field for the agri-food sector with the first likely applications to be fungal resistance in potatoes, herbicide tolerance in oilseed rape and maize, drought tolerance in maize and scab resistant apples and potatoes with reduced amylase content[xxii].

From a health perspective, researchers in laboratories over the past three years have already used CRISPR technology to correct major genetic flaws including the mutations responsible for muscular dystrophy, cystic fibrosis and one form of hepatitis and it has also been used in an attempt to eliminate HIV from the DNA of human cells[xxiii].

In December 2015, the US Food and Drug Administration broke new ground when it authorised the world's first human clinical trial for an in vivo genome editing application[xxiv]. This has been followed up with Chinese scientist pioneering gene-editing trials using CRISPR-Cas9 on patients with lung cancer[xxv] In November 2016, a Chinese group became the first to inject a person with cells that contain genes edited using the CRISPR-Cas9 technique with the aim of defeating the patient's cancer. However, the scalability of the technology is unknown as it is early in the trial stage[xxvi].

Research is currently being conducted to reduce malaria transmission with the use of GM techniques. The idea of using GM mosquitoes to help wipe out malaria has been around for some time with British based company Oxitec conducting field experiments in 2010-

2011 in Asia with the aim to reduce the mosquito numbers and limit the spread of diseases which are transmitted through the bite of females[xxvii]. It was anticipated that this research would continue for at least another 10 years before malaria-resistant mosquitoes would ever be considered for broad release in the wild[xxviii].

In a response to fight the Zika virus, Oxitec planned to evaluate the effectiveness of their GM Mosquitoes in October 2016 by releasing male insects across a 17 hectare region of Key Haven in Florida[xxix]. A poll was held with the majority of residents rejecting the proposed trial, with the Florida Keys Mosquito Control District considering the results mid-November 2016 to decide whether to proceed with the trial[xxx].

Dengue fever is the most prevalent mosquito transmitted disease infecting humans. Here in Australia, Sanofi-Aventis Australia applied for a License in September 2016 to import, transport, store and dispose of a GM dengue vaccine as part of its commercial supply as a human therapeutic product[xxxi]. Under the regulatory system in Australia, the Therapeutic Goods Administration must assess its quality, safety and efficacy before it can be registered as a human therapeutic. The draft Risk Assessment and Risk Management Plan is set to be released by the Regulator for public comment in March 2017[xxxii].

In the United States, Holstein cows have been genetically modified to produce human antibodies, proteins that fight pathogens with the aim that one day they may treat infectious diseases like Ebola, Influenza and Zika[xxxiii].

CRISPR technology has now moved into agriculture with Monsanto signing a licensing deal in September 2016 with the Broad Institute of MIT and Harvard to use CRISPR-Cas genome-editing technology to help develop new seeds and crop improvements[xxxiv]. There are restrictions in the use of the technology, with Monsanto not allowed to create sterile seeds and not being able to force a trait onto an organism and its line of descent[xxxv]. Ecologists are also exploring ways to use CRISPR technology to help protect endangered species[xxxvi].

The first non-GM, genome-edited product to be approved and commercialised is SU Canola™ developed by Cibus and grown on 4,000 hectares in the USA in 2015 with Canada also approving SU Canola™ for planting[xxxvii].

SECTION 2: CONSUMER SENTIMENT

Many consumers in developed countries demonstrate a clear preference for non-GMO crops[xxxviii] with recent quantitative research into consumer attitudes in Canada[xxxix] finding that attitudes and reactions to the topic of GM foods is not positive. The research concluded that there are some challenges for health communicators and policy makers in addressing the level of confusion as basic consumer understanding of food science and technology is low[xl]. Consumer demand has prompted Scandinavian dairy co-operative Aria Foods to pay farmers four per cent increase in their milk payments if they move away from GM feeds…although they are not saying that one type of milk is necessarily better, they are looking to supply to different needs and demands in the market[xli].

In Australia, Food Standards Australia New Zealand (FSANZ) base labelling relating to GM foods on the final 'product'[xlii]. GM foods monitors scientific literature and other information about GM foods. FSANZ examines any new information, particularly if a study has cited as evidence of adverse effects from GM foods to see if it needs to revise its previous safety assessments[xliii]. All applications for GM food in Australia are assessed by FSANZ on a case-by-case basis, with recent applications including food derived from soybean, canola, corn, potato, sugarbeet, cotton, wheat, lucerne and rice[xliv].

Non-GM Canola

Although this scan is about GM related matters, it is worth noting the consumer sentiment around non-GM canola as this crop can be grown in Tasmania. A recent South Australian Report into added-value export market opportunities has highlighted the potential to add more value to non-GM canola production for the State[xlv]. Even with the discounted GM canola exports moving into EU, there is still a demand for certified non-GM canola oil outside Australia. As an example a New South Wales company based in Riverina is supplying 1000t of verified non-GM canola into California each month alone[xlvi].

Consumer sentiment within Tasmania's key international trading partners:

As part of the annual monitoring program, a desktop study has again been completed to explore whether consumer sentiment has changed within Tasmania's key trading markets since the 2013 Departmental review into the Moratorium.

The 2016 South Australian Government commissioned Report[xlvii] claims the South Australian GM-free status, combined with overseas demand for non-GM foods and crops,

could provide a huge economic benefit for SA, driven by markets looking for 'naturally healthy' foods with non-GM ingredients. The Report notes that the greatest opportunity lies in developing a platform around 'naturally healthy' underpinned by a sophisticated verification system[xlviii]. An outline of the consumer sentiment in those export markets relevant to Tasmania is presented in the table below. This information draws from the South Australian Report and other sources as referenced.

Country	Sentiment
Japan	Japanese consumers have a high concern about food safety. The country is one of the world's largest per capita importers of GE products and it has labelling requirements for products containing GE materials. The most recent in-country survey (2013-14) on food safety indicates 49 per cent of those polled indicated they have a level of concern (ranging from some to high) regarding GE foods. However, actual consumption of products could be a sign that consumers passively accept GE products (such as oil). Industry sources estimated that approximately 40-50 per cent of food corn is either non-segregated or GE. Japanese industry is unwilling to test consumer acceptance of GM soybean.
Hong Kong	Hong Kong has no commercial production of biotechnology crops nor does it conduct field trials. The few soybean users in Hong Kong require non-GE soybeans because of market-driven factors. 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. Despite calls for mandatory labelling the Hong Kong Government has ruled out an initiative on the grounds that there is no international consensus.
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 and consumer demand is for healthier products leading to cleaner labels and more non-GMO segments. Major retailers are increasingly demanding non-GMO products and going non-GMO with their own brands. USA food manufacturers are committing to transparency and voluntarily seeking non-GMO Project verification and seal.
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.

The United Kingdom (UK)	The UK's exit from the European Union (EU) has the potential to change many policy areas, including agricultural biotechnology. However, in the short to medium term, the current landscape for cultivation and import of genetically engineered (GE) products is not expected to alter. Scotland, Ireland and Northern Ireland have 'opted-out' of cultivating GE crops under EU legislation and these stances will not change post Brexit. Products containing soy, corn, glucose or other sugar components of biotech sugar beet or oilseed rape (Canola) must be labelled. At the premium end of British shopping, the discerning customer is demonstrating that they will pay for the provenance of their food. However, the British public appears to feel that GM as an issue has lost impetus or has at least been managed out of the food supply. 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 have been communicating to their customers that for those who wished to avoid biotech fed livestock, they must now look at organic options. Price is still uppermost in mind for the majority of UK consumers.
China	China is a fragmented market but has a rapidly growing segment for 'naturally healthy' products. China is the world's largest importer of biotech crops such as soybeans, cotton, corn and soybeans for feed and processing, however is yet to approve any major biotech food crops for cultivation. Biotechnology is designated as a strategic emerging industry in China and the Government invests heavily in research. The Government is in the process of revising its biotechnology regulatory system and is reportedly preparing to submit Bt corn events for approval for domestic cultivation – the approval process is expected to take between 3-5 years. In May 2015, the Ministry of Agriculture released a draft revision to its regulatory processes that would remove timelines for approvals and add economic and social factors to the approval process for the first time. 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 have a 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.
Korea	There remain 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. Consequently there is a limited number of food products made from biotech ingredients. Local retailers are reluctant to carry GM labelled foods since they do not want to put product on their shelves that will not sell and would inevitably draw public scrutiny.

	Korea imports substantial amounts of biotech grains. In 2015, the Government announced plans to expand mandatory biotech labelling to include all products with detectable biotech ingredients and was revising its labelling standards. Mandatory GMO labelling is in place with a 3 per cent threshold for soybean.
Indonesia	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 remain very cautious about domestic cultivation of biotech crops. They are enacting mandatory labelling law and 3 per cent GM threshold. Coexistence farming among organic, biotech and conventional crops is a sensitive topic due to small farm sizes and the amount of arable land. A series of local food safety scandals including mis-labelled rice and adulterated cooking oil created an opportunity for anti-GE activities to push for increased regulations. The demand for non-GMO soybean is increasing. In 2015, the Government introduced mandatory labelling for processed GE food products and GE raw materials
New Zealand (NZ)	NZ continues to be regulated with cautious policy settings. A GE equine influenza vaccine is the only GE product approved for use in New Zealand. Media articles since 2013 are evenly divided between pro and anti GE 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 as inputs 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.

Sources: Abridged from www.ers.usda.gov and www.gain.fas.usda.gov, and www.pir.sa.gov.au and http://ussec.org/wp-content/uploads/2015/10/MarketSnapshot-1.pdf

Consumers in developed countries, do not view all applications of biotechnology uniformly[xlix]. When it comes to medical biotechnology, it is considered that we accept each production method, provided the pill actually cures, but that does not hold true in the case of food…as long as there are no adverse health effects, fashion is the strongest factor[l]. Health-related products are generally quickly accepted by consumers with fashion and ethics less predictable and more variable[li]. From a wellness perspective, what

consumers consider 'good for you' has shifted and consumers are now taking a more holistic perspective by weighing more product attributes…as an example roughly half of Americans weigh health and wellness, safety, social impact, experience and transparency in their purchasing decisions, in addition to traditional drivers of taste, price and convenience….only 26 per cent look at non-GMO[lii].

From a social media perspective, labelling appears to be the most frequent sub-topic of GMOs, far exceeding mentions of 'banning'…so it appears that whilst the debate over the safety of GMO's continues in social media, many consumers want labelling so they can make fully informed purchase decisions'[liii]. In 2015, Whole Foods USA set a target to be the first national grocery chain to set a deadline for GMO transparency for food products by 2018[liv]. Now other large corporations in America such as General Mills, Kellogg, Mars and Campbell Soup are shifting to label GMO ingredients (after the 'Vermont Law[lv]" requiring the labelling of GM foods). However, they note that this will be costly and could lower sales[lvi]. The increasing consumer demand for healthier foods or at least products that appear wholesome add a new dimension to consumer sentiment…with GMO labelling said to be turning away some shoppers because GM evokes something unnatural[lvii].

At an international level, negative sentiment against GMO can tend to focus on large institutions such as Monsanto Co. Monsanto is the world's largest producer of GMO crops and the maker of the glyphosate based herbicide Roundup. During October 2016, an international civil tribunal was held (known as the Monsanto Tribunal) at The Hague. The Monsanto Tribunal's goal was to research and evaluate all of the allegations made against Monsanto in connection to its products and impacts to human health and the environment. The Tribunal received considerable media attention and had over 750 witnesses representing 30 nationalities who provided information. The judges at the Tribunal looking to deliver an advisory opinion later in the year[lviii].

In September 2016 Berlin based pharmaceutical and chemical firm Bayer AG agreed to purchase Monsanto Co. The merger means that crop science will replace health care as Bayer's biggest business. There are some that consider that this merger will reshape the crop and seed industry as it will create the world's largest agrichemical firm[lix]. However, consumer advocates and environmental organisations are concerned that there will be a greater concentration of corporations that dominate the seed and pesticide market[lx]. In commenting about the proposed merger, the CEO of Bayer indicated that if "politics and society in Europe do not want genetically modified seeds, then we will accept that, even if we disagree on the substance"[lxi].

In China, genetically modified crops are largely banned from food destined for dinner tables even though China has ambitions to be a major player in GM food by seeking to invest in Syngenta[lxii].

Consumer sentiment within Australia:

Research recently conducted in South Australia revealed that retailers do not consider non-GM a category opportunity in the Australian retail market as most consumers are ambivalent to the presence of GM ingredients[lxiii]. Notable exceptions are biodynamic dairy products, carob products and speciality flours and pre-mixes. Health continues to be a high priority when it comes to food and drinks with consumer attitudes, from a health perspective, that food and drinks should be GMO free[lxiv].

In 2016 Australian Organic Ltd launched its certification program to provide companies with an independent certification service which verifies that their procedures and products exclude GMOs and derivatives of GMOs as far as reasonably possible[lxv].

The Productivity Commission (PC) review into Regulation into Agriculture[lxvi] Draft Report 2016 noted that the regulation of GMOs for marketing purposes was unclear as there is evidence that industry can successfully manage coexistence…with little evidence of GMO-free marketing benefits at the bulk trade level[lxvii]. The PC noted that moratoria for marketing purposes were unwarranted and that they deny farmers access to technological advances that are critical to remaining competitive internationally[lxviii]. Subsequently the PC recommended removal of the existing moratoria by jurisdictions[lxix].

However, in reviewing the submissions by Tasmanian entities to the PC Draft Report, there remain divergent views from a Tasmanian perspective. One submission[lxx] called for a discontinuing of the Tasmanian moratoria, subject to guidelines, policies and regulations to allow potential benefits to be realised. However, the majority of industry and food based submissions to the Draft Report (from the Tasmanian Farmers and Graziers Association[lxxi] Tasmanian Beekeepers Association[lxxii], Slow Food Hobart[lxxiii], Tasmanian Red Meat Industry Council[lxxiv] Harvest Launceston[lxxv] and TasFoods[lxxvi], believe that there is value in maintain the existing moratoria. This sentiment can be best summed up by TasFoods[lxxvii] which notes the potential damage to Brand Tasmania and the possible lost opportunities for TasFoods that lifting the GMO moratorium would represent and that:

> *TasFoods accepts that there are currently no documented tangible economic benefits; and there is little substantiated evidence that suggests a well-regulated and monitored introduction of GMOs would have any negative environmental, social or health impacts.*

Tas Foods does note that food science has quickly developed to the point where GMO technology is not necessarily required to create the improvements in yield for modern farming; and largely, the alleged benefits derived from the use of GMO technologies has been driven by production focused interests, with little appreciation for market demand or consumer-led need.

…It is our view, particularly in light of expanding markets in China and other international markets that the Tasmanian brand is gaining traction and is on the cusp of long-term tangible benefits. Our hope is that those results will become evident prior to the planned review of the Tasmanian moratorium and its expiry in 2019.

Other domestic matters

In January 2010 it became lawful in Western Australia for farmers to grow GM canola as the Minister could exempt persons from growing certain GM crops under the *Genetically Modified Crops Free Areas Act 2003 (WA)*. In February 2016, the High Court of Australia made a ruling regarding the Appeal in the Marsh versus Baxter case. This case involved GM canola and the loss of organic certification for a neighbouring property, due to crop drift. In making the ruling, the Supreme Court of Western Australia dismissed Stephen and Susan Marsh's application for leave to appeal a decision from The Court of Appeal (WA[lxxviii]) and an application for leave to appeal to the High Court of Australia was also dismissed .

In February 2016 as a result of the Marsh versus Baxter case, an application to alter the National Standard for Organic and Bio-Dynamic Produce was unsuccessfully made to the Standard Sub-Committee in February 2015 by the Department of Agriculture and Food Western Australia[lxxx]. One of the six certifiers Australian Organic also elected to seek a change if GM material unintentionally came onto an organic farm . A petition was organised by Food Freedom Australia to raise concerns regarding this proposed move .

In September 2016, the National Standard for Organic and Bio-Dynamic Produce was released noting that….procedures in accordance with the standard will ensure the lowest possible risk of contamination of organic or bio-dynamic products…[lxxxiii] with GMO products not compatible...certification will be withdrawn where GM crops, livestock or agricultural products are grown or produced on the same farm[lxxxiv]. At the same time, the Australian Organic Group established a new non-GMO certification which is designed to build on the strict certified organic guidelines for traceability and segregation that are already in place, with the added requirements for additional testing and verification, based on the level of risk that GMOs pose to an individual product[lxxxv].

On 21 October 2016, the Western Australian (WA) Government repealed its *Genetically Modified Crops Free Area Act (2003)*[lxxxvi]. This means that WA growers now have access to new GM crops approved by the OGTR. There are mixed views about this decision with some farmers pleased about the opportunity it creates and others feeling it was a missed opportunity to retain exclusive isolation .

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

During 2016, the National Academies of Sciences, Engineering and Medicine based in the United States of America completed a comprehensive Report into genetic engineered crops. The Report found there was "no substantiated evidence that foods from GE crops were less safe than foods from non-GE crops….that sweeping statements about GE crops are problematic because issues around them are multidimensional[lxxxviii]….that national regulatory processes vary greatly for GE crops[lxxxix]…and that these regulatory differences are likely to continue and cause trade problems[xc].

The National Academy of Sciences 2016 Report into GE crops indicates that "on available evidence, GE soybean, cotton and maize have generally had favourable economic outcomes for producers who have adopted these crops, but outcomes have been mixed depending on pest abundance, farming practices and agricultural infrastructure[xci]".

At an international level, there have been some recent investments with both animals and plants. In September 2016, the United States Department of Agriculture[xcii] approved a new line of GM apple (the third to be approved) known as Arctic Fuji, which has been engineered to be resistant to browning. A previously approved Arctic Golden apple line is to be sold in test marketing in grocery stores in the Western United States[xciii]. There are already 300,000 trees in nursery production[xciv].

New breeding techniques are now being used to produce food. During 2016, gene editing technology moved into canola cooking oil with this product being marketed as non-GM in the United States[xcv]. United States regulators indicate that cutting DNA from a plant is not the same as adding genes from another organism[xcvi] and as a consequence the US Department of Agriculture gave a green light for the first CRISPR edited organism - mushrooms[xcvii].

In July 2016, GE Wheat found its way into an unplanted agricultural field in Washington State. However, after investigation the United States Department of Agriculture Animal and Plant Health Inspection Service found no evidence of GE wheat in commerce (the farmer's full wheat harvest tested negative to GE wheat)[xcviii].

In May 2016, GM salmon ('AquAdvantage Salmon') was approved for sale as food in Canada, however it is likely to be at least one year before it will be available to consumers[xcix]. Health Canada will not require the AquAdvantage Salmon to be labelled as GM product as there are no demonstrated health risks, such as the potential to cause new food allergies or significant changes to the nutritional qualities of the food[c].

In 2016, Australia still only has two crops approved for commercial release GM canola and GM cotton (refer schematic on page 10). GM Canola seed companies are experiencing strong demand for canola seed for the 2017 season, with plantings in Western Australia alone expected to be up between 6-10 per cent from 2016[ci].

In 2016, exports of GM canola from Australia to Europe were expected to hit record highs…with heavy discounts on the crop changing EU demand preferences…the non-GM premium had reached a point where canola buyers were willing to accept the GM product[cii].

Interest in other GM crop trials remains in Australia. During the period October 2015 to October 2016, the OGTR dealt with applications relating to GMOs for GM Banana, GM Canola, GM Cotton, GM Potato, GM Safflower, GM Sugarcane and GM Wheat[ciii]:

Trials are also underway for barley, perennial ryegrass, and white clover[civ]. During the same period, the OGTR has also dealt with an application for an attenuated GM Dengue vaccine.

In addition, some GM products can be used:

• as ingredients in foods — including GM varieties of soybean, corn, potato, sugar beet, wheat and rice

• for the production of stockfeed — including GM cottonseed meal, imported GM soybean and GM canola meal.

The dairy industry in Australia sees significant opportunities from the use of new gene editing technologies and the Australian Dairy Industry Council is currently considering its engagement with the OGTR *Technical Review of Gene Technology Regulations 2001*.

Dairy Australia and DairyNZ have jointly launched a new project to independently evaluate the benefits of all new plant breeding technologies in Australia and New Zealand (including genomic selection, gene editing, genetic modification and hybridization). An independent Panel of experts has been appointed to establish a common basis for assessing the value of these new technologies and examine the costs forgone if some innovations are not commercialized or adopted. This dairy industry project will deliver tools to encourage engagement across the dairy supply chain and will be completed by mid-2017. The dairy sectors in both Australia and New Zealand will then have the opportunity to review outcomes, build further understanding of the issues and be better informed to participate in discussion.

Tasmania is maintaining the existing policy, held since 2009, that allows for the use of GMOs in pharmaceutical poppies not intended for use for food or feed, provided all statutory requirements are met and that markets for Tasmania's GMO-free food products can be maintained and appropriate co-existence arrangements developed.

In an increasingly competitive international market, the Tasmanian poppy industry has a focus on strengthening the industry and this includes an investment in research and development (R&D). Should future R&D include exploring the role that potential GM varieties could play, the industry would work with AgriGrowth Tasmania in DPIPWE and key stakeholders on co-existence strategies for managing any potential risks associated with GM.

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. 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 (ie 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.

In the 2014-15 growing season these factors contributed to a shortage of canola seed in Tasmania however, industry bodies connected with the growing of canola in Tasmania have confirmed that there has been no shortage of suitable canola seed this growing season. AgriGrowth Tasmania will continue to monitor the situation.

Appendix 1[cv]:

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.

Appendix 2

NEW GENE TECHNOLOGIES

Abridged - Tasmanian Institute of Agriculture

As highlighted in the OTGR Discussion paper (2016)[cvi] and the GMO Environmental Scan document (Dec 2015)[cvii] there are new technologies that are revolutionising the treatment of diseases and the breeding of crops and animals.

For instance, the CRISPR/Cas9 technology has already been used successfully to produce non-GM food products (e.g. mushrooms and potatoes) and is currently revolutionising medical practice by providing pathways towards cures for HIV (Kaminski, 2016), Hepatitis B and lung cancer (see highlights below). There is already precedence of rulings by regulators in the US (APHIS, 2016) that clearly state that these technologies can produce

On 28 October 2016, a team led by oncologist Lu You at Sichuan University in Chengdu delivered modified cells into a patient with aggressive lung cancer. The researchers removed immune cells from the recipient's blood and then disabled a gene in them using CRISPR–Cas9, which combines a DNA cutting enzyme with a molecular guide that can be programmed to tell the enzyme precisely where to cut. The disabled gene codes for the protein PD1, which normally puts the brakes on a cell's immune response: cancers take

non-GMO products that are indistinguishable from conventionally bred products and that do not contain any foreign DNA. Indeed many of these are analogous to currently accepted and non-regulated approaches including mutation breeding (e.g. production of the Thebaine poppy), and somaclonal cell selection (common scab resistant potatoes).

Extract from a letter by USDA's Animal and Plant Health Inspection Service (APHIS) in response to a request for confirmation that transgene-free, CRISPR-edited mushroom is not a regulated article:

… Based on the information cited in your letter, APHIS has concluded that your

Genome editing

CRISPR technologies use a synthetic RNA molecule (oligo) to enable genomic editing of organisms without incorporation of foreign DNA into the resultant plant or animal.

CRISPR/Cas9-mediated Targeted Genome Engineering Approach
Targeted gene insertion at a specific genetic locus (Safe-harbor/pre-determined locus)
No disruption of native gene function
Position and structural effects can be eliminated
Targeted gene disruption can be achieved without integrating foreign DNA (analogous to conventional breeding approaches)
More efficient generation of desired events

Transgene-free plants can be generated with desired modifications (knockouts and base pair substitutions)

Relatively less or no regulatory requirement

The scientific explanation

There are three different types of CRISPR gene editing identified but the most commonly studied is type II, the CRISPR/Cas9 system. In the process a synthetic guide RNA is produced that matches the sequence of the genomic DNA to be modified. The native system uses two short RNA molecules, one sequence specific CRISPR RNA (crRNA) and a conserved transactivating crRNA (tracrRNA) that interact through partial homology to form a complex. The crRNA:tracrRNA complex guides and activate the Cas9 nuclease to cleave double stranded DNA targets (a double strand break) at a site determined by homology within the crRNA. The crRNA and tracrRNA can be fused into a single chimeric guide molecule (sgRNA).

The cleaved DNA can be allowed to self-repair by non-homologous end joining, and through normal error mutation lead to insertions or deletions that result in disruption of the gene (gene silencing/knockout). A correct repair would of course be cleaved again – only once a change is induced would the sequence remain stable. **This is analogous to other forms of mutagenesis that are not regulated as GMOs (e.g. chemical or UV) except that the cleavage point is not random. No new DNA is incorporated into the organism. Mutagenesis occurs spontaneously in nature and is the natural process that drives evolution.** This is annotated as SDN-1 (site-directed nuclease) in the OTGR document (2016). Note, two closely positioned cleavage sites may also direct a specific deletion of the intervening sequence as another directed mutation.

An example of the use of such processes is the work of Dr Yang whom produced a white button mushroom with disrupted polyphenol oxidase gene that stops browning following bruising. In an application to the USDA this was approved as not subject to regulatory processes for GMOs in the USA as it contained no introduced genetic material.

The future of CRISPR/Cas9

The rapid progress in developing Cas9 into a set of tools for cell and molecular biology research has been remarkable, likely due to the simplicity, high efficiency and versatility of the system. Of the designer nuclease systems currently available for precision genome engineering, the CRISPR/Cas system is by far the most user friendly. It is now also clear that

Alternatively, the double stranded break can be repaired through homology directed repair using a donor DNA template provided as part of the CRISPR/Cas9 system. This will direct the repair process to incorporate specific nucleotide changes. This can allow specific repair of dysfunctional genes (e.g. as a treatment for genetic disease). This is annotated as SDN-2 and SDN-3 in the OTGR document (2016). SDN-2 involves small sequence changes that may be identical to those induced by SDN-1 processes, whilst SDN-3 uses a longer template to insert new sequences.

Intragenics

Similar to CRISPR, intragenics based on RNA interference (RNAi) technology can silence undesirable genes. This is already used for commercially important crops such as potatoes, improving their quality, shelf life and health attributes. This is particularly relevant for Tasmania.

Clasen et al. (2015) showed that problems with cold storage of potato tubers can be overcome through this technology. Cold storage is used to reduce sprouting and extend postharvest shelf life. However, cold temperature stimulates the accumulation of reducing sugars in potato tubers. Upon high-temperature processing, these reducing sugars react with free amino acids, resulting in brown, bitter-tasting products and elevated levels of acrylamide, a potential carcinogen. To minimize the accumulation of reducing sugars, Clasen et al. (2015) used RNA interference (RNAi) technology to silence the vacuolar invertase gene (VInv), which encodes a protein that breaks down sucrose to glucose and fructose. They used transcription activator-like effector nucleases (TALENs) to knockout

VInv within the commercial potato variety, Ranger Russet. The tubers from full VInv-knockout plants had undetectable levels of reducing sugars, and processed chips contained reduced levels of acrylamide and were lightly coloured. Several of the modified plant lines contained no foreign DNA, providing a framework for using the technology to quickly improve traits in commercially relevant, autotetraploid potato lines.

The scientific explanation

Intragenic approaches to genetic manipulation use GMO technologies and incorporate new genetic material into the recipient plants or animals. Yet the introduced DNA can be sourced from the recipient organism species or closely related species. For example, the "Innate" potato produced by Simplot (USA) uses DNA sequences from potato genomes only.

The innate potato uses RNAi (RNA interference or gene silencing) technologies to regulate expression of genes within the potato plant. By expressing repeat looped sequences corresponding to the mRNA of the target genes the plant will turn off or silence these genes using natural genetic sRNA regulatory systems avoiding their translation and production of the respective enzymes. The target genes (in the generation 1 Innate potato) are associated with bruising (polypehonl oxidase) and asparagine synthesis (asparagine synthase) with high asparagine content associated with the accumulation of acrylamide on cooking at high temperatures. Acrylamide is a potential carcinogen and thus minimising its production provides potential health benefits to consumers. Generation 2 Innate potatoes include a gene for resistance to late blight derived from a wild Solanum species (close potato relative).

In the past such approaches had issues with the requirement for the use and incorporation of marker genes (often antibiotic resistant genes of exogenous source) and incorporation of small flanking regions of tDNA from the bacterial plasmid vectors. However, it is now possible to avoid or remove the antibiotic gene and avoid bacterial sequences in the DNA transferred to the recipient host.

As mentioned above GMO techniques can be used to silence genes using RNA interference (gene silencing). The process of RNAi is driven by the presence of double stranded RNA that is cleaved by DICER enzymes into short interfering RNA molecules (siRNA's) of 21-25 nt length which are recruited by a RISC enzyme complex and used as a template to identify and facilitate cleavage of homologous RNA sequences. This results in mRNA degradation and failure to transcribe and express genes (gene silencing).

Traditionally this has been achieved using a GMO approach (more commonly with foreign DNA or using an intragenic approach as outlined above). Here either multiple forward and reverse copies of the gene sequence of interest (which form dsRNA upon transcription), or a genetic sequence that is transcribed to produce a hairpin-loop

structure with complementary sequences (pseudo dsRNA) are incorporated into the organism by engineering approaches. These are then recognised, sliced and recruited by the RISC to facilitate silencing.

However, in recent times attempts have been made to directly introduce siRNA's into organisms to stimulate silencing without genetic transformation. These siRNA's may be introduced on nanoparticles and are released in cells and recruited by the RISC complex. The effect may be transient.

In this instance there is no transgene or genetic engineering involved, but change in gene regulation (gene silencing) is produced. This has wide applications including disease control (targeting essential pathogen gene expression), reduced oxidation/bruising etc.

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Appendix 3 - Overview of expected regulatory status of the products resulting from the use of NBTs in selected countries

(source: http://www.nbtplatform.org/background-documents/rep-regulatory-status-of-nbts-oustide-the-eu-june-2015.pdf

Technique / Country	ZFN1	ZFN2	ZFN3	ODM	Cisgenesis	RdDM	Reverse Breeding	Grafting	Agro-infiltration
Argentina	#	#	#	#	#	#	#	#	#
Australia		#	#	#	#			#	#
Brazil									
Canada	#	#	#	#	#	#	#	#	#
China									
India	#	#	#	#	#	#	#	#	#
Japan									
Rep of Korea									
New Zealand	#								
Russia									
South Africa									
Switzerland									
USA	#	#	#	#	#	#	#	#	#

Legend

White	Information not available
Blue	Non-regulated or exempted from applicable GM legislation
Black	Regulated under applicable GM legislation
#	Case-by-case review

ZFN1/2/3 = Zinc Finger Nucleases more commonly referred to as Site Directed Nucleases (SDN) including among others ZFN-1/2/3, TALENs, Megancleases and CRISPR-Cas. **ODM** = Oligoncleotide Directed Mutagenisis. Cisgenis. RNA-Dependent DNA methylation (**RdDM**). Grafting (non-GMO scion on GMO rootstock), Reverse Breeding, Agro Infiltaration (agro-infiltration, sensu stricto, agro-inoculation)

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